

Calendar No. 446

104<sup>TH</sup> CONGRESS  
2D Session

**S. 1477**

[Report No. 104-284]

**A BILL**

To amend the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act to improve the regulation of food, drugs, devices, and biological products, and for other purposes.

JUNE 20, 1996

Reported with an amendment

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IN THE SENATE OF THE UNITED STATES

DECEMBER 13, 1995

Mrs. KASSEBAUM (for herself, Mr. INHOFE, and Mr. FRIST) introduced the following bill; which was read twice and referred to the Committee on Labor and Human Resources

JUNE 20, 1996

Reported by Mrs. KASSEBAUM, with an amendment

[Strike out all after the enacting clause and insert the part printed in *italic*]

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**A BILL**

To amend the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act to improve the regulation of food, drugs, devices, and biological products, and for other purposes.

1       *Be it enacted by the Senate and House of Representa-*  
2       *tives of the United States of America in Congress assembled,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Food and Drug Ad-  
3 ministration Performance and Accountability Act of  
4 1995”.

5 **TITLE I—MISSION AND**  
6 **ACCOUNTABILITY**

7 **SEC. 101. SHORT TITLE.**

8 This title may be cited as the “Food and Drug Ad-  
9 ministration Regulatory Reform Act of 1995”.

10 **SEC. 102. THE MISSION OF THE FOOD AND DRUG ADMINIS-**  
11 **TRATION.**

12 Section 903(a) (21 U.S.C. 393(a)) is amended by  
13 adding at the end thereof the following: “The mission of  
14 the Administration is to promote and protect the health  
15 of the American people by—

16 “(1) facilitating the rapid and efficient develop-  
17 ment and availability of products subject to its regu-  
18 lation;

19 “(2) protecting the public from unsafe or inef-  
20 fective products subject to its regulation; and

21 “(3) enforcing the applicable statutes and regu-  
22 lations in a timely, fair, consistent, and decisive  
23 manner.”.

24 **SEC. 103. PERFORMANCE STANDARDS AND REVIEW.**

25 Section 903(b) (21 U.S.C. 393(b)) is amended by  
26 adding at the end thereof the following new paragraph:

1           “(3) PERFORMANCE STANDARDS AND RE-  
2       VIEW.—Within 180 days after the date of enactment  
3       of this paragraph, the Commissioner, after consulta-  
4       tion with representatives of patient advocacy groups,  
5       health professionals, and the regulated industries,  
6       shall publish in the Federal Register quantifiable  
7       performance standards for action by the Administra-  
8       tion on applications or submissions (including peti-  
9       tions, notifications, or any other similar form of re-  
10      quest) for the review of a product that is a new  
11      drug, biological product, new animal drug, device, or  
12      food additive and that is subject to premarket review  
13      or approval of any kind under this Act. The per-  
14      formance standards shall be reviewed, and after con-  
15      sultation with representatives of patient advocacy  
16      groups, health professionals, and the regulated in-  
17      dustries, may be revised, annually by the Commis-  
18      sioner. The performance standards shall establish  
19      objectives for the Administration that—

20           “(A) expedite action on applications for  
21           new drugs and devices under sections 505(b)(1)  
22           and 515, and for biological products under sec-  
23           tion 351(a) of the Public Health Service Act  
24           (42 U.S.C. 262(a))—

1 “(i) for a serious, life-threatening, or  
2 seriously debilitating disease or condition;  
3 or

4 “(ii) for any other condition if a new  
5 drug, device, or biological product—

6 “(I) provides therapy not avail-  
7 able from other approved therapy; or

8 “(II) offers significant improve-  
9 ment over other approved therapy;

10 “(B) reduce backlogs on all applications  
11 with the objective of eliminating all backlogs by  
12 January 1, 2000; and

13 “(C) establish a schedule to bring the Ad-  
14 ministration into full compliance by July 1,  
15 1998, with the time periods specified in this Act  
16 for action on all applications.

17 For applications for which there is no statutory time  
18 period, the applicable time period for action shall be  
19 180 days. The Commissioner shall prepare and pub-  
20 lish in the Federal Register for public comment an  
21 annual report comparing the performance of the Ad-  
22 ministration with the applicable performance stand-  
23 ards, analyzing any failure to achieve any of the  
24 standards, and setting forth a plan to achieve com-  
25 pliance with the standards that have not been met.”.

1 **SEC. 104. INFORMATION SYSTEM.**

2 Chapter IX (21 U.S.C. 391 et seq.) is amended by  
3 adding at the end thereof the following new section:

4 **~~“SEC. 906. INFORMATION SYSTEM.~~**

5 ~~“The Secretary shall establish and maintain an infor-~~  
6 ~~mation system to track the status and progress of each~~  
7 ~~application or submission (including a petition, notifica-~~  
8 ~~tion, or other similar form of request) submitted to the~~  
9 ~~Food and Drug Administration requesting agency action.~~  
10 ~~The system shall permit access by the applicant.”.~~

11 **SEC. 105. POLICY STATEMENTS.**

12 Section 701(a) (21 U.S.C. 371(a)) is amended—

13 (1) by striking “(a) The” and inserting “(a)(1)  
14 The”; and

15 (2) by adding at the end thereof the following  
16 new paragraph:

17 ~~“(2)(A) The Secretary shall establish a procedure~~  
18 ~~governing the development and use of all policy statements~~  
19 ~~of general applicability (including any guideline, points-to-~~  
20 ~~consider, protocol, recommendation, or similar document~~  
21 ~~regardless of the form or designation) that are not pro-~~  
22 ~~mulgated as regulation. The procedure shall provide an~~  
23 ~~opportunity for affected persons to participate in the de-~~  
24 ~~velopment and continued use of the policy by sharing ex-~~  
25 ~~pertise, experience, or providing comment before the policy~~  
26 ~~is adopted and after the policy is implemented.~~

1       “(B) The Secretary shall establish a procedure for  
 2 the formal publication and compilation of all policy state-  
 3 ments of general applicability (including any guideline,  
 4 points-to-consider, protocol, recommendation, or similar  
 5 document regardless of the form or designation) that are  
 6 not promulgated as regulations.”.

7 **SEC. 106. ADVISORY COMMITTEES.**

8       Section 904 (21 U.S.C. 394) is amended—

9               (1) by striking “Without” and inserting “(a) IN  
 10       GENERAL.—Without”; and

11              (2) by adding at the end thereof the following  
 12       new subsections:

13       “(b) DELEGATION OF APPOINTMENT AUTHORITY.—

14 The Commissioner may delegate the appointment and  
 15 oversight authority granted under subsection (a) to a cen-  
 16 ter director. The center director may not authorize any  
 17 office or division of the center to carry out the appoint-  
 18 ment and oversight authority granted under this sub-  
 19 section.

20       “(c) MEMBERSHIP AND MEETING REQUIREMENTS.—

21              “(1) SCOPE.—A scientific review group may de-  
 22       termine the matters that the group will consider and  
 23       may establish an appropriate agenda with respect to  
 24       the determination of the matters.

1           “(2) NONVOTING MEMBERS.—A scientific re-  
2       view group shall include a nonvoting industry rep-  
3       resentative and a nonvoting public representative.

4           “(3) NOTIFICATION OF SCOPE OF DISCUS-  
5       SION.—To the extent feasible, the specific matters  
6       and questions to be discussed at a meeting of a sci-  
7       entific review group shall be publicly announced and  
8       published in the Federal Register at least 30 days  
9       prior to the date of the meeting.

10          “(4) TERMS.—A member of a scientific review  
11       group shall serve for a term of 3 years, which may  
12       be renewed for a second term. An individual may  
13       serve on more than one scientific review group. The  
14       chairperson of a scientific review group shall be a  
15       member who has served at least 3 years. The term  
16       of the chairperson may be renewed for not more  
17       than 3 terms.

18          “(5) TRAINING.—Prior to service on a scientific  
19       review group, a member of the group shall be given  
20       adequate education and training relating to the re-  
21       sponsibilities of the member.

22          “(6) FREQUENCY OF MEETINGS.—The Sec-  
23       retary shall take whatever action is necessary to en-  
24       sure that regular meetings are held by scientific re-  
25       view groups, at appropriate intervals and for a suffi-



1       cient length of time, so that any matter to be re-  
 2       viewed by any scientific review group shall be pre-  
 3       sented to the group not more than 90 days after the  
 4       matter is ready for review by the group. The meet-  
 5       ings shall occur not less than 6 times each year un-  
 6       less there are compelling reasons for fewer meetings.

7       “(d) PERSONS INVOLVEMENT WITH REVIEW  
 8 GROUPS.—

9               “(1) IN GENERAL.—All persons, including em-  
 10       ployees of the Secretary, shall have the same rights  
 11       and responsibilities regarding—

12               “(A) the submission of data and informa-  
 13       tion to, and contact and discussion with, a sci-  
 14       entific review group;

15               “(B) the participation of the persons at  
 16       meetings of the group; and

17               “(C) access to data and information sub-  
 18       mitted to a scientific review group (except for  
 19       data and information that are not available for  
 20       public disclosure under section 552 of title 5,  
 21       United States Code).

22       “(2) SUBMISSION OF INFORMATION TO FDA.—

23       In a case in which a scientific review group reviews  
 24       an application (including a petition, notification, or  
 25       other similar request), all related data and informa-

1       tion that are not available for public disclosure  
2       under section 552 of title 5, United States Code,  
3       shall be exchanged between the applicant and the  
4       Food and Drug Administration at the time the data  
5       and information are submitted to the scientific re-  
6       view group but shall not otherwise be publicly dis-  
7       closed.

8               “(3) PARTICIPATION IN MEETINGS.—Any meet-  
9       ings of a scientific review group shall provide ade-  
10      quate time for initial presentations and for response  
11      to any differing views and shall encourage free and  
12      open participation by all interested persons.

13           “(e) FDA ACTIONS.—Within 60 days after the date  
14      a scientific review group makes its conclusions and rec-  
15      ommendations on any matter under review of the group,  
16      the Food and Drug Administration official responsible for  
17      the matter shall review the conclusions and recommenda-  
18      tions of the group, shall make a final determination on  
19      the matter, and shall notify the affected persons of the  
20      determination in writing and, if the determination differs  
21      from the conclusions and recommendations of the group,  
22      shall include the reasons for the difference.

23           “(f) DEFINITION.—For purposes of this section, the  
24      term ‘center director’ means a director of a center within  
25      the Food and Drug Administration.”.

1 **SEC. 107. APPEALS WITHIN THE FOOD AND DRUG ADMINIS-**  
 2 **TRATION.**

3 Chapter IX (21 U.S.C. 391 et seq.), as amended by  
 4 section 104, is further amended by adding at the end  
 5 thereof the following new section:

6 **“SEC. 907. APPEALS WITHIN THE FOOD AND DRUG ADMIN-**  
 7 **ISTRATION.**

8 “(a) **EMPLOYEE DECISIONS.**—The Secretary shall by  
 9 regulation establish a system for the appeal within the  
 10 Food and Drug Administration of any decision by an em-  
 11 ployee of the Food and Drug Administration, except that  
 12 this subsection shall not apply to decisions involving for-  
 13 mal administrative or judicial proceedings. The Secretary  
 14 shall make publicly known the existence of the internal  
 15 appeal system and the procedures for an internal appeal.

16 “(b) **REVIEW BY SCIENTIFIC REVIEW GROUP.**—

17 “(1) **IN GENERAL.**—Any person shall have the  
 18 right to request an evaluation by an appropriate sci-  
 19 entific review group established under section 904 of  
 20 any significant scientific issue pending before, or sig-  
 21 nificant scientific decision made by, the Secretary  
 22 under this Act. An appropriate scientific review  
 23 group shall review the request and determine wheth-  
 24 er to conduct an evaluation within 30 days after the  
 25 date the request is received by the Secretary.

1           “(2) SCOPE.—The issues a scientific review  
 2           group shall evaluate shall include, but not be limited  
 3           to, matters involving a decision by the Secretary not  
 4           to permit a clinical investigation to begin or to con-  
 5           tinue, a refusal by the Secretary to file an applica-  
 6           tion, a protocol design, and decisions relating to a  
 7           pending application (including a petition, notifica-  
 8           tion, or other similar request), where the same issue  
 9           has not previously been reviewed by a scientific re-  
 10          view group.

11           “(3) TIME LIMITATION.—If a scientific review  
 12          group agrees to conduct an evaluation on an issue  
 13          under paragraph (1), the evaluation shall be sched-  
 14          uled for the next meeting of the group.

15          “(c) ADDITIONAL INFORMAL AND FORMAL PROCE-  
 16          DURES.—

17           “(1) IN GENERAL.—For purposes of obtaining  
 18          conclusions and recommendations regarding the res-  
 19          olution of any dispute, the Secretary is authorized to  
 20          use such additional informal and formal procedures  
 21          as may be considered useful. The procedures may in-  
 22          clude, but not be limited to, the use of—

23                   “(A) panels of qualified Food and Drug  
 24                   Administration officials;

1           ~~“(B) panels of qualified government em-~~  
 2           ~~ployees who are not employees of the Food and~~  
 3           ~~Drug Administration; and~~

4           ~~“(C) outside mediators and arbitrators~~  
 5           ~~who are not government employees.~~

6           ~~“(2) APPLICATION OF FACA.—The Federal Ad-~~  
 7           ~~visory Committee Act (5 U.S.C. App) shall not apply~~  
 8           ~~to a panel described in paragraph (1).~~

9           ~~“(d) REVIEW OF RECOMMENDATIONS.—Within 60~~  
 10          ~~days after any matter that is presented for resolution pur-~~  
 11          ~~suant to this section has been the subject of conclusions~~  
 12          ~~and recommendations, the Food and Drug Administration~~  
 13          ~~official responsible for the matter shall personally review~~  
 14          ~~the conclusions and recommendations, make a final deter-~~  
 15          ~~mination on the matter, and notify the parties of the de-~~  
 16          ~~termination in writing and if the determination differs~~  
 17          ~~from the conclusions and recommendations, the reasons~~  
 18          ~~for the difference.”.~~

19       **~~TITLE H—EXPEDITED ACCESS~~**  
 20       **~~TO PRODUCTS FOR SERI-~~**  
 21       **~~OUSLY ILL PATIENTS~~**

22       **~~SEC. 201. SHORT TITLE.~~**

23           ~~This title may be cited as the “Patient Rights Regu-~~  
 24          ~~latory Reform Act of 1995”.~~

1 **SEC. 202. ACCESS TO UNAPPROVED THERAPIES.**

2 Chapter V (21 U.S.C. 351 et seq.) is amended by  
3 adding at the end thereof the following new section:

4 **“SEC. 543. EXPANDED ACCESS TO UNAPPROVED THERA-**  
5 **PIES AND DIAGNOSTICS.**

6 “(a) IN GENERAL.—Any person may request from a  
7 manufacturer or distributor, and any manufacturer or dis-  
8 tributor may provide to a person after compliance with  
9 the provisions of this section, an investigational drug (in-  
10 cluding a biological product) or device for the diagnosis,  
11 monitoring, or treatment of a serious disease or condition,  
12 life-threatening or seriously debilitating disease or condi-  
13 tion, and any other disease or condition designated by the  
14 Secretary as appropriate for expanded access under this  
15 section by the person if—

16 “(1) the person has no comparable or satisfac-  
17 tory alternative therapy available to treat, diagnose,  
18 or monitor the disease or condition; or

19 “(2) the risk to the person from the investiga-  
20 tional drug or device is not greater than the risk  
21 from the disease or condition.

22 “(b) PROTOCOLS.—A manufacturer or distributor  
23 may submit to the Secretary one or more expanded access  
24 protocols covering expanded access use of a drug or device  
25 described in subsection (a). The protocols shall be subject  
26 to the provisions of section 505(i) for a drug and section

1 520 (g) and (m) for a device and may include any form  
2 of use of the drug or device outside a clinical investigation;  
3 prior to approval of the drug or device for marketing, in-  
4 cluding but not limited to protocols for treatment, use,  
5 parallel track, single patient protocols, emergency use, and  
6 uncontrolled trials.

7 “(c) FEES.—A manufacturer or distributor may  
8 charge for an investigational drug or device under an ex-  
9 panded access protocol, but the price of the drug or device  
10 may not be more than that necessary to recover the costs  
11 of manufacture, research, development, and handling for  
12 the drug or device.

13 “(d) NOTIFICATION OF AVAILABILITY.—The manu-  
14 facturer or distributor may inform national, State, and  
15 local medical associations and societies, and voluntary  
16 health associations, about the availability of an investiga-  
17 tional drug or device for expanded access use pursuant  
18 to this section but—

19 “(1) shall state that the drug or device is inves-  
20 tigational;

21 “(2) shall not represent that the drug or device  
22 is safe or effective for any use; and

23 “(3) shall not otherwise promote or advertise  
24 the availability of the product for expanded access  
25 use.

1 **SEC. 203. EXPANDING HUMANITARIAN USE OF DEVICES.**

2 Section 520(m) (21 U.S.C. 360j(m)) is amended—

3 (1) in paragraph (2), by inserting at the end  
4 thereof the following flush sentences:

5 “The request shall be in the form of an application to the  
6 Secretary. Within 30 days of the date of the receipt of  
7 the application, the Secretary shall issue an order approv-  
8 ing or denying the application.”;

9 (2) by striking paragraph (5); and

10 (3) by striking paragraph (6).

11 **SEC. 204. EXPEDITING APPROVAL OF NEW DRUGS, BIO-**  
12 **LOGICS, AND MEDICAL DEVICES FOR SERI-**  
13 **OUS CONDITIONS.**

14 (a) NEW DRUGS.—Section 505(e)(1) (21 U.S.C.  
15 355(e)(1)) is amended by adding at the end thereof the  
16 following flush sentence:

17 “In a case in which an application submitted under section  
18 505(b)(1) for a new drug, or section 351(a) of the Public  
19 Health Service Act a biological product, for a life-threaten-  
20 ing disease or condition, a seriously debilitating disease  
21 or condition, or for any other serious disease or condition  
22 that provides therapy or diagnosis not available from an-  
23 other approved drug or biological product or offers signifi-  
24 cant improvement over another approved drug or biologi-  
25 cal product, the Secretary shall approve or deny approval



1 of the application within 120 days after the receipt of the  
2 application.”.

### 3 **TITLE III—REVITALIZING THE** 4 **INVESTIGATION OF NEW** 5 **PRODUCTS**

#### 6 **SEC. 301. SHORT TITLE.**

7 This title may be cited as the “Investigational Prod-  
8 ucts Regulatory Reform Act of 1995”.

#### 9 **SEC. 302. TIMELY REVIEW AND REASONABLE DATA RE-** 10 **QUIREMENTS FOR CLINICAL RESEARCH ON** 11 **DRUGS AND BIOLOGICAL PRODUCTS.**

12 Section 505(i) (21 U.S.C. 355(i)) is amended—

13 (1) by striking “(i) The” and inserting “(i)(1)  
14 The”;

15 (2) by redesignating paragraphs (1), (2), and  
16 (3) as subparagraphs (A), (B), and (C), respectively;  
17 and

18 (3) by adding at the end thereof the following  
19 new paragraph:

20 “(2)(A) A clinical investigation of a new drug (includ-  
21 ing a biological product) may begin 30 days after the date  
22 the Secretary receives from the sponsor a notification con-  
23 taining information about the drug and the clinical inves-  
24 tigation unless, prior to the 30-day period, the Secretary  
25 informs the sponsor in writing that the investigation may

1 not begin, and specifies the basis for the decision and the  
 2 information needed in order for the clinical investigation  
 3 to commence.

4 “(B) Within 1 year after the date of enactment of  
 5 the Food and Drug Administration Performance and Ac-  
 6 countability Act of 1995, the Secretary, after consultation  
 7 with representatives of patient advocacy groups and the  
 8 regulated industries, shall publish in the Federal Register  
 9 criteria for the type and amount of information relating  
 10 to the safety of an investigational drug to be included in  
 11 a notification described in subparagraph (A), taking into  
 12 account the recommendations of the International Con-  
 13 ference on Harmonization of Technical Requirements for  
 14 Registration of Pharmaceuticals for Human Use. The Sec-  
 15 retary shall periodically review, and may revise, the cri-  
 16 teria.

17 “(C) The Commissioner shall establish a mechanism  
 18 to ensure the fair and consistent application of safety  
 19 standards for clinical investigations.”

20 **SEC. 303. TIMELY REVIEW AND REASONABLE DATA RE-**  
 21 **QUIREMENTS FOR CLINICAL RESEARCH ON**  
 22 **DEVICES.**

23 Section 520(g) (21 U.S.C. 360j(g)) is amended by  
 24 adding at the end thereof the following new paragraphs:

1       “(6) The procedures and conditions prescribed pursu-  
 2 ant to paragraph (2)(A) shall be subject to subparagraphs  
 3 (B) and (C) of section 505(i)(2).-

4       “(7) The Secretary shall, within 120 days of the date  
 5 of enactment of this paragraph, by regulation amend the  
 6 content of parts 812 and 813 of title 21 of the Code of  
 7 Federal Regulations to update the procedures and condi-  
 8 tions under which devices intended for human use may  
 9 upon application be granted an exemption from certain re-  
 10 quirements under this Act. The regulation shall—

11           “(A) permit developmental changes in devices;  
 12 including manufacturing changes, in response to in-  
 13 formation collected during an investigation without  
 14 requiring an additional approval of an application  
 15 for an investigational device exemption or the ap-  
 16 proval of a supplement to the application, if the  
 17 changes do not constitute a significant change in de-  
 18 sign or a significant change in basic principles of op-  
 19 eration; and

20           “(B) permit, without approval of a supplement  
 21 to an application for an investigational device ex-  
 22 emption, changes or modifications to clinical proto-  
 23 cols that do not affect the validity of data or infor-  
 24 mation resulting from the completion of an approved  
 25 protocol.”.

1 **SEC. 304. COLLABORATIVE RESEARCH DESIGN.**

2 Chapter V (21 U.S.C. 351 et seq.), as amended by  
3 section 202, is further amended by adding at the end  
4 thereof the following new section:

5 **“SEC. 544. COLLABORATIVE RESEARCH DESIGN.**

6 **“(a) REVIEW OF DESIGN.—**

7 **“(1) REQUEST.—**Any person who intends to  
8 sponsor a preclinical or clinical investigation of a  
9 drug (including a biological product) or device may  
10 request a meeting with the Secretary to review the  
11 design of one or more protocols or part or all of a  
12 development plan for the drug or device.

13 **“(2) FORM.—**A request described in paragraph  
14 (1) shall be in writing and shall include a proposal  
15 for which the review is requested.

16 **“(3) WRITTEN REVIEW.—**The Secretary shall  
17 meet with the person within 30 days of the request  
18 and shall provide to the person a written review of  
19 the proposal, including any deficiencies in the pro-  
20 posal. A written summary shall be made of the  
21 meeting. The summary shall include the written re-  
22 view of the proposal and, after agreement by the in-  
23 dividuals who attended the meeting, shall be made  
24 part of the product review file maintained by the  
25 Food and Drug Administration.

1       ~~“(b) MODIFICATION OF AGREEMENTS.—Agreements~~  
 2       reached through meetings under subsection (a) may be  
 3       changed in writing by mutual consent of the sponsor and  
 4       the Secretary at any time.

5       ~~“(c) MODIFICATION OF AGREEMENTS BY THE~~  
 6       FDA.—Agreements reached through meetings under sub-  
 7       section (a) may be changed unilaterally only—

8               ~~“(1) by the director of the office of the Food~~  
 9               and Drug Administration responsible for regulating  
 10              a drug or device subject to review under this section;  
 11              who may not delegate such responsibility; and

12              ~~“(2) in writing and specifying the basis therefor~~  
 13              and demonstrating the substantial public health rea-  
 14              sons that require the change.

15       ~~“(d) PANEL REVIEW.—~~

16              ~~“(1) IN GENERAL.—Any person requesting a~~  
 17              meeting under subsection (a) may obtain review  
 18              from a panel established under subsection 513(b) of  
 19              a determination of the Secretary to disapprove a  
 20              protocol or product development plan.

21              ~~“(2) AGREEMENT MODIFICATIONS.—Any per-~~  
 22              son who has reached an agreement with the Sec-  
 23              retary under subsection (b) may obtain review from  
 24              a panel described in paragraph (1) of a modification  
 25              of the agreement under subsection (c).”.

1 **TITLE IV—EFFICIENT, ACCOUNT-**  
 2 **ABLE, AND FAIR PRODUCT**  
 3 **REVIEW**

4 **SEC. 401. REFERENCE.**

5 This title may be cited as the “Product Review Regu-  
 6 latory Reform Act of 1995”.

7 **SEC. 402. THE CONTENT AND REVIEW OF AN APPLICATION.**

8 Chapter VII (21 U.S.C. 371 et seq.) is amended by  
 9 adding at the end thereof the following new subchapter:

10 **“SUBCHAPTER D—REVIEW OF APPLICATIONS**

11 **“SEC. 741. CONTENT AND REVIEW OF AN APPLICATION.**

12 **“(a) IN GENERAL.—**This section applies to any appli-  
 13 cation (including a petition, notification, or other similar  
 14 request) submitted for a food additive, new drug, biologi-  
 15 cal product, new animal drug, animal feed bearing or con-  
 16 taining a new animal drug, device, or color additive.

17 **“(b) FILING REQUIREMENTS.—**The Commissioner  
 18 shall establish a mechanism to ensure the fair and consist-  
 19 ent application of filing requirements.

20 **“(c) CLASSIFICATION OF A PRODUCT.—**Within 60  
 21 days of the receipt of a written request of any person for  
 22 information respecting the classification of a product as  
 23 a drug, biological product, or device or the component of  
 24 the Food and Drug Administration that will regulate the  
 25 product (including a request respecting a combination

1 product subject to section 503(g)) the Secretary shall pro-  
2 vide the person a written statement of the classification  
3 of the product or the component of the Food and Drug  
4 Administration that will regulate the product. The Sec-  
5 retary's statement shall be binding and may not be  
6 changed by the Secretary except with the written agree-  
7 ment of the person who submitted the request. If the Sec-  
8 retary does not provide the statement within the 60-day  
9 period, the classification and component designated by the  
10 person submitting the request shall be final and binding  
11 and may not be changed by the Secretary except with the  
12 written agreement of the person. All radiopharmaceutical  
13 products shall be regulated in a separate division under  
14 the Center for Devices and Radiological Health.

15       “(d) ~~REASONABLE DATA REQUIREMENTS.~~—Within 1  
16 year after the date of enactment of the Food and Drug  
17 Administration Performance and Accountability Act of  
18 1995, the Secretary, after consultation with patient advo-  
19 cacy groups and the regulated industries, shall publish in  
20 the Federal Register criteria for the type and amount of  
21 information relating to safety and effectiveness to be in-  
22 cluded in an application for the approval of a product, or  
23 a new use of an approved product, described in subsection  
24 (e). In developing the criteria, the Secretary shall consider  
25 any recommendations of the International Conference on

1 Harmonization of Technical Requirements for Registra-  
 2 tion of Pharmaceuticals for Human Use.”.

3 **SEC. 403. CONTRACTS FOR EXPERT REVIEW.**

4 Chapter VII (21 U.S.C. 371 et seq.), as amended by  
 5 section 402, is further amended by adding at the end  
 6 thereof the following new section:

7 **“SEC. 742. CONTRACTS FOR EXPERT REVIEW.**

8 “(a) IN GENERAL.—The Secretary may contract with  
 9 outside organizations and individuals, with expertise in  
 10 relevant disciplines, to review, evaluate, and make conclu-  
 11 sions and recommendations to the Secretary on parts or  
 12 all of any application (including a petition, notification,  
 13 or other similar request for Food and Drug Administra-  
 14 tion action). Any such contract shall be subject to the re-  
 15 quirements of section 708. Funds obtained under part 2  
 16 of subchapter C may be used for external review of any  
 17 drug (including a biological product) for which a user fee  
 18 was paid.

19 **“(b) REVIEW OF EXPERT’S EVALUATION.—**

20 “(1) IN GENERAL.—Subject to paragraph (2),  
 21 the Food and Drug Administration official respon-  
 22 sible for any matter for which expert review is used  
 23 pursuant to this section shall personally review the  
 24 conclusions and recommendations of the expert re-  
 25 view organization or individual and shall make a



1 final decision regarding the matter under review  
 2 within 60 days after receiving the conclusions and  
 3 recommendation.

4 “(2) LIMITATION.—A final decision under para-  
 5 graph (1) shall be made within the applicable pre-  
 6 scribed time period for review of an application as  
 7 set forth in this Act.”

8 **SEC. 404. PROMPT AND EFFICIENT REVIEW.**

9 Chapter VII (21 U.S.C. 371 et seq.), as amended by  
 10 section 403, is further amended by adding at the end  
 11 thereof the following new section:

12 **“SEC. 743. PROMPT AND EFFICIENT REVIEW.**

13 “(a) IN GENERAL.—The provisions of this section  
 14 shall apply to any of the following applications (including  
 15 a petition, notification, or other similar request):

16 “(1) An application for approval of a human  
 17 food additive or animal feed additive under section  
 18 409.

19 “(2) An application for approval of a new drug  
 20 under section 505(b)(1).

21 “(3) An application for approval of a new ani-  
 22 mal drug or an animal feed bearing or containing a  
 23 new animal drug under subsection (b)(1) or (m) of  
 24 section 512, respectively.

1           ~~“(4) A submission for a determination that a~~  
2           ~~device is substantially equivalent to a predicate de-~~  
3           ~~vice under sections 513(f)(1) and 513(i).~~

4           ~~“(5) An application for approval of a device~~  
5           ~~under section 515.~~

6           ~~“(6) An application for the listing of a color ad-~~  
7           ~~ditive under section 721.~~

8           ~~“(b) REVIEW PROCEDURES AND POLICIES.—The~~  
9           ~~Secretary shall establish procedures and policies to facili-~~  
10          ~~tate a collaborative review process between the Food and~~  
11          ~~Drug Administration and the applicant with respect to an~~  
12          ~~application or submission described in subsection (a). As~~  
13          ~~part of this collaborative process—~~

14                 ~~“(1) open, informal, and prompt communica-~~  
15                 ~~tions shall be encouraged;~~

16                 ~~“(2) meetings (except meetings with respect to~~  
17                 ~~submissions to determine substantial equivalence of~~  
18                 ~~a device to a predicate device) shall be held after the~~  
19                 ~~expiration of one-half of the statutory time period~~  
20                 ~~for review of the application and after the expiration~~  
21                 ~~of three-quarters of such period, or within 15 days~~  
22                 ~~after a scientific review group has convened and~~  
23                 ~~made recommendations on an application, unless the~~  
24                 ~~Food and Drug Administration and the applicant~~  
25                 ~~determine that a meeting is unnecessary; and~~

1           ~~“(3) the Secretary shall, prior to the meetings~~  
 2           ~~described in paragraph (2), present to the applicant~~  
 3           ~~in writing a description of any deficiencies of the ap-~~  
 4           ~~plication and the information necessary to bring the~~  
 5           ~~application into a form that would require approval.~~

6           ~~“(e) APPROVAL, DISAPPROVAL, AND CLASSIFICA-~~  
 7           ~~TION.—~~

8           ~~“(1) APPROVAL BASED ON FAILURE TO ACT.—~~

9           ~~Beginning 1 year after the date of publication of an~~  
 10          ~~applicable performance standard under section~~  
 11          ~~903(b), or 18 months after the date of enactment of~~  
 12          ~~the Food and Drug Administration Performance and~~  
 13          ~~Accountability Act of 1995, whichever occurs first, if~~  
 14          ~~the Secretary fails to meet a time period for action~~  
 15          ~~on an application established in the standard and~~  
 16          ~~the product that is a new drug, biological product,~~  
 17          ~~new animal drug, device, or food additive that is the~~  
 18          ~~subject of the application has met the marketing re-~~  
 19          ~~quirements of the European Union or the United~~  
 20          ~~Kingdom, at the request of the applicant the appli-~~  
 21          ~~cation shall be deemed to be approved unless, within~~  
 22          ~~30 days after the expiration of the time period es-~~  
 23          ~~tablished in the standard, the Secretary notifies the~~  
 24          ~~applicant in writing that the application is dis-~~  
 25          ~~approved, setting forth the reasons for disapproval,~~

1 and, with the consent of the applicant, publishes a  
 2 notice, within 30 days of notifying the applicant, in  
 3 the Federal Register disapproving the application  
 4 under paragraph (2) and setting forth the reasons  
 5 for the disapproval.

6 “(2) APPEAL.—A person whose application has  
 7 been disapproved under this subsection may appeal  
 8 using one of the following procedures:

9 “(A) PROCEDURES UNDER THE ACT.—The  
 10 procedures established for the product under  
 11 other provisions of this Act.

12 “(B) APPEAL.—An appeal to a United  
 13 States District Court to determine whether the  
 14 Secretary’s decision is supported by substantial  
 15 evidence in the administrative record.

16 “(d) CONTRACTS FOR EXPERT REVIEW.—

17 “(1) IN GENERAL.—Beginning July 1, 1998, if  
 18 the Secretary in any fiscal year fails to meet the  
 19 statutory time period for action on an application  
 20 for at least 95 percent of the applications in a par-  
 21 ticular category, the Secretary shall in the following  
 22 fiscal year, with the consent of the applicant, con-  
 23 tract with expert individuals and organizations  
 24 under section 742 to review new applications and  
 25 applications for which the Secretary has failed to

1 meet the statutory time period for action for the  
2 particular product category.

3 “(2) **APPROVAL.**—If an individual or organiza-  
4 tion selected to conduct a review under paragraph  
5 (1) determines that an application described in para-  
6 graph (1) should be approved, the application shall  
7 be considered to be approved unless, within 30 days  
8 after the date the Secretary receives the determina-  
9 tion of the individual or organization, the Secretary  
10 publishes a notice in the Federal Register disapprov-  
11 ing the application and setting forth the reasons for  
12 disapproval. An applicant may appeal the dis-  
13 approval under subsection (c)(2).”.

14 **SEC. 405. GOOD MANUFACTURING PRACTICE INSPECTION.**

15 Chapter VII is (21 U.S.C. 371 et seq.), as amended  
16 by section 404, is further amended by adding at the end  
17 thereof the following new section:

18 **“SEC. 744. GOOD MANUFACTURING PRACTICE INSPECTION.**

19 “(a) **IN GENERAL.**—In order to comply with inspec-  
20 tion requirements of this Act, the Secretary may accredit  
21 organizations to conduct inspections under section 704 to  
22 evaluate compliance of a manufacturer with applicable re-  
23 quirements for good manufacturing practice.

24 “(b) **ELIGIBILITY REQUIREMENTS.**—The Secretary  
25 shall by regulation establish the requirements that an or-

1 ganization shall meet to be eligible to be accredited to par-  
 2 ticipate as a qualified organization to conduct inspections  
 3 under subsection (a).

4 “(c) ACCREDITATION.—Within 90 days after the date  
 5 the Secretary receives an application for accreditation  
 6 under this section, the Secretary shall review the applica-  
 7 tion and determine whether an applicant is in compliance  
 8 with the requirements established under this section.  
 9 Within the 90-day period, the Secretary shall grant ac-  
 10 creditation or shall deny accreditation and specify in writ-  
 11 ing the reasons for the denial and the requirements that  
 12 shall be met to obtain accreditation.

13 “(d) REVOCATION OF ACCREDITATION.—The Sec-  
 14 retary may at any time revoke accreditation granted under  
 15 subsection (c) for failure to comply with the requirements  
 16 established under this section after specifying in writing  
 17 the reasons for the revocation and the requirements that  
 18 shall be met to retain accreditation and after an informal  
 19 hearing on the revocation.

20 “(e) INSPECTIONS.—Any organization accredited  
 21 under this subsection that conducts an inspection under  
 22 this subsection at the request of the Secretary shall—

23 “(1) apply all relevant principles of good manu-  
 24 facturing practice established in this Act and in reg-  
 25 ulations promulgated by the Secretary; and

1           “(2) provide to the Secretary and the manufac-  
 2           turer within 30 days after the completion of the in-  
 3           spection an adequate report of the findings of the in-  
 4           spection.”

5           “(f) LIMITATION.—When an accredited organization  
 6           has conducted a good manufacturing practice inspection  
 7           under section 704, the Secretary may not perform such  
 8           an inspection for a period of 2 years after the date of the  
 9           receipt of the report required under subsection (e)(2), un-  
 10          less justified by good cause.”

11   **SEC. 406. ENVIRONMENTAL IMPACT REVIEW.**

12          Chapter VII (21 U.S.C. 371 et seq.), as amended by  
 13          section 405, is further amended by adding at the end  
 14          thereof the following new section:

15   **“SEC. 745. ENVIRONMENTAL IMPACT REVIEW.**

16          “Notwithstanding any provision of other law, no ac-  
 17          tion by the Secretary pursuant to this Act shall be subject  
 18          to an environmental assessment, an environmental impact  
 19          statement, or other environmental consideration unless the  
 20          director of the office responsible for the action dem-  
 21          onstrates, in writing and specifying the basis therefor—

22               “(1) that there is a reasonable probability that  
 23               the environmental impact of the action is sufficiently  
 24               substantial and within the factors that the Secretary  
 25               is authorized to consider under this Act; and

1           ~~“(2) that consideration of the environmental~~  
 2           ~~impact will directly affect the decision on the ac-~~  
 3           ~~tion.”.~~

4   **SEC. 407. INFORMATION EXCHANGE.**

5           Chapter VII (21 U.S.C. 371 et seq.), as amended by  
 6   section 406, is further amended by adding at the end  
 7   thereof the following new sections:

8   **~~“SEC. 746. DISSEMINATION OF INFORMATION ON DRUGS.~~**

9           ~~“(a) DISSEMINATION.—~~

10           ~~“(1) IN GENERAL.—Notwithstanding sections~~  
 11           ~~301(d) and 502(f), and subject to the requirements~~  
 12           ~~of paragraph (2) and subsection (b), a person may~~  
 13           ~~disseminate to any person that is a health care prac-~~  
 14           ~~titioner or other provider of health care goods or~~  
 15           ~~services, a pharmacy benefit manager, a health~~  
 16           ~~maintenance organization or other managed health~~  
 17           ~~care organization, or a health care insurer or gov-~~  
 18           ~~ernmental agency, written information, or an oral or~~  
 19           ~~written summary of the written information, con-~~  
 20           ~~cerning—~~

21           ~~“(A) a treatment use for an investigational~~  
 22           ~~new drug (including a biological product) ap-~~  
 23           ~~proved by the Secretary for such treatment use;~~  
 24           ~~or~~



1           “(B) a use (whether or not such use is  
 2           contained in the official labeling) of a new drug  
 3           for which an approval of an application filed  
 4           under section 505(b) is in effect.

5           “(2) REQUIREMENTS.—A person may dissemi-  
 6           nate information under paragraph (1)(B) only if—

7           “(A) the information is an unabridged—

8           “(i) reprint or copy of a peer-reviewed  
 9           article from a scientific or medical journal  
 10          that is published by an organization that is  
 11          independent of the pharmaceutical indus-  
 12          try; or

13          “(ii) chapter, authored by an expert  
 14          or experts in the disease to which the use  
 15          relates, from a recognized reference text-  
 16          book that is published by an organization  
 17          that is independent of the pharmaceutical  
 18          industry;

19          “(B) the text of the information has been  
 20          approved by a continuing medical education ac-  
 21          crediting agency that is independent of the  
 22          pharmaceutical industry as part of a scientific  
 23          or medical educational program approved by the  
 24          agency;

1           “(C) the information relates to a use that  
2           is recognized under Federal law for purposes of  
3           third-party coverage or reimbursement, and—

4           “(i) the text of the information has  
5           been approved by an organization referred  
6           to in such Federal law; and

7           “(ii) the information is part of a dis-  
8           ease management program or treatment  
9           guideline with respect to the use; or

10          “(D) the information is an accurate and  
11          truthful summary of the information described  
12          in subparagraph (A), (B), or (C).

13          “(b) DISCLOSURE STATEMENT.—In order to afford  
14          a full and fair evaluation of the information described in  
15          subsection (a), a person disseminating the information  
16          shall include a statement that discloses—

17          “(1) if applicable, that the use of a new drug  
18          described in subparagraph (A) or (B) of subsection  
19          (a)(1) and the information with respect to the use  
20          have not been approved by the Food and Drug Ad-  
21          ministration;

22          “(2) if applicable, that the information is being  
23          disseminated at the expense of the sponsor of the  
24          new drug;

1           “(3) if applicable, that one or more authors of  
2           the information being disseminated are employees of  
3           or consultants to the sponsor of the new drug; and

4           “(4) the official labeling for the drug and bio-  
5           logical product, or in the case of a treatment use of  
6           an investigational new drug, the investigator bro-  
7           chure and all updates thereof.

8           “(e) DEFINITION.—As used in this section, the term  
9           ‘expense’ includes financial, in-kind, and other contribu-  
10          tions provided for the purpose of disseminating the infor-  
11          mation described in subsection (a).

12          “(d) SPECIAL RULE.—In the case of a professional  
13          disagreement between the Secretary and other qualified  
14          experts with respect to the application of section 502(a),  
15          the Secretary may not use section 502 to prohibit the dis-  
16          semination of information in the types of circumstances  
17          and under the conditions set forth in subsections (a) and  
18          (b).

19          **“SEC. 747. DISSEMINATION OF INFORMATION ON DEVICES.**

20          “(a) IN GENERAL.—Notwithstanding sections 301,  
21          501(f), 501(i), 502(a), 502(f), and 502(o), or any other  
22          provision of law, and subject to subsections (b) and (c),  
23          a person may disseminate to any person that is a health  
24          care practitioner or other provider of health care goods  
25          or services, a pharmacy benefit manager, a health mainte-

1 nance organization or other managed health care organi-  
 2 zation, or a health care insurer or governmental agency,  
 3 written or oral information (including information ex-  
 4 changed at scientific and educational meetings, work-  
 5 shops, or demonstrations) relating to a use, whether or  
 6 not the use is described in the official labeling, of a device  
 7 produced by a manufacturer registered pursuant to sec-  
 8 tion 510.

9 “(b) DISCLOSURE STATEMENTS AND REQUIRE-  
 10 MENTS.—

11 “(1) DISCLOSURE STATEMENTS.—To the extent  
 12 practicable, the requirement with respect to a state-  
 13 ment of disclosure under subsection (b) of section  
 14 746 shall apply to the dissemination of written and  
 15 oral information under this section, except that this  
 16 paragraph shall not apply to the dissemination of  
 17 written or oral information with respect to the in-  
 18 tended use described in the labeling of a device.

19 “(2) ADDITIONAL REQUIREMENTS.—A person  
 20 may disseminate information under subsection (a)  
 21 only if—

22 “(A) the information is an unabridged—

23 “(i) reprint or copy of a peer-reviewed  
 24 article from a scientific or medical journal  
 25 that is published by an organization that is

1 independent of the medical device industry;

2 or

3 “(ii) chapter, authored by an expert  
4 or experts in the medical specialty to which  
5 the use relates, from a recognized ref-  
6 erence textbook that is published by an or-  
7 ganization that is independent of the medi-  
8 cal device industry;

9 “(B) the information has been approved by  
10 a continuing medical education accrediting  
11 agency that is independent of the medical de-  
12 vice industry as part of a scientific or medical  
13 educational program approved by the agency;

14 “(C) the information relates to a use that  
15 is recognized under Federal law for purposes of  
16 third-party reimbursement, and—

17 “(i) the text of the information has  
18 been approved by an organization referred  
19 to in such Federal law; and

20 “(ii) the information is part of a dis-  
21 ease management program or treatment  
22 guideline with respect to such use; or

23 “(D) the oral or written information is—

24 “(i) part of an exchange of informa-  
25 tion solely among health care practitioners;

1 health care reimbursement officials, and  
2 the industry;

3 “(ii) exchanged for educational or sci-  
4 entific purposes; or

5 “(iii) presented at continuing medical  
6 education programs, seminars, workshops,  
7 or demonstrations.

8 “(3) APPLICABILITY.—The requirements under  
9 subsection (a)(1)(A) and (B) of section 746 shall not  
10 apply with respect to devices.

11 **“SEC. 748. POLICY ON INFORMATION DISSEMINATION.**

12 “(a) CONSTRUCTION.—Notwithstanding section 502  
13 (a), (f), and (o), or any other provision of law, the written  
14 or oral dissemination of information relating to a new use  
15 of a new drug or device, in accordance with sections 746  
16 and 747, shall not be construed as evidence of a new in-  
17 tended use of the new drug or device that is different from  
18 the intended use of the new drug or device set forth in  
19 the official labeling. The dissemination shall not be consid-  
20 ered as labeling, adulteration, or misbranding of the new  
21 drug or device.

22 “(b) RESPOND TO UNSOLICITED QUESTIONS.—Noth-  
23 ing in this Act shall affect the ability of manufacturers  
24 to respond fully to unsolicited questions from health care

1 practitioners and other persons about drugs (including bi-  
2 ological products) or devices.

3 **“SEC. 749. APPROVAL OF NEW USES.**

4       “(a) IN GENERAL.—As an alternative to the proce-  
5 dures established in section 505(c)(1) for a new drug (in-  
6 cluding a biological product) and section 515(d)(1)(A) for  
7 a device, the Secretary shall approve an application under  
8 this section for a new use of a previously approved new  
9 drug or device if experts qualified by scientific training  
10 and experience to evaluate the safety and effectiveness of  
11 drugs or devices conclude that a new use that has not been  
12 reviewed or approved by the Secretary represents sound  
13 medical practice based upon reliable clinical experience  
14 and other confirmatory information, unless the Secretary  
15 demonstrates that there are other compelling public health  
16 reasons related to the safety or effectiveness of the drug  
17 or device why approval would harm the health of individ-  
18 ual patients.

19       “(b) PETITION.—The holder of an approved applica-  
20 tion may submit a petition to the Secretary presenting in-  
21 formation that new use of a previously approved new drug  
22 or device meets the criteria for approval established in this  
23 subsection. The petition shall include data and informa-  
24 tion relating to the new use and shall demonstrate that  
25 the new use—

1           “(1) has existed in clinical practice for at least  
2       five years;

3           “(2) is common among clinicians experienced in  
4       the field; and

5           “(3) represents reasonable medical practice  
6       based upon reliable clinical experience and other  
7       confirmatory information.

8           “(e) ACTION ON PETITION.—Upon receipt of the pe-  
9       tition, the Secretary shall obtain the conclusions and rec-  
10      ommendations of a scientific review group established  
11      under section 904 and grant or deny the petition within  
12      180 days of the receipt of the petition.”.

13   **SEC. 408. EFFECTIVENESS, OUTCOME, AND COST-EFFEC-**  
14                           **TIVENESS STANDARDS.**

15       Section 741, as added by section 402, is amended by  
16       adding at the end thereof the following new subsection:

17       “(e) In reviewing an application for a product that  
18       is a new drug, biological product, new animal drug, animal  
19       feed bearing or containing a new animal drug, or device  
20       the determination of effectiveness shall not include the  
21       evaluation of—

22           “(1) relative effectiveness, unless the effective-  
23       ness of the product is explicitly compared to the ef-  
24       fectiveness of another product in the labeling;



1           ~~“(2) any potential use not explicitly included in~~  
 2           ~~the labeling;~~

3           ~~“(3) the cost-effectiveness of the product de-~~  
 4           ~~scribed in this subsection as compared to the cost-~~  
 5           ~~effectiveness of a similar product, unless the labeling~~  
 6           ~~explicitly includes a representation about cost-effec-~~  
 7           ~~tiveness; and~~

8           ~~“(4) the clinical outcome resulting from use of~~  
 9           ~~a device, unless the labeling explicitly includes a rep-~~  
 10          ~~resentation regarding clinical outcome.”.~~

11 **SEC. 409. DEFINITION OF A DAY FOR PURPOSES OF PROD-**  
 12 **UCT REVIEW.**

13          Section 201 ~~(21 U.S.C. 321)~~ is amended by adding  
 14 at the end thereof the following:

15          ~~“(gg) For purposes of reviewing any application, noti-~~  
 16          ~~fication or petition, or any document, with respect to a~~  
 17          ~~product that is a new drug, biological product, new animal~~  
 18          ~~drug, device, or food additive that is submitted to the Sec-~~  
 19          ~~retary to obtain approval of marketing, or to establish or~~  
 20          ~~clarify the regulatory status of the product, the term ‘day’~~  
 21          ~~means a calendar day (excluding any calendar day be-~~  
 22          ~~tween the date of receipt by the submitter of a written~~  
 23          ~~communication from the Secretary setting forth the action~~  
 24          ~~of the Secretary on a submission and the date of receipt~~  
 25          ~~by the Secretary of the written response of the submitter~~

1 to the action) in which the Secretary has responsibility to  
 2 review such a submission.”.

3 **TITLE V—DRUG, BIOLOGICAL**  
 4 **PRODUCTS, DEVICES EXPORT**  
 5 **REFORM**

6 **SEC. 501. SHORT TITLE.**

7 This title may be cited as the “Drug, Biological Prod-  
 8 ucts, Devices Export Reform Act of 1995”.

9 **SEC. 502. EXPORT OF DRUGS AND DEVICES.**

10 (a) EXPORTS AND IMPORTS.—Section 801 (21  
 11 U.S.C. 381) is amended—

12 (1) in subsection (d), by adding at the end  
 13 thereof the following new paragraph:

14 “(3) No component, part or accessory of a drug, bio-  
 15 logical product, or device, including a drug in bulk form,  
 16 shall be excluded from importation into the United States  
 17 under paragraph (a), if the component, part, or accessory  
 18 will be incorporated into a device, drug, or biological prod-  
 19 uct that will be exported from the United States in accord-  
 20 ance with subsection (e) of section 802 or section 351(h)  
 21 of the Public Health Service Act.”;

22 (2) in subsection (e)(1), by striking the second  
 23 sentence; and

1           ~~(3)~~ in subsection ~~(c)(2)~~, by inserting before the  
 2           period at the end thereof the following: “or that the  
 3           device is eligible for export under section 802”.

4           ~~(b) EXPORT OF CERTAIN UNAPPROVED DRUGS AND~~  
 5           ~~DEVICES.—~~Section 802 ~~(21 U.S.C. 382)~~ is amended to  
 6           read as follows:

7           **“SEC. 802. EXPORTS OF CERTAIN UNAPPROVED PRODUCTS.**

8           ~~“(a) IN GENERAL.—~~A drug (including a biological  
 9           product) intended for human or animal use or a device  
 10          for human use—

11               ~~“(1)(A) which, in the case of a drug—~~

12                       ~~“(i) requires approval by the Secretary~~  
 13                       ~~under section 505 or section 512; or~~

14                       ~~“(ii) requires licensing by the Secretary~~  
 15                       ~~under section 351 of the Public Health Service~~  
 16                       ~~Act or by the Secretary of Agriculture under~~  
 17                       ~~the Act of March 4, 1913 (known as the Virus-~~  
 18                       ~~Serum Toxin Act);~~

19          before the drug may be introduced or delivered for  
 20          introduction into interstate commerce to a country;  
 21          and

22               ~~“(B) which—~~

23                       ~~“(i) does not have such approval or license;~~

24                       ~~“(ii) is not exempt from such sections or~~  
 25          Act; and

1           “(iii) is introduced or delivered for intro-  
 2           duction into interstate commerce to a country;  
 3           or

4           “(2) which, in the case of a device—

5           “(A) does not comply with an applicable  
 6           requirement under section 514 or 515;

7           “(B) is exempt under section 520(g) from  
 8           section 514 or 515; or

9           “(C) is a banned device under section 516;  
 10          is adulterated, misbranded, and in violation of such sec-  
 11          tions or Act unless the export of the drug or device is au-  
 12          thorized under subsection (b), (c), (e), or (f) or under sec-  
 13          tion 801(e)(2).

14          “(b) EXPORTATION TO ANY COUNTRY OR A SPECIFIC  
 15          COUNTRY.—

16           “(1) EXPORTATIONS TO ANY COUNTRY.—Ex-  
 17          cept as otherwise provided in this section, a drug  
 18          (including a biological product) or device may be ex-  
 19          ported to any country, if the drug or device complies  
 20          with the laws of that country and has valid market-  
 21          ing authorization by the appropriate approval au-  
 22          thority—

23           “(A) in Australia, Canada, Israel, Japan,  
 24          New Zealand, or Switzerland; or

1           “(B) in the European Union or a country  
2           in the European Economic Area (the countries  
3           in the European Union and the European Free  
4           Trade Association) if the drug or device is mar-  
5           keted in that country or the drug or device is  
6           authorized for general marketing in the Euro-  
7           pean Economic Area.

8           “(2) EXPORTATION TO A CERTAIN COUNTRY.—  
9           A drug or device may be exported to the countries  
10          described in paragraph (1) if the drug or device  
11          complies with the laws of any such country and has  
12          a valid marketing authorization by the appropriate  
13          approval authority in that country.

14          “(c) EXPORTATION TO A COUNTRY WITH A REGU-  
15          LATORY SYSTEM.—

16          “(1) IN GENERAL.—A drug or device may be  
17          exported under this section to any other country  
18          that has an adequate regulatory system to protect  
19          the health of the citizens of such a country. The  
20          Comptroller General, in consultation with the Sec-  
21          retary and other appropriate parties, shall develop a  
22          list of countries to which a drug or device may be  
23          exported under this paragraph and a list of rec-  
24          ommended criteria for additions or deletions of coun-  
25          tries to the list of countries.

1           “(2) REQUEST DESIGNATION.—An appropriate  
2           country official, manufacturer, or exporter, may re-  
3           quest the Secretary to designate a country to receive  
4           drugs or devices exported under this section that  
5           meets the requirements of paragraph (1) by submit-  
6           ting documentation in support of such designation to  
7           the Secretary. Any person other than an appropriate  
8           country official requesting such designation shall  
9           provide a letter from the country indicating the de-  
10          sire of the country to be designated.

11          “(3) TIME LIMITATION FOR DESIGNATION.—If  
12          the Secretary fails to, within 90 days of the date of  
13          the receipt of a request under paragraph (2), re-  
14          spond to the request with a denial of the requested  
15          designation, the request shall be considered granted  
16          and the country that is the subject of the request  
17          shall be designated as eligible to receive drugs or de-  
18          vices exported under this subsection.

19          “(4) WITHDRAWAL OF DESIGNATION.—If infor-  
20          mation is provided to the Secretary that indicates  
21          that, due to a public health emergency or systematic  
22          patterns of abuse of the regulatory system in a  
23          country designated under paragraph (3), the country  
24          is no longer able to carry out the functions described  
25          in paragraph (1), or if the country no longer meets

1 the requirements for designation under this sub-  
2 section, the Secretary may withdraw the designation  
3 of the country.

4 “(d) LIMITATIONS.—A drug or device may not be ex-  
5 ported under this section if—

6 “(1) the drug or device is not manufactured,  
7 processed, packaged, and held in conformity with  
8 current good manufacturing practice or is adulter-  
9 ated under paragraph (1), (2)(A), or (3) of section  
10 501(a) or subsection (c) or (d) of section 501;

11 “(2) the drug or device is not labeled and ad-  
12 vertised in accordance with the requirements and  
13 conditions for use of any country in which the drug  
14 or device is approved, either in English or the pre-  
15 dominant language of the country to which the drug  
16 or device is being exported, except that with respect  
17 to advertising alternative methods of communication  
18 that are consistent with the requirements of the ap-  
19 proving country shall be allowed if authorized by the  
20 receiving country;

21 “(3) the requirements of subparagraphs (A)  
22 through (D) of section 801(c)(1) have not been met;

23 “(4) the drug or device has been the subject of  
24 a finding by the Secretary under section 505, 512  
25 or 515 or under section 351 of the Public Health

1 Service Act (42 U.S.C. 262), or by the Secretary of  
2 Agriculture under the Act of March 4, 1913 (37  
3 Stat. 832–833) (commonly known as the ‘Virus  
4 Serum Toxin Act’) that the drug or device has not  
5 been shown to be safe or effective for labeled indica-  
6 tion of the drug or device;

7 “(5) the Secretary finds that the drug or device  
8 poses an unreasonable and substantial risk to public  
9 health in the receiving country;

10 “(6) the drug or device is the subject of a no-  
11 tice by the Secretary or the Secretary of Agriculture  
12 of a determination that the possibility of reimporta-  
13 tion of the exported drug or device would present an  
14 imminent hazard to the public health and safety of  
15 the United States and the only means of limiting the  
16 hazard is to prohibit the export of the drug or de-  
17 vice; or

18 “(7) the drug or device will be re-exported or  
19 transshipped to a country not authorized to receive  
20 an exported drug or device under this section.

21 In making a finding under paragraph (5), the Secretary,  
22 to the maximum extent possible, shall consult with the af-  
23 fected country.

24 “(e) EXPORTATION OF DRUG FOR INVESTIGATIONAL  
25 USE.—A drug intended for investigational use in any



1 country described in subsection (b) or designated under  
 2 subsection (c) may be exported in accordance with the  
 3 laws of that country and still be exempt from regulation  
 4 under section 505(i) or section 512(j).

5 ~~“(f) EXPORTATION OF A DRUG FOR TROPICAL DIS-~~  
 6 ~~EASE.—~~

7 ~~“(1) IN GENERAL.—A drug (including a biologi-~~  
 8 ~~cal product) that is to be used in the prevention or~~  
 9 ~~treatment of a tropical disease may, upon approval~~  
 10 ~~of an application submitted under paragraph (2), be~~  
 11 ~~exported if—~~

12 ~~“(A) the Secretary finds, based on credible~~  
 13 ~~scientific evidence, including clinical investiga-~~  
 14 ~~tions, that the drug is safe and effective in the~~  
 15 ~~country to which the drug is to be exported in~~  
 16 ~~the prevention or treatment of a tropical dis-~~  
 17 ~~ease in such country;~~

18 ~~“(B) the drug is manufactured, processed,~~  
 19 ~~packaged, and held in conformity with current~~  
 20 ~~good manufacturing practice and is not adulter-~~  
 21 ~~ated under paragraphs (1), (2)(A), and (3) of~~  
 22 ~~subsection (a), and subsection (c) or (d), of sec-~~  
 23 ~~tion 501;~~

24 ~~“(C) the outside of the shipping package is~~  
 25 ~~labeled with the following statement: ‘This drug~~

1 may be sold or offered for sale only in the fol-  
2 lowing countries;², the blank space being filled  
3 with a list of the countries to which export of  
4 the drug is authorized under this subsection;

5 “(D) the drug is not the subject of a notice  
6 by the Secretary or the Secretary of Agriculture  
7 of a determination that the manufacture of the  
8 drug in the United States for export to a coun-  
9 try is contrary to the public health and safety  
10 of the United States; and

11 “(E) the requirements of subparagraphs  
12 (A) through (D) of section 801(d)(1) have been  
13 met.

14 “(2) APPLICATION.—Any person may apply to  
15 have a drug exported under paragraph (1). The ap-  
16 plication shall—

17 “(A) describe the drug to be exported;

18 “(B) list each country to which the drug is  
19 to be exported;

20 “(C) contain a certification by the appli-  
21 cant that the drug will not be exported to a  
22 country for which the Secretary cannot make a  
23 finding described in paragraph (1)(A);

24 “(D) identify the establishments in which  
25 the drug is manufactured; and

1           “(E) demonstrate to the Secretary that the  
2           drug meets the requirements of paragraph (1).

3           ~~“(3) REQUIRED REPORTING.—~~The holder of an  
4           approved application for the export of a drug under  
5           this subsection shall report to the Secretary—

6           ~~“(A) the receipt of any information indi-~~  
7           ~~cating that the drug is being or may have been~~  
8           ~~exported from a country for which the Sec-~~  
9           ~~retary made a finding under paragraph (1)(A)~~  
10          ~~to a country for which the Secretary cannot~~  
11          ~~make such a finding; and~~

12          ~~“(B) the receipt of any information indi-~~  
13          ~~cating any adverse reactions to such drug.~~

14          ~~“(4) ADDITIONAL LIMITATIONS.—~~

15          ~~“(A) FAILURE TO MEET CERTAIN RE-~~  
16          ~~QUIREMENTS.—If the Secretary determines~~  
17          ~~that—~~

18                 ~~“(i) a drug for which an application is~~  
19                 ~~approved under paragraph (2) does not~~  
20                 ~~continue to meet the requirements of para-~~  
21                 ~~graph (1);~~

22                 ~~“(ii) the holder of the application has~~  
23                 ~~not made the report required by paragraph~~  
24                 ~~(3); or~~

1           “(iii) the manufacture of the drug in  
2           the United States for export is contrary to  
3           the public health and safety of the United  
4           States and an application for the export of  
5           the drug has been approved under para-  
6           graph (2);

7           then before taking action against the holder of an  
8           application for which a determination was made  
9           under clause (i), (ii), or (iii), the Secretary shall no-  
10          tify the holder in writing of the determination and  
11          provide the holder 30 days to take such corrective  
12          actions as may be required by the Secretary to pre-  
13          vent the Secretary from taking action against the  
14          holder. If the Secretary takes action against the  
15          holder because of the determination, the Secretary  
16          shall provide the holder a written statement specify-  
17          ing the reasons for the determination and provide  
18          the holder, on request, an opportunity for an infor-  
19          mal hearing with respect to the determination.

20               “(B) LIMITATION ON THE EXPORTATION  
21               OF A HAZARDOUS DRUG BY AN IMPORTER.—If  
22               at any time the Secretary, or in the absence of  
23               the Secretary, the official designated to act on  
24               behalf of the Secretary determines that—

1           “(i) the holder of an approved applica-  
2           tion under paragraph (2) is exporting a  
3           drug from the United States to an im-  
4           porter;

5           “(ii) the importer is exporting the  
6           drug to a country for which the Secretary  
7           cannot make a finding under paragraph  
8           (1)(A); and

9           “(iii) the export presents an imminent  
10          hazard to the public health in the country;  
11          the Secretary shall immediately prohibit the ex-  
12          port of the drug to the importer, provide the  
13          person exporting the drug from the United  
14          States prompt notice of the determination, and  
15          afford the person an opportunity for an expe-  
16          dited hearing. A determination by the Secretary  
17          under this subparagraph may not be stayed  
18          pending final action by a reviewing court. The  
19          authority conferred by this subparagraph may  
20          not be delegated by the Secretary.

21          “(C) LIMITATION ON THE EXPORTATION  
22          OF A HAZARD DRUG BY A HOLDER.—If the Sec-  
23          retary, or in the absence of the Secretary, the  
24          official designated to act on behalf of the Sec-  
25          retary determines that the holder of an ap-

proved application under paragraph (2) is exporting a drug to a country for which the Secretary cannot make a finding under paragraph (1)(A), and that the export of the drug presents an imminent hazard, the Secretary shall immediately prohibit the export of the drug to such country, provide the holder prompt notice of the determination, and afford the holder an opportunity for an expedited hearing. A determination by the Secretary under this subparagraph may not be stayed pending final action by a reviewing court. The authority conferred by this subparagraph shall not be delegated by the Secretary.

“(D) LIMITATION ON THE EXPORTATION OF OTHER DRUGS BY A HOLDER.—If the Secretary receives credible evidence that the holder of an application approved under paragraph (2) is exporting a drug to a country for which the Secretary cannot make a finding under paragraph (1)(A), the Secretary shall give the holder 60 days to provide information to the Secretary respecting such evidence and shall provide the holder an opportunity for an informal hearing on such evidence. Upon the expiration

1 of such 60 days, the Secretary shall prohibit the  
 2 export of such drug to such country if the Sec-  
 3 retary determines the holder is exporting the  
 4 drug to a country for which the Secretary can-  
 5 not make a finding under paragraph (1)(A).

6 “(E) LIMITATION OF THE EXPORTATION  
 7 OF OTHER DRUGS BY AN IMPORTER.—If the  
 8 Secretary receives credible evidence that an im-  
 9 porter is exporting a drug to a country for  
 10 which the Secretary cannot make a finding  
 11 under paragraph (1)(A), the Secretary shall no-  
 12 tify the holder of the application authorizing  
 13 the export of such drug of such evidence and  
 14 shall require the holder to investigate the export  
 15 by such importer and to report to the Secretary  
 16 within 14 days of the receipt of such notice the  
 17 findings of the holder. If the Secretary deter-  
 18 mines that the importer has exported a drug to  
 19 such a country, the Secretary shall prohibit  
 20 such holder from exporting such drug to the  
 21 importer unless the Secretary determines that  
 22 the export by the importer was unintentional.”.

23 **SEC. 503. PARTIALLY PROCESSED BIOLOGICAL PRODUCTS.**

24 Subsection (h) of section 351 of the Public Health  
 25 Service Act (42 U.S.C. 262) is amended to read as follows:

1       “(h) A partially processed biological product that—  
 2               “(1) is not in a form applicable to the preven-  
 3       tion, treatment, or cure of diseases or injuries of  
 4       man;  
 5               “(2) is not intended for sale in the United  
 6       States; and  
 7               “(3) is intended for further manufacture into  
 8       final dosage form outside the United States;  
 9       shall be subject to no restriction on the export of the prod-  
 10      uct under this Act or the Federal Food, Drug, and Cos-  
 11      metic Act (21 U.S.C. 321 et seq.) if the product is manu-  
 12      factured, processed, packaged, and held in conformity with  
 13      current good manufacturing practice and meets the re-  
 14      quirements of section 801(e)(1) of the Federal Food,  
 15      Drug, and Cosmetic Act (21 U.S.C. 381(e)(1)).”.

## 16 **TITLE VI—DRUG AND BIOLOGI-** 17 **CAL PRODUCTS REGULATORY** 18 **REFORM**

### 19 **SEC. 601. SHORT TITLE.**

20       This title may be cited as the “Drug and Biological  
 21      Product Regulatory Reform Act of 1995”.

### 22 **SEC. 602. NEW DRUG APPROVAL STANDARD.**

23       Section 505(d) (21 U.S.C. 355(d)) is amended by  
 24      adding at the end thereof the following new sentence:  
 25      “Substantial evidence may consist of data from one well-



1 controlled clinical investigation (which may be waived by  
 2 the Secretary) and confirmatory evidence (obtained either  
 3 before or after such investigation).”.

4 **SEC. 603. PILOT AND SMALL SCALE MANUFACTURE.**

5 Section 505(e) (21 U.S.C. 355(e)) is amended by  
 6 adding at the end thereof the following new paragraph:

7 “(4) A new drug or biological product manufactured  
 8 in a pilot or other small facility may be used to dem-  
 9 onstrate the safety and effectiveness of the drug or prod-  
 10 uct and to obtain approval prior to scaling up to a larger  
 11 facility, unless the Secretary demonstrates in writing and  
 12 specifying in detail the reasons, after an informal hearing,  
 13 that a full scale production facility is necessary to ensure  
 14 the safety or effectiveness of the drug or product.”.

15 **SEC. 604. MANUFACTURING CHANGES.**

16 Chapter VII (21 U.S.C. 371 et seq.), as amended by  
 17 section 407, is further amended by adding at the end  
 18 thereof the following new section:

19 **“SEC. 750. MANUFACTURING CHANGES.**

20 “(a) IN GENERAL.—A change in the manufacture of  
 21 a new drug, biological product, or new animal drug, may  
 22 be made in accordance with this section.

23 “(b) DRUG AND BIOLOGICAL PRODUCT.—A change  
 24 in the manufacture of a new drug, a biological product  
 25 that is the subject of a monograph in an official compen-

1 dium, a biological product that can be adequately charac-  
2 terized by chemical, physical, or biological means, or a new  
3 animal drug shall require—

4 “(1) validation; and

5 “(2)(A) if there is no change in the approved  
6 qualitative and quantitative formulation or in the  
7 approved release specifications; or if there is a  
8 change in the approved qualitative or quantitative  
9 formula or in the approved release specifications of  
10 a type permitted by the Secretary by regulation; may  
11 be made at any time and shall be reported annually  
12 to the Secretary; and

13 “(B) for any other change, shall require com-  
14 pletion of an appropriate study demonstrating  
15 equivalence according to criteria established by the  
16 Secretary (unless such requirement is waived by the  
17 Secretary); may be made at any time; and shall be  
18 reported to the Secretary through a supplement or  
19 amendment submitted at the time the change is  
20 made.

21 “(c) BIOLOGICAL PRODUCT NOT SUBJECT TO A  
22 MONOGRAPH.—A change in the manufacture of a biologi-  
23 cal product that is not the subject of a monograph in an  
24 official compendium and cannot be adequately character-

1 ized by chemical, physical, or biological means shall re-  
2 quire validation and—

3       “(1) if the change relates solely to a modifica-  
4 tion of the manufacturing facility or change in per-  
5 sonnel, with no change in the approved manufactur-  
6 ing process or release specifications, may be made at  
7 any time and shall be reported annually to the Sec-  
8 retary; and

9       “(2) for any other change, shall require comple-  
10 tion of a bioassay or other appropriate study dem-  
11 onstrating equivalence according to criteria estab-  
12 lished by the Secretary (unless such requirement is  
13 waived by the Secretary), may be made at any time,  
14 and shall be reported to the Secretary through an  
15 amendment submitted at the time the change is  
16 made.

17       “(d) SPECIAL DETERMINATION FOR A BIOLOGICAL  
18 PRODUCT.—A determination shall be made prior to ap-  
19 proval of a biological product under section 351(a) of the  
20 Public Health Service Act (42 U.S.C. 262(a)) whether the  
21 product can be adequately characterized for purposes of  
22 this subsection. With respect to biological products ap-  
23 proved prior to the date of enactment of the Food and  
24 Drug Administration Performance and Accountability Act  
25 of 1995, the determination shall be made within 90 days

1 after the date of enactment of such Act. Any determina-  
 2 tion under this subsection is subject to change based upon  
 3 new scientific information.”.

4 **SEC. 605. INSULIN AND ANTIBIOTICS.**

5 (a) CERTIFICATION OF DRUGS CONTAINING INSU-  
 6 LIN.—Section 506 (21 U.S.C. 356) is repealed.

7 (b) CERTIFICATION OF ANTIBIOTICS.—Section 507  
 8 (21 U.S.C. 357) is repealed.

9 (c) EXPORTATION.—Section 802 (21 U.S.C. 382), as  
 10 amended by section 502(b), is further amended by adding  
 11 at the end thereof the following new subsection:

12 “(g) EXPORTATION OF UNAPPROVED PRODUCTS.—  
 13 Insulin and antibiotics may be exported without regard to  
 14 the requirements in this section if the insulin and anti-  
 15 biotics meet the requirements in subsection (c)(1).”.

16 **SEC. 606. BIOLOGICAL PRODUCTS.**

17 (a) MODERNIZATION OF REGULATION OF BIOLOGI-  
 18 CAL PRODUCTS.—

19 (1) IN GENERAL.—Section 351 of the Public  
 20 Health Service Act (42 U.S.C. 262) is amended by  
 21 striking “SEC. 351. (a)” and all that follows through  
 22 “exchange the same.” and inserting the following:

23 “SEC. 351. (a)(1) Except as provided in paragraph  
 24 (4), no person shall introduce or deliver for introduction  
 25 into interstate commerce any biological product unless—

1           “(A) a product license has been issued for the  
2           biological product;

3           “(B) the biological product has been propa-  
4           gated, manufactured, or prepared in accordance with  
5           good manufacturing practices established by the Sec-  
6           retary under section 501(a) of the Federal Food,  
7           Drug, and Cosmetic Act (21 U.S.C. 351(a)); and

8           “(C) each package of the biological product is  
9           plainly marked with the proper name of the biologi-  
10          cal product contained therein, the name, address  
11          and license number of the manufacturer of the bio-  
12          logical product, and the expiration date of the bio-  
13          logical product.

14          “(2) The Secretary shall establish, by regulation, re-  
15          quirements for product license applications for biological  
16          products. A product license application for a biological  
17          product, other than blood, blood components, and blood  
18          products, shall be approved based upon a demonstration  
19          that the product that is the subject of the application is  
20          safe and effective in accordance with section 505(d) of the  
21          Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
22          355(d)). A license application for blood, a blood compo-  
23          nent, or a blood product shall be approved based upon a  
24          demonstration that the product that is the subject of the  
25          application is safe, pure, and, where appropriate, potent.

1       “(3)(A) If the Secretary determines that grounds for  
2 a suspension or revocation of a license for a biological  
3 product exist that constitute a danger to health, the Sec-  
4 retary shall suspend the license, notify the licensee of the  
5 suspension, and require notification of the suspension to  
6 any consignee. Within 30 days after the date of the receipt  
7 by the licensee of a notification of suspension, the Sec-  
8 retary shall afford the licensee an opportunity for a hear-  
9 ing in accordance with section 554 of title 5, United States  
10 Code.

11       “(B) If at any time before the Secretary has taken  
12 final action to suspend or revoke a license the licensee re-  
13 quests an inspection by the Secretary to determine wheth-  
14 er the licensee is in compliance with applicable standards,  
15 the Secretary shall conduct an inspection within 30 days  
16 of the date of the request. If the Secretary fails to conduct  
17 the inspection within the 30 days, the action to suspend  
18 or revoke the license shall become null and void. If the  
19 inspection confirms that the licensee is in compliance with  
20 all applicable requirements, the Secretary shall withdraw  
21 any proposed action within 30 days of the inspection.

22       “(4) The requirements of paragraph (1) do not apply  
23 to a biological product for which there is in effect an inves-  
24 tigational new drug application under section 505(i) of the  
25 Federal Food, Drug, and Cosmetic Act.”.

1           (2) LABELING.—Section 351(b) of the Public  
2       Health Service Act (42 U.S.C. 262(b)) is amended  
3       to read as follows:

4       “(b) No person shall falsely label or mark any pack-  
5       age or container of any biological product or alter any  
6       label or mark on the package so as to falsify the label  
7       or mark.”.

8           (3) INSPECTION.—Section 351(c) of the Public  
9       Health Service Act (42 U.S.C. 262(c)) is amended  
10      by striking “virus, serum, toxin, antitoxin, vaccine,  
11      blood, blood component, or blood product, or deriva-  
12      tive allergenic product or other product aforesaid”  
13      and inserting “biological product”.

14          (4) DEFINITION; APPLICATION.—Part F of title  
15      III of the Public Health Service Act (42 U.S.C. 262  
16      et seq.) is amended by adding at the end thereof the  
17      following new subsections:

18      “(i) For purposes of this section, the term ‘biological  
19      product’ means a virus, therapeutic serum, toxin, anti-  
20      toxin, vaccine, blood, blood component or derivative, aller-  
21      genic biologic product, or arsphenamine or its derivative  
22      (or any other analogous biological product) applicable to  
23      the prevention, treatment, or cure of diseases or conditions  
24      of human beings.

1       “(j)(1) Sections 505(i), 903, and 904 of the Federal  
 2 Food, Drug, and Cosmetic Act shall apply to all biological  
 3 products and references in those sections to new drug ap-  
 4 plications shall be deemed to include product license appli-  
 5 cations.

6       “(2) Requirements involving labeling or advertising  
 7 for biological products shall be established in accordance  
 8 with sections 201(m) and 502(n) of the Federal Food,  
 9 Drug, and Cosmetic Act.

10       (b) HARMONIZATION OF REGULATION OF BIOLOGI-  
 11 CAL PRODUCTS AND NEW DRUGS.—Not later than 2  
 12 years after the date of enactment of this section, the Sec-  
 13 retary of Health and Human Services shall harmonize reg-  
 14 ulations governing product license applications required  
 15 under section 354 of the Public Health Service Act (42  
 16 U.S.C. 262) with the regulations governing new drug ap-  
 17 plications required under section 505 of the Federal Food,  
 18 Drug, and Cosmetic Act (21 U.S.C. 355).

19 **SEC. 607. REQUIREMENTS FOR EMERGING BIO-**  
 20 **TECHNOLOGY PRODUCTS.**

21       Not later than 180 days after the date of enactment  
 22 of this Act, the Secretary of Health and Human Services  
 23 shall establish proposed regulations governing products of  
 24 human tissue and cell therapy that shall—



(1) ensure the safety and effectiveness of the products under section 351 of the Public Health Service Act (42 U.S.C. 262 et seq.); and

(2) take in account whether regulation of facilities in which the products are manufactured or processed is sufficient to ensure safety and effectiveness of the products.

## TITLE VII—DEVICE REGULATORY REFORM

### SEC. 701. SHORT TITLE.

This title may be cited as the “Medical Device Reform Act of 1995”.

### SEC. 702. PREMARKET NOTIFICATION.

(a) EXEMPTION OF CERTAIN DEVICES.—Section 510 (21 U.S.C. 360) is amended—

(1) in subsection (k), by striking “intended for human use” and inserting “intended for human use (except a device that is classified into class I under section 513 or 520 or a device that is classified into class II under section 513 or 520, and is exempt from the requirements of this subsection under subsection (1))”;

(2) by adding at the end of subsection (k) (as amended by paragraph (1)) the following:

1 “The Secretary shall review the notification required by  
 2 this subsection and make a determination under section  
 3 513(f)(1)(A) within 90 days of receiving the notification.”;  
 4 and

5 (3) by adding at the end thereof the following  
 6 new subsections:

7 “(l) Within 30 days of the date of enactment of this  
 8 subsection, the Secretary shall publish in the Federal Reg-  
 9 ister a list of each type of class II device that does not  
 10 require a report under subsection (k) to provide reasonable  
 11 assurance of safety and effectiveness. Each type of class  
 12 II device so identified by the Secretary not to require the  
 13 report shall be exempt from the requirement to file a re-  
 14 port under subsection (k) as of the date of the publication  
 15 of the list in the Federal Register. Beginning on the date  
 16 that is 1 day after the date of the publication of a list  
 17 under this subsection, any person may petition the Sec-  
 18 retary to exempt a type of class II device from subsection  
 19 (k). The Secretary shall respond to the petition within 120  
 20 days of the receipt of the petition and determine whether  
 21 or not to grant the petition in whole or in part.

22 “(m) The Secretary may not withhold a determina-  
 23 tion of the initial classification of a device under sub-  
 24 section 513(f)(1) because of a failure to comply with any  
 25 provision of this Act unrelated to a substantial equivalence

1 decision, including a finding that the facility in which a  
 2 device is manufactured is not in compliance with good  
 3 manufacturing practice requirements as set forth in regu-  
 4 lations promulgated under the authority of subsection  
 5 520(f).”.

6 (b) INITIAL CLASSIFICATION.—Section 513(f)(1) (21  
 7 U.S.C. 360c(f)(1)) is amended in the second sentence, by  
 8 striking the period at the end thereof and inserting the  
 9 following: “, unless within 30 days of receiving an order  
 10 classifying the device into class III, the individual who  
 11 submits a notification under section 510(k) requests an  
 12 advisory committee review and recommendation with re-  
 13 spect to the classification of the device and a final order  
 14 of classification from the Secretary. After the request, a  
 15 device classified into class III under this paragraph shall  
 16 not be deemed to be finally classified until an advisory  
 17 committee established under subsection (b) reviews the re-  
 18 quest with respect to the classification of the device and,  
 19 within 60 days of the date of receiving the request, rec-  
 20 ommends to the Secretary a classification for the device  
 21 based on the classification criteria set forth in subpara-  
 22 graphs (A) through (C) of subsection(a)(1). Thereafter,  
 23 the Secretary shall have 10 days to determine by order  
 24 the final classification of the device by applying the classi-

1 fication criteria set forth in subparagraphs (A) through  
 2 (C) of subsection(a)(1).

3 (c) ~~SUBSTANTIAL EQUIVALENCE.~~—Section 513(i)(1)  
 4 (21 U.S.C. 360c(i)(1)) is amended by adding at the end  
 5 thereof the following new subparagraph:

6 “(C) For the purpose of determining the intended use  
 7 of a predicate device under paragraph (A), each use in-  
 8 cluded within a general use for the predicate device shall  
 9 be deemed a legally marketed use of the predicate device  
 10 for purposes of premarket notifications required under  
 11 subsection 510(k).”.

12 (d) ~~DEVICE MODIFICATION.~~—Section 513(i) (21  
 13 U.S.C. 360c(i)) is amended by adding at the end thereof  
 14 the following new paragraph:

15 “(4) Any change or modification to a device initially  
 16 classified under section 513(f), other than a major change  
 17 (including any major modification) in the intended use,  
 18 shall not require an additional submission under section  
 19 510(k) if such change or modification is supported by ap-  
 20 propriate data or information, and the change or modifica-  
 21 tion can be shown to not adversely affect the safety or  
 22 effectiveness of the device. All data or information relied  
 23 upon to document that a change to (including any modi-  
 24 fication of) the device does not require an additional notifi-  
 25 cation under section 510(k) shall be made available to the

1 Secretary upon request and shall be maintained, at least  
 2 for a period of time equal to the commercial life of the  
 3 device.”.

4 **SEC. 703. MEDICAL DEVICE APPROVAL STANDARDS.**

5 Section 513(a)(3)(A) (21 U.S.C. 360e(a)(3)(A)) is  
 6 amended—

7 (1) by striking “well-controlled investigations”  
 8 and inserting “a scientific investigation”;

9 (2) by striking “clinical investigations” and in-  
 10 serting “a clinical investigation”;

11 (3) by striking “investigations it” and inserting  
 12 “investigation it”; and

13 (4) by adding the following to the end thereof  
 14 the following new sentence: “The Secretary may re-  
 15 quire a well-controlled clinical investigation to dem-  
 16 onstrate effectiveness if the director of the Office of  
 17 Device Evaluation explains in writing the basis  
 18 therefor.”.

19 **SEC. 704. TRACKING.**

20 Section 519(e) (21 U.S.C. 360i(e)) is amended to  
 21 read as follows:

22 “DEVICE TRACKING

23 “(e) The Secretary may by regulation require a man-  
 24 ufacturer to adopt a method of tracking a class II or class  
 25 III device—

1           “(1) the failure of which would be life-threaten-  
 2           ing or have permanently debilitating effects; and  
 3           “(2) which is—  
 4                   “(A) permanently implanted; or  
 5                   “(B) life sustaining or life supporting and  
 6           used outside a device user facility.”.

7   **SEC. 705. POSTMARKET SURVEILLANCE.**

8           Section 522(1) (21 U.S.C. 360l) is amended to read  
 9 as follows:

10 **“SEC. 522. POSTMARKET SURVEILLANCE.**

11           “(a) IN GENERAL.—The Secretary may require a  
 12 manufacturer to conduct postmarket surveillance for any  
 13 device of the manufacturer first introduced or delivered  
 14 for introduction into interstate commerce after January  
 15 1, 1991, that—

16           “(1) is a permanent implant the failure of  
 17           which may cause serious, adverse health con-  
 18           sequences or death;

19           “(2) is intended for a use in supporting or sus-  
 20           taining human life; or

21           “(3) potentially presents a serious risk to  
 22           human health.

23           “(b) SURVEILLANCE APPROVAL.—Each manufac-  
 24 turer required to conduct a surveillance of a device under  
 25 subsection (a) shall, within 30 days of receiving notice

1 from the Secretary that the manufacturer is required  
 2 under this section to conduct the surveillance; submit for  
 3 the approval of the Secretary; a protocol for the required  
 4 surveillance. The Secretary, within 60 days of the date of  
 5 the receipt of the protocol, shall determine if the principal  
 6 investigator proposed to be used in the surveillance has  
 7 sufficient qualifications and experience to conduct the sur-  
 8 veillance and if the protocol will result in collection of use-  
 9 ful data or other information necessary to protect the pub-  
 10 lic health and to provide safety and effectiveness informa-  
 11 tion for the device. The Secretary may not approve the  
 12 protocol until the protocol has been reviewed by a qualified  
 13 scientific and technical review committee established by  
 14 the Secretary.”.

15 **SEC. 706. DEVICE DISTRIBUTOR REPORTING.**

16 Section 519 (21 U.S.C. 360i) is amended—

17 (1) by striking “, importer, or distributor” each  
 18 place it appears and inserting “or importer”;

19 (2) in subsection (a)—

20 (A) in paragraph (8), by striking “; and”  
 21 and inserting a period; and

22 (B) by striking paragraph (9); and

23 (3) by striking subsection (f).

1 **SEC. 707. PREMARKET APPROVAL.**

2 (a) ACTION ON APPLICATION.—Section 515(d) (21  
3 U.S.C. 360e(d)) is amended—

4 (1) in paragraph (1)(A), by striking “paragraph  
5 (2) of this subsection” each place it appears and in-  
6 serting “paragraph (4)”;

7 (2) in paragraph (1)(B), by adding at the end  
8 thereof the following new clause:

9 “(iii) The Secretary shall accept and review data and  
10 any other information from investigations conducted  
11 under the authority of regulations required by section  
12 520(g) to make a determination of whether there is a rea-  
13 sonable assurance of safety and effectiveness of a device  
14 subject to a pending application under this section if—

15 “(I) the data or information is derived from in-  
16 vestigations of an earlier version of the device, the  
17 device has been modified during or after the inves-  
18 tigation, and the modification of the device does not  
19 constitute a significant change in the design or in  
20 the basic principles of operation of the device that  
21 would invalidate the data or information; or

22 “(II) the data or information on a device ap-  
23 proved under this section is available for use under  
24 this Act and is relevant to the design and intended  
25 use of the device subject to the pending applica-  
26 tion.”;



1           ~~(3)~~ by redesignating paragraphs ~~(2)~~ and ~~(3)~~ as  
2           paragraphs (4) and (5), respectively; and

3           ~~(4)~~ by inserting after paragraph (1) the follow-  
4           ing new paragraph:

5           ~~“(2)~~ Each application received under section 515(c)  
6           shall be reviewed in the following manner to achieve final  
7           action on the application within 180 days of the receipt  
8           of the application:

9           ~~“(A)~~ The Secretary shall meet with an appli-  
10          cant within 90 days of the receipt of the application  
11          to discuss the review status of the application. If the  
12          application does not appear in a form that would re-  
13          quire an approval under subsection (d), the Sec-  
14          retary shall in writing, and prior to the meeting,  
15          present to the applicant a description of any defi-  
16          ciencies in the application and what information is  
17          required to bring the application into a form that  
18          would require an approval.

19          ~~“(B)~~ The Secretary shall refer an application to  
20          a panel established under section 513 for review and  
21          an approval recommendation, unless a panel is not  
22          required under subsection (c)(2), within 30 days of  
23          the date of the meeting referred to in subparagraph  
24          (A) or at the next scheduled panel meeting following

1 the meeting referred to in subparagraph (A), which-  
2 ever occurs later.

3 “(C) The Secretary shall meet with the appli-  
4 cant within 15 days of the date of the panel review  
5 to discuss the status of the application, including a  
6 discussion on what action is necessary to bring the  
7 application into a form that would require approval  
8 under this subsection. Prior to the meeting, the Sec-  
9 retary shall in writing shall set forth an agenda for  
10 the meeting (including a complete description of the  
11 subject matter to be discussed at the meeting), and  
12 a full description of the additional information nec-  
13 essary to bring the application into a form that  
14 would require an approval under subsection (d). Par-  
15 ticipation of the applicant at such a meeting shall be  
16 at the discretion of the applicant.

17 “(D) The Secretary shall meet with the appli-  
18 cant not later than 135 days after the receipt of an  
19 application under subsection (c), if an advisory panel  
20 is not required under subsection (c)(2), and inform  
21 the applicant whether or not the application is in a  
22 form that would require approval under subsection  
23 (d). If the application is in such form, the Secretary  
24 shall, at or prior to the meeting, present in writing  
25 to the applicant a description of all additional infor-

1       mation necessary to require an approval of the appli-  
 2       cation under subsection (d). If the application is not  
 3       in such form, the Secretary shall deny approval of  
 4       the application and prior to the meeting, present in  
 5       writing to the applicant each basis for denying ap-  
 6       proval of the application and the additional informa-  
 7       tion required to bring the application into a form  
 8       that would require approval.

9           “(E) The Secretary shall issue an order approv-  
 10       ing or denying an application within 180 days of the  
 11       receipt of the application under subsection (e).

12       “(3)(A) Except as provided in subparagraph (B), the  
 13       time for the review of an application by the Secretary  
 14       under this subsection shall take not more than 180 days  
 15       and may not be extended if the application is amended.

16       “(B) The Secretary may not take more than 120 days  
 17       for the review of an application subject to an expedited  
 18       review under paragraph (1)(A) and may not extend the  
 19       120-day period if the application is amended.”.

20       (b) REGULATIONS.—The Secretary shall revise  
 21       through notice and comment procedures the regulations  
 22       set forth in part 814 of title 21 of the Code of Federal  
 23       Regulations, to conform to the amendment made by para-  
 24       graph (1) and to eliminate premarket approval of supple-

1 ments that relate to manufacturing changes and other  
 2 changes that do not affect device safety or effectiveness.

3 **SEC. 708. DEVICE PERFORMANCE STANDARDS.**

4 (a) **ALTERNATIVE PROCEDURE.**—Section 514 (21  
 5 U.S.C. 360d) is amended by adding at the end thereof  
 6 the following new subsection:

7 “PRODUCT REVIEW

8 “(c)(1) For the purpose of facilitating a review of a  
 9 device under sections 510(k), 515, and 520, any person  
 10 may submit a petition under this subsection for the rec-  
 11 ognition by the Secretary of an existing performance  
 12 standard for a device.

13 “(2) A petition under this subsection shall be made  
 14 following the adoption of a voluntary performance stand-  
 15 ard by any qualified governmental or nongovernmental or-  
 16 ganization established to develop performance standards.

17 “(3) The petition shall identify the specific standard,  
 18 the organization that adopted the standard, and the date  
 19 on which the standard was adopted by the organization.

20 “(4) Upon the receipt of a petition under this sub-  
 21 section, the Secretary shall place the petition on public dis-  
 22 play and within 30 days after the date of the receipt of  
 23 the petition, the Secretary shall publish a notice in the  
 24 Federal Register setting forth the proposed standard, stat-  
 25 ing that the entire application is publicly available for re-  
 26 view, and providing 60 days for public comment.

1       ~~“(5) Within 150 days after the receipt by the Sec-~~  
2 ~~retary of the application, the Secretary shall—~~

3           ~~“(A)(i) grant the petition in whole or in part;~~  
4       ~~or~~

5           ~~“(ii) deny the petition in whole or in part if the~~  
6       ~~Secretary demonstrates that the standard does not~~  
7       ~~establish an adequate performance standard for the~~  
8       ~~functions of a device for which the standard is rep-~~  
9       ~~resented to apply; and~~

10          ~~“(B) publish a notice of the determination in~~  
11       ~~the Federal Register.~~

12       ~~“(6) Upon the approval of the petition, the Secretary~~  
13 ~~shall publish in the Federal Register the order listing the~~  
14 ~~name of the recognized standard and shall provide any~~  
15 ~~person who requests the recognized standard a copy of the~~  
16 ~~standard.~~

17       ~~“(7) Following the publication of a final regulation~~  
18 ~~listing a recognized standard, any premarket notification~~  
19 ~~for a device submitted under sections 510(k), 513(f)(1),~~  
20 ~~and 513(i) and any premarket approval application sub-~~  
21 ~~mitted under section 515 may include a certification of~~  
22 ~~compliance with the standard, which shall constitute full~~  
23 ~~and complete satisfaction of the requirements for safety~~  
24 ~~and effectiveness for the functions of the device for which~~  
25 ~~the standard is represented to apply.~~

1       “(8) Any modification of a recognized standard shall  
 2 be subject to review under the procedure established in  
 3 this subsection for the modified standard to become a rec-  
 4 ognized standard.”.

5       (b) ADULTERATED DEVICE.—Section 501(e) (21  
 6 U.S.C. 351(e)) is amended by striking “section 514” and  
 7 inserting “section 514(b)”.

## 8           **TITLE VIII—ANIMAL DRUG** 9           **REGULATORY REFORM**

### 10   **SEC. 801. SHORT TITLE.**

11       This title may be cited as the “Animal Drug Regu-  
 12 latory Reform Act of 1995”.

### 13   **SEC. 802. NEW ANIMAL DRUG APPROVAL STANDARDS.**

14       (a) SUBSTANTIAL EVIDENCE.—Section 512(d)(3)  
 15 (21 U.S.C. 360b(d)(3)) is amended by adding at the end  
 16 thereof the following new sentences: “Substantial evidence  
 17 shall consist of at least data from one scientifically sound  
 18 study (designed and conducted in a manner that is con-  
 19 sistent with generally recognized scientific procedures and  
 20 principles), which may be waived by the Secretary, and  
 21 confirmatory evidence obtained before or after the study.  
 22 The Director of the Center for Veterinary Medicine may  
 23 require a field trial as part of substantial evidence if the  
 24 Director of the Center for Veterinary Medicine dem-  
 25 onstrates, in writing and specifying the basis therefor, that

1 no other form of scientifically sound study is adequate to  
2 show the effectiveness of the drug.”.

3 (b) COMBINATION OF DRUGS.—Section 512(d) (21  
4 U.S.C. 360b(d)) is amended by adding at the end thereof  
5 the following new paragraph:

6 “(4) If a new animal drug contains more than one  
7 active ingredient or the labeling provides for the drug’s  
8 use in combination with one or more other animal drugs,  
9 in evaluating such combination the Secretary shall con-  
10 sider whether—

11 “(A) the combination affects the safety of any  
12 active ingredient;

13 “(B) the combination interferes with a method  
14 of analysis for any active ingredient;

15 “(C) if the active ingredients have the same in-  
16 tended effect, each of the active ingredients makes  
17 a significant contribution to the labeled effectiveness;  
18 and

19 “(D) if the active ingredients do not have the  
20 same intended effect, the active ingredients provide  
21 appropriate concurrent therapy for a labeled target  
22 population.”.

23 (c) APPROVAL.—Section 512(e)(2)(F)(iii) (21 U.S.C.  
24 360b(e)(2)(F)(iii)) is amended—

1           (1) by striking “reports of new clinical or field  
2           investigations (other than bioequivalence or residue  
3           studies) and” and inserting “substantial evidence of  
4           effectiveness as defined in subsection (d)(4), any  
5           study of animal safety, or”; and

6           (2) by striking “essential to” and inserting “,  
7           required for”.

8   **SEC. 803. RESIDUE LIMITATION.**

9           Section 512(d)(1)(F) (21 U.S.C. 360b(d)(1)(F)) is  
10          amended to read as follows:

11           “(F) on the basis of information in the applica-  
12          tion or otherwise available to the Secretary, any la-  
13          beled use of the drug will result in an unsafe residue  
14          of the drug;”.

15   **SEC. 804. ADULTERATED DRUGS.**

16          Section 501(a)(2) (21 U.S.C. 351(a)(2)) is  
17          amended—

18           (1) in subparagraph (A), by striking “health;  
19          or” and inserting “health”; and

20           (2) in subparagraph (B), by striking “possess;”  
21          and inserting the following: “possess; or (C) if it is  
22          a drug intended for use by animals other than man  
23          and the methods used in, or the facilities or controls  
24          used for, its manufacture, processing, packing, or  
25          holding do not conform to or are not operated or ad-



1 ministered in conformity with current good manufac-  
 2 turing practice requirements (appropriate for animal  
 3 drugs) adopted pursuant to regulations issued by the  
 4 Secretary to ensure that such drug meets the re-  
 5 quirements of this Act as to safety and has the iden-  
 6 tity and strength, and meets the quality and purity  
 7 characteristics, which it purports or is represented  
 8 to possess for use in animals other than man;”.

## 9 **TITLE IX—FOOD REGULATORY** 10 **REFORM**

### 11 **SEC. 901. SHORT TITLE.**

12 This title may be cited as the “Food Regulatory Re-  
 13 form Act of 1995”.

### 14 **SEC. 902. INDIRECT FOOD ADDITIVES.**

15 (a) **APPROVAL.**—Section 409 (21 U.S.C. 348) is  
 16 amended by adding at the end thereof the following new  
 17 subsection:

#### 18 “ALTERNATIVE APPROVAL PROCEDURE

19 “(j)(1) As an alternative to the approval procedure  
 20 established under subsection (b), any person may submit  
 21 a notification for an indirect food additive under this sub-  
 22 section.

23 “(2) Any person who proposes to begin the introduc-  
 24 tion or delivery for introduction into interstate commerce  
 25 of a product intended for use as an indirect food additive  
 26 may submit to the Secretary, at least 90 days prior to

1 making such introduction or delivery, a notification con-  
 2 taining information demonstrating that the labeled use of  
 3 the product is safe.

4 “(3)(A) Within 90 days after the receipt of the notifi-  
 5 cation by the Secretary, the Secretary shall either—

6 “(A)(i) approve the notification if the product is  
 7 safe for its intended use; or

8 “(ii) disapprove the notification if there is a  
 9 reasonable possibility that the article is not safe for  
 10 its intended use; and

11 “(B) publish a notice of this determination in  
 12 the Federal Register and, if the notification is ap-  
 13 proved, promulgate an appropriate regulation pursu-  
 14 ant to subsection (c).

15 If the Secretary does not publish such a notice in the Fed-  
 16 eral Register within the 90-day period, the notification  
 17 shall be deemed to be approved and the Secretary shall  
 18 immediately approve the notification and promulgate an  
 19 appropriate regulation in the Federal Register pursuant  
 20 to subsection (c).”.

21 (b) DEFINITION.—Section 201 (21 U.S.C. 321), as  
 22 amended by section 606(c), is further amended by adding  
 23 at the end thereof the following new subsection:

1       “(ii) The term ‘indirect food additive’ means a food  
 2 additive that is intended to contact food but that is not  
 3 intended for consumption as a food ingredient.”.

4       **SECTION 1. SHORT TITLE.**

5       *This Act may be cited as the “Food and Drug Admin-  
 6 istration Performance and Accountability Act of 1996”.*

7       **SEC. 2. TABLE OF CONTENTS.**

8       *The table of contents for this Act is as follows:*

*Sec. 1. Short title.  
 Sec. 2. Table of contents.  
 Sec. 3. References.*

**TITLE I—MISSION AND ACCOUNTABILITY**

*Sec. 101. Short title.  
 Sec. 102. The mission of the Food and Drug Administration.  
 Sec. 103. Performance standards and review.  
 Sec. 104. Interagency collaboration.  
 Sec. 105. Information system.  
 Sec. 106. Policy statements.  
 Sec. 107. Scientific review groups.  
 Sec. 108. Appeals within the Food and Drug Administration.  
 Sec. 109. Appointment and term of the Commissioner of Food and Drugs.*

**TITLE II—EXPEDITED ACCESS TO PRODUCTS FOR SERIOUSLY ILL  
 PATIENTS**

*Sec. 201. Short title.  
 Sec. 202. Access to unapproved therapies.  
 Sec. 203. Expanding humanitarian use of devices.  
 Sec. 204. Expediting approval of new drugs, biologics, and medical devices for se-  
       rious conditions.*

**TITLE III—REVITALIZING THE INVESTIGATION OF NEW PRODUCTS**

*Sec. 301. Short title.  
 Sec. 302. Timely review and reasonable data requirements for clinical research on  
       drugs and biological products.  
 Sec. 303. Timely review and reasonable data requirements for clinical research on  
       devices.  
 Sec. 304. Sense of the committee concerning mutual recognition agreements.  
 Sec. 305. Collaborative research design.*

**TITLE IV—EFFICIENT, ACCOUNTABLE, AND FAIR PRODUCT REVIEW**

*Sec. 401. Short title.  
 Sec. 402. The content and review of an application.  
 Sec. 403. Contracts for expert review.*

- Sec. 404. Prompt and efficient review.*
- Sec. 405. Good manufacturing practice inspection.*
- Sec. 406. Environmental impact review.*
- Sec. 407. Effectiveness, outcome, and cost-effectiveness standards.*
- Sec. 408. Definition of a day for purposes of product review.*
- Sec. 409. Approval of supplemental applications for approved products.*
- Sec. 410. Pediatric studies marketing exclusivity.*
- Sec. 411. Notifications for device market clearance.*

#### *TITLE V—DRUG AND BIOLOGICAL PRODUCTS REGULATORY REFORM*

- Sec. 501. Short title.*
- Sec. 502. New drug approval standard.*
- Sec. 503. Pilot and small scale manufacture.*
- Sec. 504. Manufacturing changes.*
- Sec. 505. Insulin and antibiotics.*
- Sec. 506. Modernization of regulation of biological products.*
- Sec. 507. Effective medication guides.*
- Sec. 508. State and local requirements respecting nonprescription drugs intended for human use.*
- Sec. 509. Requirement of radiopharmaceuticals.*

#### *TITLE VI—DEVICE REGULATORY REFORM*

- Sec. 601. Short title.*
- Sec. 602. Premarket notification.*
- Sec. 603. Medical device approval standards.*
- Sec. 604. Tracking.*
- Sec. 605. Postmarket surveillance.*
- Sec. 606. Device distributor reporting.*
- Sec. 607. Premarket approval.*
- Sec. 608. Device performance standards.*
- Sec. 609. Accredited-party participation.*

#### *TITLE VII—ANIMAL DRUG REGULATORY REFORM*

- Sec. 701. Short title.*
- Sec. 702. Evidence of effectiveness.*
- Sec. 703. Limitation of residues.*
- Sec. 704. Adulterated drugs.*
- Sec. 705. Veterinary feed directives.*
- Sec. 706. Timeframes for approval.*

#### *TITLE VIII—FOOD REGULATORY REFORM*

- Sec. 801. Short title.*
- Sec. 802. Indirect food additives.*
- Sec. 803. Health claims of food products.*

#### *TITLE IX—ESTABLISHMENT OF CENTERS FOR EDUCATION AND RESEARCH ON DRUGS, DEVICES, AND BIOLOGICAL PRODUCTS*

- Sec. 901. Centers for Education and Research on Drugs, Devices, and Biological Products.*

## TITLE X—PROGRAM IN CLINICAL PHARMACOLOGY

*Sec. 1001. Reauthorization of clinical pharmacology program.*

1 **SEC. 3. REFERENCES.**

2 *Except as otherwise expressly provided, whenever in*  
 3 *this Act an amendment or repeal is expressed in terms of*  
 4 *an amendment to, or repeal of, a section or other provision,*  
 5 *the reference shall be considered to be made to a section or*  
 6 *other provision of the Federal Food, Drug, and Cosmetic*  
 7 *Act (21 U.S.C. 321 et seq.).*

8 **TITLE I—MISSION AND**  
 9 **ACCOUNTABILITY**

10 **SEC. 101. SHORT TITLE.**

11 *This title may be cited as the “Food and Drug Admin-*  
 12 *istration Regulatory Reform Act of 1996”.*

13 **SEC. 102. THE MISSION OF THE FOOD AND DRUG ADMINIS-**  
 14 **TRATION.**

15 *Section 903(a) (21 U.S.C. 393(a)) is amended by add-*  
 16 *ing at the end thereof the following: “The mission of the*  
 17 *Administration is to promote and protect the public health*  
 18 *by—*

19 *“(1) facilitating the rapid and efficient develop-*  
 20 *ment and availability of articles subject to the regula-*  
 21 *tion of the Administration;*

22 *“(2) protecting the public from unsafe or ineffec-*  
 23 *tive articles subject to the regulation of the Adminis-*  
 24 *tration; and*

1           “(3) enforcing the applicable statutes and regula-  
 2           tions in a timely, fair, consistent, and decisive man-  
 3           ner.”.

4 **SEC. 103. PERFORMANCE STANDARDS AND REVIEW.**

5           Section 903(b) (21 U.S.C. 393(b)) is amended by add-  
 6           ing at the end thereof the following new paragraph:

7           “(3) *PERFORMANCE STANDARDS AND REVIEW.*—

8                   “(A) *IN GENERAL.*—Not later than 180  
 9                   days after the date of enactment of this para-  
 10                  graph, the Secretary, after consultation with ex-  
 11                  perts in the development, clinical investigation,  
 12                  and regulation of drugs, biological products, new  
 13                  animal drugs, devices, food additives, and color  
 14                  additives and representatives of patient and  
 15                  consumer advocacy groups, health and tech-  
 16                  nology professionals, and the regulated indus-  
 17                  tries, shall develop and publish in the Federal  
 18                  Register quantifiable performance standards for  
 19                  action by the Administration on—

20                   “(i) applications or submissions (in-  
 21                   cluding petitions, notifications, or any other  
 22                   similar form of request) for review of a pro-  
 23                   tocol, a product investigation, a product ap-  
 24                   proval, a new use approval, a manufactur-  
 25                   ing change, a change in labeling, or any

1           *other form of regulatory action relating to*  
2           *the review of an article that is a new drug,*  
3           *biological product, new animal drug, device,*  
4           *food additive, or color additive and that is*  
5           *subject to premarket review or approval*  
6           *under this Act; and*

7           “(ii) *the scheduling of advisory com-*  
8           *mittee meetings, and the action taken by the*  
9           *Administration following an advisory com-*  
10          *mittee recommendation, relating to the ap-*  
11          *plications and submissions described in*  
12          *clause (i).*

13          “(B) *REVIEW OF PERFORMANCE STAND-*  
14          *ARDS.—The performance standards required by*  
15          *subparagraph (A) shall be reviewed annually by*  
16          *the Secretary, and after consultation with ex-*  
17          *perts in the development, clinical investigation,*  
18          *and regulation of drugs, biological products, new*  
19          *animal drugs, devices, food additives, and color*  
20          *additives, and representatives of patient and*  
21          *consumer advocacy groups, health and tech-*  
22          *nology professionals, and the regulated indus-*  
23          *tries, may be revised, annually by the Secretary.*

24          “(C) *AGENCY OBJECTIVES.—The perform-*  
25          *ance standards required by subparagraph (A)*

1       *shall establish objectives for the Administration*  
2       *that—*

3               “(i) *expedite the clinical investigation*  
4               *of an article that is a new drug, device, or*  
5               *biological product through closer collabora-*  
6               *tion between the Administration and the*  
7               *sponsor of the investigation;*

8               “(ii) *expedite the review of an applica-*  
9               *tion for a new drug, device, or biological*  
10              *product—*

11               “(I) *for an immediately life-*  
12               *threatening disease or condition; or*

13               “(II) *for any other serious condi-*  
14               *tion if the new drug, device, or biologi-*  
15               *cal product provides therapy that is*  
16               *not available from another approved*  
17               *therapy or offers significant improve-*  
18               *ment over another approved therapy or*  
19               *diagnostic or monitoring agents;*

20               “(iii) *reduce backlogs in the review of*  
21               *all applications with the objective of elimi-*  
22               *nating all backlogs in the review of applica-*  
23               *tions by January 1, 1998;*

24               “(iv) *establish a schedule to bring the*  
25               *Administration into full compliance by*



1           *July 1, 1998, with the time periods speci-*  
 2           *fied in this Act for the review of all applica-*  
 3           *tions; and*

4           “(v) improve the consistency and fair-

5           ness of the regulatory process of the Admin-

6           istration.

7           *The Secretary shall issue such other performance*  
 8           *standards that the Secretary determines will con-*  
 9           *tribute to the efficient, fair, and effective oper-*  
 10          *ation of the Administration.*

11          “(D) *ANNUAL REPORT.*—*The Secretary*  
 12          *shall prepare and publish in the Federal Register*  
 13          *for public comment an annual report that—*

14               “(i) provides detailed data on the ac-

15               tual performance of the Administration re-

16               lating to the action taken by the Adminis-

17               tration with respect to the applications and

18               submissions described in subparagraph

19               (A)(i) and the activities relating to advisory

20               committees described in subparagraph

21               (A)(ii);

22               “(ii) compares the performance of the

23               Administration with each applicable per-

24               formance standard developed and published

25               under subparagraph (A);

1 “(iii) describes—

2 “(I) any priorities established  
3 with respect to action to be taken by  
4 the Administration on matters relating  
5 to the applications and submissions de-  
6 scribed in subparagraph (A)(i) and the  
7 activities relating to advisory commit-  
8 tees described in subparagraph (A)(ii);

9 “(II) how such priorities are im-  
10 plemented; and

11 “(III) the data on each priority  
12 category;

13 “(iv) analyzes any failure to achieve  
14 any of the performance standards;

15 “(v) identifies regulatory policies that  
16 have a significant impact on compliance  
17 with the performance standards and ana-  
18 lyzes how such policies could be modified in  
19 order to achieve compliance with the per-  
20 formance standards; and

21 “(vi) sets forth a plan to achieve com-  
22 pliance with the performance standards that  
23 have not been met.

24 “(E) STATISTICAL INFORMATION.—The re-  
25 port described in subparagraph (D) shall include

1       *a full statistical presentation relating to all ap-*  
2       *plications, petitions, or notifications for a new*  
3       *drug, device, biological product, new animal*  
4       *drug, food additive, or color additive approved*  
5       *by the Administration during the year, taking*  
6       *into account the date of—*

7               “(i) *the submission of any investiga-*  
8               *tional application;*

9               “(ii) *the application of any clinical*  
10              *hold;*

11              “(iii) *the submission of any applica-*  
12              *tion, petition, or notification for approval*  
13              *or clearance;*

14              “(iv) *the acceptance for filing of any*  
15              *application, petition, or notification for ap-*  
16              *proval or clearance;*

17              “(v)    *the occurrence of any*  
18              *unapprovable action;*

19              “(vi) *the occurrence of any approvable*  
20              *action; and*

21              “(vii) *the approval or clearance of any*  
22              *application, petition, or notification.”.*

1 **SEC. 104. INTERAGENCY COLLABORATION.**

2       Section 903(b) (21 U.S.C. 393(b)), as amended by sec-  
3 tion 103, is further amended by adding at the end thereof  
4 the following new paragraph:

5               “(4) *INTERAGENCY COLLABORATION.*—The Sec-  
6 retary shall implement programs and policies that  
7 will foster collaboration between the Administration,  
8 the National Institutes of Health, and other Federal  
9 science-based agencies, to enhance the scientific exper-  
10 tise available to the Commissioner for the evaluation  
11 of emerging medical therapies, including complemen-  
12 tary therapies, and advances in nutrition and food  
13 science.”.

14 **SEC. 105. INFORMATION SYSTEM.**

15       Chapter IX (21 U.S.C. 391 et seq.) is amended by add-  
16 ing at the end thereof the following new section:

17 **“SEC. 906. INFORMATION SYSTEM.**

18       “The Secretary shall establish and maintain an infor-  
19 mation system to track the status and progress of each ap-  
20 plication or submission (including a petition, notification,  
21 or other similar form of request) for the approval or clear-  
22 ance of a drug, biological product, new animal drug, device,  
23 food additive, or color additive submitted to the Food and  
24 Drug Administration. The system shall permit access by the  
25 applicant, petitioner, or the person who submits a notifica-  
26 tion.”.

1 **SEC. 106. POLICY STATEMENTS.**

2 *Section 701(a) (21 U.S.C. 371(a)) is amended—*

3 *(1) by striking “(a) The” and inserting “(a)(1)*  
4 *The”; and*

5 *(2) by adding at the end thereof the following*  
6 *new paragraph:*

7 *“(2)(A) Not later than 180 days after the date of enact-*  
8 *ment of the Food and Drug Administration Performance*  
9 *and Accountability Act of 1996, the Secretary shall estab-*  
10 *lish a procedure governing the development and use of all*  
11 *policy statements of general applicability that provide guid-*  
12 *ance relating to the conduct of preclinical or clinical inves-*  
13 *tigations or other testing to support an application or sub-*  
14 *mission (including a petition, notification, or any other*  
15 *similar form of request) under section 409, 505, 510(k), 512,*  
16 *515, or 721 or that provide guidance on the submission of*  
17 *an application or submission (including a petition, notifi-*  
18 *cation, or any other similar form of request) under section*  
19 *409, 505, 510(k), 512, 515, or 721 (including any guidance,*  
20 *guideline, points-to-consider, protocol, recommendation, or*  
21 *similar document regardless of the form or designation).*  
22 *The procedure shall provide an opportunity for affected per-*  
23 *sons to participate in the development and continued use*  
24 *of a policy statement by sharing expertise or experience,*  
25 *or providing comment, before the policy statement is adopt-*  
26 *ed and after the policy statement is implemented, except*

1 *that if the Secretary determines that there is a public health*  
 2 *need to issue the policy statement immediately, the Sec-*  
 3 *retary shall provide an opportunity for affected persons to*  
 4 *provide comment promptly after the policy statement is is-*  
 5 *sued.*

6       “(B) *The Secretary shall establish a procedure for the*  
 7 *periodic compilation and publication of all policy state-*  
 8 *ments of general applicability (including any guideline,*  
 9 *points-to-consider, protocol, recommendation, or similar*  
 10 *document regardless of the form or designation).’’.*

11 **SEC. 107. SCIENTIFIC REVIEW GROUPS.**

12       *Section 904 (21 U.S.C. 394) is amended—*

13               *(1) by striking “Without” and inserting “(a) IN*  
 14 *GENERAL.—Without”; and*

15               *(2) by adding at the end thereof the following*  
 16 *new subsections:*

17       “(b) *DELEGATION OF APPOINTMENT AUTHORITY.—*  
 18 *The Commissioner may not delegate the appointment and*  
 19 *oversight authority granted under subsection (a).*

20       “(c) *MEMBERSHIP AND MEETING REQUIREMENTS.—*

21               “(1) *SCOPE.—The Commissioner shall consult*  
 22 *with a scientific review group in determining the*  
 23 *matters that the group will consider at the meetings*  
 24 *of the scientific review group.*

1           “(2) *NOTIFICATION OF SCOPE OF DISCUSSION.*—  
2           *To the extent feasible, the specific matters (including*  
3           *questions) to be discussed at a meeting of a scientific*  
4           *review group shall be publicly announced and pub-*  
5           *lished in the Federal Register at least 30 days prior*  
6           *to the date of the meeting.*

7           “(3) *TERMS.*—*A member of a scientific review*  
8           *group shall serve for a term of 3 years, and may have*  
9           *such membership renewed for not more than 1 addi-*  
10           *tional term. An individual may serve on more than*  
11           *one scientific review group. The chairperson of a sci-*  
12           *entific review group shall be a member who has served*  
13           *on the scientific group for at least 3 years. The term*  
14           *of the chairperson may be renewed for not more than*  
15           *3 terms.*

16           “(4) *TRAINING.*—*Prior to service on a scientific*  
17           *review group, a member of the group shall be given*  
18           *adequate education and training relating to the re-*  
19           *sponsibilities of the member.*

20           “(5) *FREQUENCY OF MEETINGS.*—*The Secretary*  
21           *shall take whatever action is necessary to ensure that*  
22           *regular meetings are held by scientific review groups,*  
23           *at appropriate intervals and for a sufficient length of*  
24           *time. The meetings shall occur not less than 3 times*

1        *each year unless the Secretary determines that there*  
2        *are sufficient reasons for fewer meetings.*

3        *“(d) ACCESS TO INFORMATION; PARTICIPATION BY IN-*  
4        *TERESTED PERSONS IN MEETINGS.—*

5            *“(1) IN GENERAL.—When a scientific review*  
6        *group reviews an application or submission (includ-*  
7        *ing a petition, notification, or any other similar form*  
8        *of request) for approval or clearance, or some part*  
9        *thereof, submitted for an article under section 409,*  
10       *505, 510(k), 513(f), 512, 515, or 721, the Secretary*  
11       *shall provide the person who submitted the applica-*  
12       *tion or submission with copies of all documents pro-*  
13       *vided to the members of the scientific review group in*  
14       *preparation for a meeting of the scientific review*  
15       *group. The Secretary shall provide such documents to*  
16       *the person at the same time such documents are pro-*  
17       *vided to the members of the scientific review group.*  
18       *Before the meeting, the person shall have an oppor-*  
19       *tunity to submit documents to the members of the sci-*  
20       *entific review group in response to the Secretary’s*  
21       *documents. The person shall provide the documents to*  
22       *the Secretary, who shall immediately provide copies*  
23       *of the documents to the members of the scientific re-*  
24       *view group.*



1           “(2) *PARTICIPATION IN MEETINGS.*—Any meet-  
 2           ing of a scientific review group shall include adequate  
 3           time for initial presentations and for response to any  
 4           differing views and the group shall encourage free and  
 5           open participation by all interested persons.

6           “(e) *FDA ACTIONS.*—Not later than 60 days after the  
 7           date a scientific review group makes its conclusions and  
 8           recommendations on any matter under review of the group,  
 9           the official of the Food and Drug Administration respon-  
 10          sible for the matter shall review the conclusions and rec-  
 11          ommendations of the group, make a final determination on  
 12          the matter, and notify the affected persons of the determina-  
 13          tion in writing and, if the determination differs from the  
 14          conclusions and recommendations of the group, include the  
 15          reasons for the difference.”.

16   **SEC. 108. APPEALS WITHIN THE FOOD AND DRUG ADMINIS-**  
 17                           **TRATION.**

18           Chapter IX (21 U.S.C. 391 et seq.), as amended by  
 19           section 105, is further amended by adding at the end thereof  
 20           the following new section:

21   **“SEC. 907. APPEALS WITHIN THE FOOD AND DRUG ADMINIS-**  
 22                           **TRATION.**

23           “(a) *EMPLOYEE DECISIONS.*—The Secretary shall by  
 24           regulation establish an internal appeal system within the  
 25           Food and Drug Administration for the appeal of any deci-

1 sion made by an employee of the Food and Drug Adminis-  
 2 tration, except that this subsection shall not apply to deci-  
 3 sions involving formal administrative or judicial proceed-  
 4 ings. As the final stage in the internal appeal system, the  
 5 Secretary shall provide for the right to request an evalua-  
 6 tion by an appropriate scientific review group of a final  
 7 decision of the Secretary on an appeal involving a signifi-  
 8 cant scientific issue. Upon receipt of such a request, the Sec-  
 9 retary shall refer the request to the chairperson of the appro-  
 10 priate scientific review group, or a member designated by  
 11 the chairperson, who shall review the request and determine  
 12 whether the scientific review group should conduct an eval-  
 13 uation. The Secretary shall make publicly known the exist-  
 14 ence of the internal appeal system and the procedures for  
 15 an internal appeal.

16 “(b) REVIEW BY SCIENTIFIC REVIEW GROUP.—

17 “(1) IN GENERAL.—The sponsor of a preclinical  
 18 or clinical investigation, or the applicant for the ap-  
 19 proval or clearance of an application or submission  
 20 (including a petition, notification, or any other simi-  
 21 lar form of request), shall have the right to request an  
 22 evaluation by an appropriate scientific review group  
 23 established under section 904 of any significant sci-  
 24 entific issue pending before, or any significant sci-  
 25 entific decision made by, the Secretary under this

1     *Act. An appropriate scientific review group shall re-*  
 2     *view the request and determine whether to conduct an*  
 3     *evaluation within 30 days after the date the request*  
 4     *is received by the Secretary.*

5             “(2) *SCOPE.*—*The significant scientific issues*  
 6     *that a scientific review group may evaluate include*  
 7     *matters involving a decision by the Secretary not to*  
 8     *permit a clinical investigation to begin or to con-*  
 9     *tinue, a refusal by the Secretary to file an applica-*  
 10    *tion, a protocol design, and decisions relating to a*  
 11    *pending application or submission (including a peti-*  
 12    *tion, notification, or any other similar form of re-*  
 13    *quest). The significant scientific issues shall not have*  
 14    *been previously reviewed by a scientific review group.*

15            “(3) *TIME LIMITATION.*—*If a scientific review*  
 16    *group agrees to conduct an evaluation on an issue*  
 17    *under paragraph (1), the evaluation shall be sched-*  
 18    *uled for the next meeting of the group.*

19            “(c) *ADDITIONAL INFORMAL AND FORMAL PROCE-*  
 20    *DURES.*—

21            “(1) *IN GENERAL.*—*For purposes of obtaining*  
 22    *conclusions and recommendations regarding the reso-*  
 23    *lution of any significant scientific dispute, the Sec-*  
 24    *retary is authorized to use such additional informal*

1       *and formal procedures as may be considered useful.*

2       *The procedures may include the use of—*

3               “(A) *panels of qualified Food and Drug Ad-*  
4               *ministration officials to make conclusions and*  
5               *recommendations regarding the resolution of any*  
6               *significant scientific dispute;*

7               “(B) *panels of qualified Federal Govern-*  
8               *ment employees who are not employees of the*  
9               *Food and Drug Administration to make conclu-*  
10              *sions and recommendations regarding the resolu-*  
11              *tion of any significant scientific dispute; and*

12              “(C) *outside mediators and arbitrators who*  
13              *are not Federal Government employees to make*  
14              *conclusions and recommendations regarding the*  
15              *resolution of any significant scientific dispute.*

16              “(2) *APPLICATION OF FACA.—The Federal Advi-*  
17              *sory Committee Act (5 U.S.C. App. 2) shall not apply*  
18              *to a panel described in paragraph (1).*

19              “(d) *REVIEW OF RECOMMENDATIONS.—Not later than*  
20              *60 days after the date on which a matter that is presented*  
21              *for resolution under this section has been the subject of con-*  
22              *clusions and recommendations, the official of the Food and*  
23              *Drug Administration responsible for the matter shall review*  
24              *the conclusions and recommendations, make a final deter-*  
25              *mination on the matter, and notify the parties of the deter-*

1 mination in writing and if the determination differs from  
 2 the conclusions and recommendations, the reasons for the  
 3 difference.”.

4 **SEC. 109. APPOINTMENT AND TERM OF THE COMMISSIONER**  
 5 **OF FOOD AND DRUGS.**

6 (a) *PURPOSE.*—It is the purpose of this section to pro-  
 7 mote increased accountability of the Commissioner of Food  
 8 and Drugs by providing for a limited term of appointment  
 9 for the Commissioner of Food and Drugs.

10 (b) *LIMITATION.*—Section 903(b)(1) (21 U.S.C.  
 11 393(b)(1)) is amended by striking “the Senate.” and insert-  
 12 ing “the Senate for a term of 5 years. The Commissioner  
 13 shall be appointed to serve 1 term. An individual serving  
 14 in the office of Commissioner may be removed from office  
 15 only pursuant to a finding by the President of neglect of  
 16 duty or malfeasance in office.”.

17 (c) *APPLICABILITY.*—The amendment made by sub-  
 18 section (b) shall not apply to the tenure of the individual  
 19 who is serving as the Commissioner of Food and Drugs on  
 20 the date of enactment of this Act.

1 **TITLE II—EXPEDITED ACCESS**  
 2 **TO PRODUCTS FOR SERI-**  
 3 **OUSLY ILL PATIENTS**

4 **SEC. 201. SHORT TITLE.**

5 *This title may be cited as the “Patient Rights Regu-*  
 6 *latory Reform Act of 1996”.*

7 **SEC. 202. ACCESS TO UNAPPROVED THERAPIES.**

8 *Chapter V (21 U.S.C. 351 et seq.) is amended by add-*  
 9 *ing at the end thereof the following new subchapter:*

10 **“Subchapter D—Unapproved Therapies and**  
 11 **Diagnostics and Collaborative Research**

12 **“SEC. 551. EXPANDED ACCESS TO UNAPPROVED THERAPIES**  
 13 **AND DIAGNOSTICS.**

14 *“(a) IN GENERAL.—Any person, through a licensed*  
 15 *health care practitioner or licensed health care professional,*  
 16 *may request from a manufacturer or distributor, and any*  
 17 *manufacturer or distributor may provide to a person after*  
 18 *compliance with the provisions of this section, an investiga-*  
 19 *tional drug (including a biological product) or investiga-*  
 20 *tional device for the diagnosis, monitoring, or treatment of*  
 21 *a serious disease or condition, an immediately life-threaten-*  
 22 *ing or seriously debilitating disease or condition, or any*  
 23 *other disease or condition designated by the Secretary as*  
 24 *appropriate for expanded access under this section if—*

1           “(1) the person has no comparable or satisfac-  
2           tory alternative therapy available to treat, diagnose,  
3           or monitor the disease or condition;

4           “(2) the risk to the person from the investiga-  
5           tional drug or device is not greater than the risk from  
6           the disease or condition; and

7           “(3) an exemption for the investigational drug or  
8           device is in effect under a regulation promulgated  
9           pursuant to section 505(i) or 520(g) and the sponsor  
10          and investigators comply with such regulation.

11          “(b) *PROTOCOLS*.—A manufacturer or distributor may  
12          submit to the Secretary 1 or more expanded access protocols  
13          covering expanded access use of a drug or device described  
14          in subsection (a). The protocols shall be subject to the provi-  
15          sions of section 505(i) for a drug and section 520(g) for  
16          a device and may include any form of use of the drug or  
17          device outside a clinical investigation, prior to approval of  
18          the drug or device for marketing, including protocols for  
19          treatment, use, parallel track, emergency use, uncontrolled  
20          trials, and single patient protocols.

21          “(c) *FEES*.—A manufacturer or distributor may assess  
22          a fee for an investigational drug or device under an ex-  
23          panded access protocol so long as the fee is not more than  
24          that necessary to recover the costs of the manufacture and

1 *handling of the drug or device. The Secretary shall be noti-*  
 2 *fied in advance of the assessing of any such fees.*

3 “(d) *NOTIFICATION OF AVAILABILITY.*—*The Commis-*  
 4 *sioner shall inform national, State, and local medical asso-*  
 5 *ciations and societies, voluntary health associations, and*  
 6 *other appropriate persons about the availability of an in-*  
 7 *vestigational drug or device under expanded access protocols*  
 8 *under this section. Such notification shall identify—*

9 “(1) *the investigational drug or device;*

10 “(2) *the expanded access use of the investiga-*  
 11 *tional drug or device; and*

12 “(3) *the name and address of the manufacturer*  
 13 *or distributor that is providing the investigational*  
 14 *drug or device for expanded access use.”.*

15 **SEC. 203. EXPANDING HUMANITARIAN USE OF DEVICES.**

16 *Section 520(m) (21 U.S.C. 360j(m)) is amended—*

17 (1) *in paragraph (2), by inserting at the end*  
 18 *thereof the following flush sentences:*

19 “*The request shall be in the form of an application submit-*  
 20 *ted to the Secretary. Not later than 30 days after the date*  
 21 *of the receipt of the application, the Secretary shall issue*  
 22 *an order approving or denying the application.”;*

23 (2) *by striking paragraph (5); and*

24 (3) *by striking paragraph (6).*



1 **SEC. 204. EXPEDITING APPROVAL OF NEW DRUGS, BIO-**  
 2 **LOGICS, AND MEDICAL DEVICES FOR SERI-**  
 3 **OUS CONDITIONS.**

4 (a) *NEW DRUGS.*—Section 505(c)(1) (21 U.S.C.  
 5 355(c)(1)) is amended by adding at the end thereof the fol-  
 6 lowing flush sentence:

7 “In a case in which an application is submitted under sub-  
 8 section (b)(1) for a new drug, or section 351(a) of the Public  
 9 Health Service Act for a biological product, that is intended  
 10 for use for an immediately life-threatening or serious dis-  
 11 ease or condition and that provides therapy or diagnosis  
 12 not available from another approved drug or biological  
 13 product or offers significant improvement over another ap-  
 14 proved drug or biological product, the Secretary shall ap-  
 15 prove or deny approval of the application within 180 days  
 16 after the receipt of the application.”.

17 (b) *PREMARKET APPROVAL.*—

18 (1) *AMENDMENT.*—Section 515(d)(1)(A) (21  
 19 U.S.C. 360e(d)(1)(A)) is amended by adding at the  
 20 end thereof the following flush sentence:

21 “With respect to an application submitted under this sub-  
 22 section for a device for a life-threatening disease or condi-  
 23 tion, a seriously debilitating disease or condition, or for any  
 24 other serious disease or condition that provides therapy or  
 25 diagnosis not available from another approved device or of-  
 26 fers a significant improvement over another approved de-

1 *vice, the Secretary shall approve or deny the approval of*  
 2 *the application within 180 days after the receipt of the ap-*  
 3 *plication.”.*

4 (2) *EFFECTIVE DATE.*—*The amendment made by*  
 5 *paragraph (1) shall take effect on July 1, 1998.*

6 **TITLE III—REVITALIZING THE**  
 7 **INVESTIGATION OF NEW**  
 8 **PRODUCTS**

9 **SEC. 301. SHORT TITLE.**

10 *This title may be cited as the “Investigational Prod-*  
 11 *ucts Regulatory Reform Act of 1996”.*

12 **SEC. 302. TIMELY REVIEW AND REASONABLE DATA RE-**  
 13 **QUIREMENTS FOR CLINICAL RESEARCH ON**  
 14 **DRUGS AND BIOLOGICAL PRODUCTS.**

15 *Section 505(i) (21 U.S.C. 355(i)) is amended—*

16 (1) *by striking “(i) The” and inserting “(i)(1)*  
 17 *The”;*

18 (2) *by redesignating paragraphs (1), (2), and (3)*  
 19 *as subparagraphs (A), (B), and (C), respectively; and*

20 (3) *by adding at the end thereof the following*  
 21 *new paragraphs:*

22 “(2)(A) *A clinical investigation of a new drug (includ-*  
 23 *ing a biological product) may begin 30 days after the date*  
 24 *on which the Secretary receives from the sponsor of the in-*  
 25 *vestigation a notification containing information about the*

1 *drug and the clinical investigation unless, prior to the 30-*  
2 *day period, the Secretary informs the sponsor in writing*  
3 *that the investigation may not begin, and specifies the basis*  
4 *for the decision and the information needed in order for*  
5 *the clinical investigation to commence.*

6       “(B) *Not later than 1 year after the date of enactment*  
7 *of the Food and Drug Administration Performance and Ac-*  
8 *countability Act of 1996, the Secretary, after consultation*  
9 *with experts in the development, clinical investigation, and*  
10 *regulation of drugs, physicians and other health care prac-*  
11 *titioners, and representatives of patient and consumer ad-*  
12 *vocacy groups and the regulated industries, shall publish*  
13 *in the Federal Register criteria for the type and amount*  
14 *of information relating to the safety of an investigational*  
15 *drug to be included in a notification described in subpara-*  
16 *graph (A). In the establishment of the criteria, the Secretary*  
17 *shall take into account the recommendations of the Inter-*  
18 *national Conference on Harmonization of Technical Re-*  
19 *quirements for Registration of Pharmaceuticals for Human*  
20 *Use. The Secretary shall periodically review, and may re-*  
21 *vise, the criteria.*

22       “(C) *The Secretary shall establish a mechanism to en-*  
23 *sure the fair and consistent application of safety standards*  
24 *for clinical investigations.*

1       “(3)(A) *The Secretary may place a clinical hold on*  
 2 *any ongoing clinical investigation if the Secretary deter-*  
 3 *mines that such action is necessary for the protection of*  
 4 *human subjects.*

5       “(B) *If the Secretary places a clinical hold on a clini-*  
 6 *cal investigation, the Secretary shall immediately advise*  
 7 *the sponsor for the investigation in writing of such action,*  
 8 *and provide the sponsor an opportunity to meet with the*  
 9 *Secretary, not later than 10 business days after the receipt*  
 10 *of such a communication, to discuss the clinical hold. Not*  
 11 *later than 10 days after such a meeting, the Secretary shall*  
 12 *provide to the sponsor in writing the conditions for the*  
 13 *withdrawal of the clinical hold. Any written request re-*  
 14 *ceived by the Secretary from the sponsor requesting that a*  
 15 *clinical hold be removed shall receive a decision, in writing*  
 16 *and specifying the reasons therefor, not later than 20 days*  
 17 *after the receipt of the request.”.*

18 **SEC. 303. TIMELY REVIEW AND REASONABLE DATA RE-**  
 19 **QUIREMENTS FOR CLINICAL RESEARCH ON**  
 20 **DEVICES.**

21       *Section 520(g) (21 U.S.C. 360j(g)) is amended by add-*  
 22 *ing at the end thereof the following new paragraphs:*

23       “(6) *The procedures and conditions prescribed pursu-*  
 24 *ant to paragraph (2)(A) shall be subject to subparagraphs*  
 25 *(B) and (C) of section 505(i)(2), except that the provision*

1 *of subparagraph (B) of such section relating to the consider-*  
2 *ation of the recommendations of the International Con-*  
3 *ference on Harmonization of Technical Requirements for*  
4 *Registration of Pharmaceuticals for Human Use shall not*  
5 *apply to this paragraph.*

6       “(7) *The Secretary shall, not later than 120 days after*  
7 *the date of enactment of this paragraph, by regulation*  
8 *amend the content of parts 812 and 813 of title 21 of the*  
9 *Code of Federal Regulations to update the procedures and*  
10 *conditions under which devices intended for human use*  
11 *may upon application be granted an exemption from cer-*  
12 *tain requirements under this Act. The regulation shall—*

13           “(A) *permit developmental changes in devices,*  
14 *including manufacturing changes, in response to in-*  
15 *formation collected during an investigation without*  
16 *requiring an additional approval of an application*  
17 *for an investigational device exemption or the ap-*  
18 *proval of a supplement to the application, if the spon-*  
19 *sor of the investigation determines that, prior to mak-*  
20 *ing any changes, the changes do not constitute a sig-*  
21 *nificant change in design or a significant change in*  
22 *basic principles of operation; and*

23           “(B) *permit, without approval of a supplement*  
24 *to an application for an investigational device exemp-*  
25 *tion, changes or modifications to clinical protocols*

1        *that do not affect the validity of data or information*  
 2        *resulting from the completion of an approved protocol*  
 3        *so long as such changes do not affect any patient pro-*  
 4        *tection provisions of the protocol.”.*

5    **SEC. 304. SENSE OF THE COMMITTEE CONCERNING MU-**  
 6                                    **TUAL RECOGNITION AGREEMENTS.**

7        *(a) FINDINGS.—The Committee on Labor and Human*  
 8        *Resources of the Senate finds that there have been lengthy*  
 9        *discussions between the members of the European Union*  
 10       *and the Commissioner of Food and Drugs on the issue of*  
 11       *mutual recognition agreements relating to the regulation of*  
 12       *drugs, biological products, devices, foods, food additives, and*  
 13       *color additives, and the regulation of good manufacturing*  
 14       *practices.*

15       *(b) SENSE OF THE COMMITTEE.—It is the sense of the*  
 16       *Committee on Labor and Human Resources of the Senate*  
 17       *that—*

18                *(1) the Secretary of Health and Human Serv-*  
 19        *ices, in consultation with the Secretary of Commerce,*  
 20        *should move toward the acceptance of mutual recogni-*  
 21        *tion agreements relating to the regulation of drugs,*  
 22        *biological products, devices, foods, food additives, and*  
 23        *color additives, and the regulation of good manufac-*  
 24        *turing practices, reached between the European*  
 25        *Union and the Commissioner of Food and Drugs;*

1           (2) *the Secretary of Health and Human Services*  
 2           *should regularly participate in meetings with other*  
 3           *foreign governments to discuss and reach agreement*  
 4           *on methods and approaches to harmonize regulatory*  
 5           *requirements; and*

6           (3) *the Office of International Relations of the*  
 7           *Department of Health and Human Services (as estab-*  
 8           *lished under section 803 of the Federal Food, Drug,*  
 9           *and Cosmetic Act (21 U.S.C. 383)) should have the*  
 10          *responsibility of ensuring that the process of harmo-*  
 11          *nizing international regulatory requirements is con-*  
 12          *tinuous.*

13 **SEC. 305. COLLABORATIVE RESEARCH DESIGN.**

14          *Chapter V (21 U.S.C. 351 et seq.), as amended by sec-*  
 15          *tion 202, is further amended by adding at the end thereof*  
 16          *the following new section:*

17 **“SEC. 552. COLLABORATIVE RESEARCH DESIGN.**

18          **“(a) REVIEW OF DESIGN.—**

19               **“(1) REQUEST.—***Any person who intends to*  
 20               *sponsor a preclinical or clinical investigation of a*  
 21               *drug (including a biological product) or device may*  
 22               *request a meeting with the Secretary to review the de-*  
 23               *sign of 1 or more protocols for the preclinical or clini-*  
 24               *cal testing of the drug or device.*

1           “(2) *FORM.*—A request described in paragraph  
2           (1) shall be in writing and shall include any protocol  
3           for which the review is requested. A protocol shall be  
4           designed so that the fewest number of patients and  
5           procedures necessary to obtain data necessary for the  
6           approval of a new drug, biological product, or device  
7           is required, consistent with public health and safety.

8           “(3) *WRITTEN REVIEW.*—The Secretary shall  
9           meet with the person within 30 days after the request  
10          and shall provide to the person a written review of  
11          the protocol, including any deficiencies in the proto-  
12          col. A written summary shall be made of the meeting.  
13          The summary shall include the written review of the  
14          protocol and, after agreement by the person and the  
15          Secretary, shall be made part of the product review  
16          file maintained by the Food and Drug Administra-  
17          tion.

18          “(b) *MODIFICATION OF AGREEMENTS.*—Any agree-  
19          ments reached through meetings with respect to the design  
20          of any protocol under subsection (a) may be modified only  
21          in accordance with the following provisions:

22               “(1) An agreement may be modified at any time  
23               by mutual consent of the sponsor of a preclinical or  
24               clinical investigation and the Secretary.



1           “(2) *An agreement may be modified by the spon-*  
2           *sor unilaterally, if the change is to a protocol and the*  
3           *change is one that would not require the approval of*  
4           *the Secretary under the applicable regulations.*

5           “(3) *An agreement may be modified by the Sec-*  
6           *retary unilaterally, if the change to the agreement*  
7           *is—*

8                   “(A) *made by the director of the office of the*  
9                   *Food and Drug Administration responsible for*  
10                  *regulating the drug or device that is the subject*  
11                  *of the agreement; and*

12                   “(B) *set forth in writing, including an ex-*  
13                  *planation of the scientific or clinical need for the*  
14                  *change.*

15           *The director described in paragraph (3)(A) may not dele-*  
16           *gate the regulatory responsibility described in such para-*  
17           *graph.*

18           “(c) *APPEALS.—Any person requesting a meeting*  
19           *under subsection (a) may appeal the decision of the Sec-*  
20           *retary to disapprove or modify an agreement or protocol*  
21           *under section 907.*

22           “(d) *GUIDELINES AND LIMITATION.—The Secretary*  
23           *shall issue guidelines to implement this section. Such guide-*  
24           *lines shall address the responsibilities of the person request-*  
25           *ing the meeting, as well as the responsibilities of the Sec-*

1 *retary. Repeated failure to follow the guidelines may be*  
 2 *grounds for a refusal by the Secretary to meet with a person*  
 3 *requesting a meeting under this section.”.*

4 ***TITLE IV—EFFICIENT, ACCOUNT-***  
 5 ***ABLE, AND FAIR PRODUCT RE-***  
 6 ***VIEW***

7 ***SEC. 401. SHORT TITLE.***

8 *This title may be cited as the “Product Review Regu-*  
 9 *latory Reform Act of 1996”.*

10 ***SEC. 402. THE CONTENT AND REVIEW OF AN APPLICATION.***

11 *Chapter VII (21 U.S.C. 371 et seq.) is amended by*  
 12 *adding at the end thereof the following new subchapter:*

13 ***“Subchapter D—Review of Applications, In-***  
 14 ***spections, Environmental Impact Reviews,***  
 15 ***and Manufacturing Changes***

16 ***“SEC. 741. CONTENT AND REVIEW OF AN APPLICATION.***

17 *“(a) IN GENERAL.—This section applies to an appli-*  
 18 *cation or submission (including a petition, notification, or*  
 19 *any other similar form of request) submitted for approval*  
 20 *or clearance of a new drug, device, biological product, new*  
 21 *animal drug, animal feed bearing or containing a new ani-*  
 22 *mal drug, color additive, or food additive.*

23 *“(b) FILING REQUIREMENTS.—Not later than 60 days*  
 24 *after the date of enactment of this section, the Commissioner*  
 25 *shall establish and publish in the Federal Register a mecha-*

1 *nism to ensure the fair and consistent application of filing*  
 2 *requirements.*

3       “(c) *CLASSIFICATION OF A PRODUCT.*—Not later than  
 4 60 days after the receipt of a written request of a person  
 5 who submits an application or submission (including a pe-  
 6 tition, notification, or any other similar form of request)  
 7 for information respecting the classification of an article  
 8 as a drug, biological product, or device or the component  
 9 of the Food and Drug Administration that will regulate the  
 10 article (including a request respecting a combination prod-  
 11 uct subject to section 503(g)), the Secretary shall provide  
 12 the person a written statement that identifies the classifica-  
 13 tion of the article or the component of the Food and Drug  
 14 Administration that will regulate the article. The Sec-  
 15 retary’s statement shall be binding and may not be modified  
 16 by the Secretary except with the written agreement of the  
 17 person who submitted the request. If the Secretary does not  
 18 provide the statement within the 60-day period, the classi-  
 19 fication and component designated by the person submit-  
 20 ting the request shall be final and binding and may not  
 21 be modified by the Secretary except with the written agree-  
 22 ment of the person.

23       “(d) *REASONABLE DATA REQUIREMENTS.*—Not later  
 24 than 1 year after the date of enactment of the Food and  
 25 Drug Administration Performance and Accountability Act

1 of 1996, the Secretary, after consultation with experts in  
 2 the development and testing of articles that are new drugs,  
 3 biological products, devices, food additives, new animal  
 4 drugs, animal feed bearing or containing a new animal  
 5 drug, color additives, or food additives, experts in the regu-  
 6 lation of such articles, consumer and patient advocacy  
 7 groups, and the regulated industries, shall publish in the  
 8 Federal Register criteria for the type and amount of infor-  
 9 mation relating to safety or effectiveness to be included in  
 10 an application for the approval of an article that is a new  
 11 drug, biological product, device, food additive, new animal  
 12 drug, animal feed bearing or containing a new animal  
 13 drug, color additive, or food additive, or a new use of an  
 14 approved article that is a new drug, biological product, de-  
 15 vice, food additive, new animal drug, animal feed bearing  
 16 or containing a new animal drug, color additive, or food  
 17 additive. In establishing the criteria for drugs, the Sec-  
 18 retary shall consider any recommendations of the Inter-  
 19 national Conference on Harmonization of Technical Re-  
 20 quirements for Registration of Pharmaceuticals for Human  
 21 Use.”.

22 **SEC. 403. CONTRACTS FOR EXPERT REVIEW.**

23 Chapter VII (21 U.S.C. 371 et seq.), as amended by  
 24 section 402, is further amended by adding at the end thereof  
 25 the following new section:

1 **“SEC. 742. CONTRACTS FOR EXPERT REVIEW.**

2 “(a) *IN GENERAL.*—

3 “(1) *AUTHORITY.*—*The Secretary may contract*  
4 *with outside organizations and individuals, with ex-*  
5 *pertise in relevant disciplines, to review, evaluate,*  
6 *and make conclusions and recommendations to the*  
7 *Secretary on parts or all of any application or sub-*  
8 *mission (including a petition, notification, or any*  
9 *other similar form of request). The Secretary shall re-*  
10 *tain full authority to make determinations with re-*  
11 *spect to the approval or disapproval of any article, or*  
12 *the classification of a device under section 513(f)(1).*  
13 *Any such contract shall be subject to the requirements*  
14 *of section 708. Funds obtained under part 2 of sub-*  
15 *chapter C may be used for external review of any*  
16 *drug (including a biological product) for which a user*  
17 *fee was paid.*

18 “(2) *INCREASED EFFICIENCY AND EXPERTISE*  
19 *THROUGH CONTRACTS.*—*The Secretary shall use the*  
20 *authority granted in paragraph (1)—*

21 “(A) *for the review of categories of indirect*  
22 *food additive petitions and notifications for*  
23 *clearance under section 510(k);*

24 “(B) *whenever contracts will improve the ef-*  
25 *iciency, timeliness, and quality of the review of*  
26 *applications or submissions (including petitions,*

1       *notifications, or any other similar form of re-*  
2       *quests) for the approval or clearance of new*  
3       *drugs, new animal drugs, biological products, de-*  
4       *vices, and food additives; and*

5               “(C) *whenever contracts will increase the*  
6       *scientific and technical expertise that is nec-*  
7       *essary to keep informed of emerging new thera-*  
8       *pies and technologies that pose significant new*  
9       *scientific and technical issues.*

10       *The Secretary shall retain full authority to make de-*  
11       *terminations with respect to the approval or dis-*  
12       *approval of an article, or the classification of an arti-*  
13       *cle as a device under section 513(f)(1).*

14       “(b) *ELIGIBILITY REQUIREMENTS.—Not later than 90*  
15       *days after the date of enactment of this section, the Sec-*  
16       *retary shall by regulation establish the requirements that*  
17       *an organization or individual shall meet to be eligible to*  
18       *conduct reviews under subsection (a). Such regulations shall*  
19       *provide for the protection of confidential or proprietary in-*  
20       *formation and shall provide for protection against conflicts*  
21       *of interest.*

22       “(c) *REVIEW OF EXPERT’S EVALUATION.—*

23               “(1) *IN GENERAL.—Subject to paragraph (2), the*  
24       *official of the Food and Drug Administration respon-*  
25       *sible for any matter for which expert review is used*

1       pursuant to this section shall review the conclusions  
 2       and recommendations of the expert review organiza-  
 3       tion or individual and shall make a final decision re-  
 4       garding the matter under review within 60 days after  
 5       receiving the conclusions and recommendation.

6               “(2) *LIMITATION.*—A final decision under para-  
 7       graph (1) shall be made within the applicable pre-  
 8       scribed time period for review of an application as set  
 9       forth in this Act.

10          “(d) *REPORT TO CONGRESS.*—Not later than 2 years  
 11       after the date of enactment of this section, the Secretary  
 12       shall prepare and submit to Congress a report on the use  
 13       of the authority to contract with outside organizations and  
 14       individuals for expert reviews. Such report shall include an  
 15       evaluation of the extent to which such contracting improves  
 16       the efficiency of review and the expertise available to the  
 17       Food and Drug Administration.”.

18       **SEC. 404. PROMPT AND EFFICIENT REVIEW.**

19       Chapter VII (21 U.S.C. 371 et seq.), as amended by  
 20       section 403, is further amended by adding at the end thereof  
 21       the following new section:

22       **“SEC. 743. PROMPT AND EFFICIENT REVIEW.**

23               “(a) *IN GENERAL.*—The provisions of this section shall  
 24       apply to any of the following applications, petitions, and  
 25       notifications:

1           “(1) *A petition for the issuance of a regulation*  
2           *prescribing the safe use of a human food additive or*  
3           *animal feed additive under section 409.*

4           “(2) *An application for approval of a new drug*  
5           *under section 505.*

6           “(3) *An application for approval of a new ani-*  
7           *mal drug or an animal feed bearing or containing a*  
8           *new animal drug under subsection (b) or (m) of sec-*  
9           *tion 512, respectively.*

10          “(4) *A notification submitted under section*  
11          *510(k) for classification of a device.*

12          “(5) *An application for approval of a device*  
13          *under section 515.*

14          “(6) *A petition for issuance of a regulation for*  
15          *the listing of a color additive under section 721.*

16          “(b) *REVIEW PROCEDURES AND POLICIES.—The Sec-*  
17          *retary shall establish procedures and policies to facilitate*  
18          *a collaborative review process between the Commissioner*  
19          *and the applicant, petitioner, or person who submits a noti-*  
20          *fication with respect to an application, petition, or notifica-*  
21          *tion described in subsection (a). As part of this collaborative*  
22          *process—*

23                 “(1) *open, informal, and prompt communica-*  
24                 *tions shall be encouraged;*



1           “(2) meetings (except that meetings shall not be  
2       required with respect to matters relating to a notifica-  
3       tion submitted under section 510(k)) shall be held be-  
4       fore the expiration of one-half of the statutory time  
5       period for review of the application or petition and  
6       before the expiration of three-quarters of such period,  
7       or within 15 days after a scientific review group has  
8       convened and made recommendations on an applica-  
9       tion or petition, unless the Commissioner and the ap-  
10      plicant or petitioner determine that a meeting is un-  
11      necessary;

12           “(3) by mutual consent, the Commissioner and  
13      the applicant or petitioner may establish a different  
14      schedule for meetings required under paragraph (2);  
15      and

16           “(4) the Secretary shall, prior to the meetings  
17      described in paragraph (2), present to the applicant  
18      or petitioner in writing a description of any defi-  
19      ciencies of the application or petition and the infor-  
20      mation necessary to bring the application or petition  
21      into a form that would require approval.

22      The Secretary and the applicant or petitioner may agree  
23      to supersede any procedures and policies adopted under this  
24      section and the requirements of paragraphs (2) and (3).

1 *Any such agreement shall be in writing, and shall specify*  
 2 *how any such agreement shall be modified or set aside.*

3 “(c) *APPROVAL, DISAPPROVAL, AND CLASSIFICA-*  
 4 *TION.—*

5 “(1) *CONSIDERATION OF INTERNATIONAL AP-*  
 6 *PROVALS.—Beginning July 1, 1998, if the Secretary*  
 7 *fails to meet a time period for action on an applica-*  
 8 *tion or notification for the approval or clearance of*  
 9 *an article that is a new drug, device, biological prod-*  
 10 *uct, or new animal drug that offers a significant im-*  
 11 *provement over an existing approved article or a peti-*  
 12 *tion for the approval of a direct food additive that*  
 13 *has the potential to make foods more wholesome and*  
 14 *contribute to a healthier diet, and such an article has*  
 15 *been approved for marketing in the European Union*  
 16 *or the United Kingdom, the Secretary shall, within*  
 17 *30 days after a request of a person who submits an*  
 18 *application, notification, or petition described in this*  
 19 *paragraph, either approve or disapprove the applica-*  
 20 *tion, notification, or petition and notify the person in*  
 21 *writing of that decision. In the case of a disapproval,*  
 22 *or a determination that a device is not substantially*  
 23 *equivalent, such notification shall set forth the reasons*  
 24 *for the disapproval or the determination.*

1           “(2) *APPEAL*.—A person whose application, no-  
 2           tification, or petition has been disapproved (including  
 3           a determination that a device does not meet the re-  
 4           quirements relating to substantial equivalence) under  
 5           paragraph (1) may obtain judicial review under—

6                     “(A) section 505(h) for the disapproval of a  
 7                     new drug under paragraph (1);

8                     “(B) section 517 for the disapproval of a  
 9                     device or a determination of not substantially  
 10                    equivalent relating to a device under paragraph  
 11                    (1);

12                    “(C) chapter VII of title 5, United States  
 13                    Code, for the disapproval of a license for a bio-  
 14                    logical product under paragraph (1);

15                    “(D) section 512(h) for the disapproval of a  
 16                    new animal drug under paragraph (1); and

17                    “(E) section 409(g) for the disapproval of a  
 18                    direct food additive under paragraph (1).

19           “(d) *CONTRACTS FOR EXPERT REVIEW*.—

20                    “(1) *IN GENERAL*.—Beginning July 1, 1998, if  
 21                    the Secretary in any fiscal year fails to meet the stat-  
 22                    utory time period for action on an application, noti-  
 23                    fication, or petition for at least 95 percent of the ap-  
 24                    plications, notifications, and petitions submitted in a  
 25                    particular product category, the Secretary shall—

1           “(A) in the following fiscal year, contract  
2           with expert organizations and individuals under  
3           section 742, to review applications, notifications,  
4           and petitions of persons who submit the applica-  
5           tions, notifications, and petitions in that follow-  
6           ing fiscal year and who consent to the review;  
7           and

8           “(B) in the following fiscal year and with  
9           the consent of the persons described in this sub-  
10          paragraph, contract with expert organizations  
11          and individuals under section 742, to review ap-  
12          plications, notifications, and petitions that were  
13          submitted by persons in any preceding fiscal  
14          year and that the Secretary has failed to review  
15          within the statutory time period for action on  
16          the applications, notifications, and petitions  
17          with respect to the particular product category.

18          “(2) APPROVAL.—If an organization or individ-  
19          ual selected to conduct a review under paragraph (1)  
20          recommends the approval or clearance of an applica-  
21          tion, notification, or petition described in paragraph  
22          (1), the Secretary shall, within 60 days after receiv-  
23          ing the determination of the organization or individ-  
24          ual (but not later than the time period for review set  
25          forth in this Act), either approve or disapprove the

1        application, notification, or petition, and, in the case  
 2        of a disapproval, notify the person who submitted the  
 3        application, notification, or petition in writing of the  
 4        basis for the disapproval. The person may appeal an  
 5        adverse decision under subsection (c)(2).”.

6    **SEC. 405. GOOD MANUFACTURING PRACTICE INSPECTION.**

7        Chapter VII is (21 U.S.C. 371 et seq.), as amended  
 8        by section 404, is further amended by adding at the end  
 9        thereof the following new section:

10    **“SEC. 744. GOOD MANUFACTURING PRACTICE INSPECTION.**

11        “(a) *IN GENERAL.*—In order to comply with the in-  
 12        spection requirements of this Act, the Secretary may ac-  
 13        credit organizations to conduct inspections under section  
 14        704 to evaluate compliance of a manufacturer with applica-  
 15        ble requirements for good manufacturing practice.

16        “(b) *ELIGIBILITY REQUIREMENTS.*—If the Secretary  
 17        elects to accredit organizations to conduct inspections under  
 18        section 704, the Secretary shall by regulation, within 90  
 19        days after the date of enactment of this section, establish  
 20        the requirements that an organization shall meet to be eligi-  
 21        ble to be accredited to participate as a qualified organiza-  
 22        tion to conduct inspections under subsection (a). Such regu-  
 23        lation shall provide for the protection of confidential or pro-  
 24        prietary information and shall provide for protection  
 25        against conflicts of interest.

1       “(c) *ACCREDITATION.*—Not later than 90 days after  
 2   the date on which the Secretary receives an application for  
 3   accreditation under this section, the Secretary shall review  
 4   the application and determine whether an applicant is in  
 5   compliance with the requirements established under this sec-  
 6   tion. Within the 90-day period, the Secretary shall grant  
 7   accreditation or shall deny accreditation and specify in  
 8   writing the reasons for the denial and the requirements that  
 9   shall be met to obtain accreditation.

10       “(d) *REVOCATION OF ACCREDITATION.*—The Secretary  
 11   may at any time revoke accreditation granted under sub-  
 12   section (c) for failure to comply with the requirements es-  
 13   tablished under this section after specifying in writing the  
 14   reasons for the revocation and the requirements that shall  
 15   be met to retain accreditation and after an informal hear-  
 16   ing on the revocation.

17       “(e) *INSPECTIONS.*—Any organization accredited  
 18   under this section that conducts an inspection under this  
 19   section at the request of the Secretary shall—

20               “(1) apply all relevant principles of good manu-  
 21   facturing practice established in this Act and in regu-  
 22   lations promulgated by the Secretary;

23               “(2) provide to the Secretary and the manufac-  
 24   turer within 30 days after the completion of the in-  
 25   spection a report of the findings of the inspection; and

1           “(3) immediately provide the Secretary with a  
2           notice of any condition that could cause or contribute  
3           to a significant threat to the public health.”.

4   **SEC. 406. ENVIRONMENTAL IMPACT REVIEW.**

5           Chapter VII (21 U.S.C. 371 et seq.), as amended by  
6           section 405, is further amended by adding at the end thereof  
7           the following new section:

8   **“SEC. 745. ENVIRONMENTAL IMPACT REVIEW.**

9           “Notwithstanding any other provision of law, no ac-  
10          tion by the Secretary pursuant to this Act shall be subject  
11          to an environmental assessment, an environmental impact  
12          statement, or other environmental consideration unless the  
13          director of the office responsible for the action demonstrates,  
14          in writing—

15                 “(1) that there is a reasonable probability that  
16                 the environmental impact of the action is sufficiently  
17                 substantial and within the factors that the Secretary  
18                 is authorized to consider under this Act; and

19                 “(2) that consideration of the environmental im-  
20                 pact will directly affect the decision on the action.”.

21   **SEC. 407. EFFECTIVENESS, OUTCOME, AND COST-EFFEC-**  
22                 **TIVENESS STANDARDS.**

23           Section 741, as added by section 402, is amended by  
24           adding at the end thereof the following new subsection:

1       “(e) *LIMITATION ON DETERMINATION OF EFFECTIVE-*  
 2 *NESS.—In a review of an application for an article that*  
 3 *is a new drug, device, biological product, new animal drug,*  
 4 *or animal feed bearing or containing a new animal drug,*  
 5 *the determination of effectiveness shall not include the eval-*  
 6 *uation of—*

7               “(1) *any potential use not included in the label-*  
 8 *ing;*

9               “(2) *the cost-effectiveness of an article described*  
 10 *in this subsection, unless the proposed labeling explic-*  
 11 *itly includes a representation about cost-effectiveness;*  
 12 *and*

13               “(3) *the clinical outcome resulting from the use*  
 14 *of a diagnostic device, unless the labeling explicitly*  
 15 *includes a representation regarding clinical out-*  
 16 *come.”.*

17 **SEC. 408. DEFINITION OF A DAY FOR PURPOSES OF PROD-**  
 18 **UCT REVIEW.**

19       *Section 201 (21 U.S.C. 321) is amended by adding*  
 20 *at the end thereof the following new paragraph:*

21       “(gg) *For purposes of reviewing any application or*  
 22 *submission (including a petition, notification, or any other*  
 23 *similar form of request), or any document, with respect to*  
 24 *an article that is a new drug, device, biological product,*  
 25 *new animal drug, an animal feed bearing or containing*



1 *a new animal drug, color additive, or food additive, that*  
 2 *is submitted to the Secretary to obtain marketing approval,*  
 3 *to obtain classification of a device under section 513(f)(1),*  
 4 *or to establish or clarify the regulatory status of the article,*  
 5 *the term ‘day’ means a calendar day in which the Secretary*  
 6 *has responsibility to review such a submission (excluding*  
 7 *any calendar day between the date of receipt by the submit-*  
 8 *ter of a written communication from the Secretary setting*  
 9 *forth the action of the Secretary on a submission and the*  
 10 *date of receipt by the Secretary of the written response of*  
 11 *the submitter to the action).”.*

12 **SEC. 409. APPROVAL OF SUPPLEMENTAL APPLICATIONS**  
 13 **FOR APPROVED PRODUCTS.**

14 (a) *PERFORMANCE STANDARDS.*—Not later than 180  
 15 days after the date of enactment of this section, the Sec-  
 16 retary of Health and Human Services shall publish in the  
 17 Federal Register performance standards for the prompt re-  
 18 view of supplemental applications submitted for approved  
 19 articles under the Federal Food, Drug, and Cosmetic Act  
 20 (21 U.S.C. 321 et seq.).

21 (b) *GUIDANCE TO INDUSTRY.*—Not later than 180 days  
 22 after the date of enactment of this section, the Secretary  
 23 of Health and Human Services shall issue guidances to  
 24 clarify the requirements and facilitate the submission of  
 25 data to support the approval of supplemental applications

1 *for the approved articles described in subsection (a). The*  
2 *guidances shall—*

3           (1) *clarify circumstances in which published*  
4 *matter may be the basis for approval of a supple-*  
5 *mental application;*

6           (2) *specify data requirements that will avoid du-*  
7 *plication by recognizing the availability of data pre-*  
8 *viously submitted in support of an original applica-*  
9 *tion; and*

10          (3) *define supplemental applications that are eli-*  
11 *gible for priority review.*

12          (c) *RESPONSIBILITIES OF CENTERS.—The Secretary of*  
13 *Health and Human Services shall designate an individual*  
14 *in each center within the Food and Drug Administration*  
15 *(except the Center for Food Safety and Applied Nutrition)*  
16 *to be responsible for—*

17           (1) *encouraging the prompt review of supple-*  
18 *mental applications for approved products; and*

19           (2) *working with sponsors to facilitate the devel-*  
20 *opment and submission of data to support supple-*  
21 *mental applications.*

22          (d) *COLLABORATION.—The Secretary of Health and*  
23 *Human Services shall implement programs and policies*  
24 *that will foster collaboration between the Food and Drug*  
25 *Administration, the National Institutes of Health, profes-*

1 sional medical and scientific societies, and others persons,  
 2 to identify published and unpublished studies that could  
 3 support a supplemental application, and to encourage  
 4 sponsors to make supplemental applications or conduct fur-  
 5 ther research in support of a supplemental application  
 6 based, in whole or in part, on such studies.

7 **SEC. 410. PEDIATRIC STUDIES MARKETING EXCLUSIVITY.**

8 Chapter V of the Federal Food, Drug, and Cosmetic  
 9 Act (21 U.S.C. 351 et seq.) is amended by inserting after  
 10 section 505 the following new section:

11 **“SEC. 505A. PEDIATRIC STUDIES FOR NEW DRUG APPLICA-**  
 12 **TIONS.**

13 “(a) *MARKET EXCLUSIVITY FOR APPROVED APPLICA-*  
 14 *TIONS WITH PEDIATRIC STUDIES SUBMITTED BY AN AP-*  
 15 *PLICANT.*—If an application submitted under section  
 16 505(b)(1) is approved on or after the date of enactment of  
 17 this section, and such application includes reports of pedi-  
 18 atric studies described and requested in subsection (c), and  
 19 such studies are completed and the reports thereof submitted  
 20 in accordance with subsection (c)(2) or completed and the  
 21 reports thereof accepted in accordance with subsection  
 22 (c)(3), the Secretary may not make the approval of an ap-  
 23 plication submitted under section 505(b)(2) or 505(j) that  
 24 refers to the drug for which the section 505(b)(1) approval  
 25 is granted effective prior to the expiration of 6 months from

1 *the earliest date on which the approval of such application*  
 2 *for the drug under section 505(b)(2) or 505(j), respectively,*  
 3 *could otherwise be made effective under the applicable pro-*  
 4 *visions of this chapter.*

5       “(b) *MARKET EXCLUSIVITY FOR APPROVED APPLICA-*  
 6 *TIONS WITH PEDIATRIC STUDIES REQUESTED BY THE*  
 7 *SECRETARY.—If the Secretary makes a written request for*  
 8 *pediatric studies described in subsection (c) to the holder*  
 9 *of an approval under section 505(b)(1) for a drug, and such*  
 10 *studies are completed and the reports thereof submitted in*  
 11 *accordance with subsection (c)(2) or completed and the re-*  
 12 *ports thereof accepted in accordance with subsection (c)(3),*  
 13 *the Secretary may not make the approval of an application*  
 14 *submitted under section 505(b)(2) or 505(j) that refers to*  
 15 *the drug subject to the section 505(b)(1) approval effective*  
 16 *prior to the expiration of 6 months from the earliest date*  
 17 *on which an approval of such application under section*  
 18 *505(b)(2) or 505(j), respectively, could otherwise be made*  
 19 *effective under the applicable provisions of this chapter.*  
 20 *Nothing in this subsection shall affect the ability of the Sec-*  
 21 *retary to make effective a section 505(b)(2) or 505(j) ap-*  
 22 *proval for a subject drug if such approval is proper under*  
 23 *such section and is made effective prior to the submission*  
 24 *of the reports of pediatric studies described in subsection*  
 25 *(c).*

1       “(c) *CONDUCT OF PEDIATRIC STUDIES.*—

2               “(1) *AGREEMENT FOR STUDIES.*—*The Secretary*  
3       *may, pursuant to a written request for studies and*  
4       *after consultation with the sponsor of an application*  
5       *or holder of an approval for a drug under section*  
6       *505(b)(1), agree with the sponsor or holder concerning*  
7       *the conduct of pediatric studies for such drug.*

8               “(2) *WRITTEN PROTOCOLS TO MEET THE STUD-*  
9       *IES REQUIREMENT.*—*If the sponsor or holder and the*  
10       *Secretary agree upon written protocols for such stud-*  
11       *ies, the studies requirement of subsection (a) or (b) is*  
12       *satisfied upon the completion of the studies in accord-*  
13       *ance with the protocols and the submission of the re-*  
14       *ports thereof to the Secretary. Not later than 60 days*  
15       *after the submission of the report of the studies, the*  
16       *Secretary shall determine if such studies were or were*  
17       *not conducted in accordance with the written proto-*  
18       *cols and reported in accordance with the requirements*  
19       *of the Secretary for filing and so notify the sponsor*  
20       *or holder.*

21               “(3) *OTHER METHODS TO MEET THE STUDIES*  
22       *REQUIREMENT.*—*If the sponsor or holder and the Sec-*  
23       *retary have not agreed in writing on the protocols for*  
24       *the studies, the studies requirement of subsection (a)*  
25       *or (b) is satisfied when such studies have been com-*

1       pleted and the reports accepted by the Secretary. Not  
2       later than 90 days after the submission of the reports  
3       of the studies, the Secretary shall accept or reject such  
4       reports and so notify the sponsor or holder. The Sec-  
5       retary's only responsibility in accepting or rejecting  
6       the reports shall be to determine, within 90 days, that  
7       the studies fairly respond to the written request, that  
8       such studies have been conducted in accordance with  
9       commonly accepted scientific principles and protocols,  
10      and that such studies have been reported in accord-  
11      ance with the requirements of the Secretary for filing.

12      “(d) *DELAY OF EFFECTIVE DATE FOR CERTAIN APPLI-*  
13      *CATIONS; PERIOD OF MARKET EXCLUSIVITY.*—If the Sec-  
14      retary determines that an approval of an application under  
15      section 505(b)(2) or 505(j) for a drug may be made effective  
16      after the submission of reports of pediatric studies under  
17      this section but before the Secretary has determined whether  
18      the requirements of subsection (c) have been satisfied, the  
19      Secretary may delay the effective date of any approval  
20      under section 505(b)(2) or 505(j), respectively, until the de-  
21      termination under subsection (c) is made, but such delay  
22      shall not exceed 90 days. In the event that the requirements  
23      of this section are satisfied, the 6-month period referred to  
24      in subsection (a) or (b) shall be deemed to have begun on  
25      the date an approval of an application under section

1 505(b)(2) or 505(j), respectively, would have been permitted  
 2 absent action under this subsection.

3 “(e) *NOTICE OF DETERMINATIONS ON STUDIES RE-*  
 4 *QUIREMENT.*—The Secretary shall publish notice of any de-  
 5 termination that the requirements of paragraph (2) or (3)  
 6 of subsection (c) have been met and that approvals under  
 7 section 505(b)(2) or 505(j) for a drug will be subject to de-  
 8 ferred effective dates under this section.

9 “(f) *DEFINITIONS.*—As used in this section, the term  
 10 ‘pediatric studies’ or ‘studies’ means at least 1 human clini-  
 11 cal investigation in a population of adolescent age or  
 12 younger. At the Secretary’s discretion, pharmacokinetic  
 13 studies may be considered as clinical investigations.”.

14 **SEC. 411. NOTIFICATIONS FOR DEVICE MARKET CLEAR-**  
 15 **ANCE.**

16 Section 510(k) (21 U.S.C. 360(k)) is amended by strik-  
 17 ing “report to” and inserting “shall notify the Secretary  
 18 to report to”.

19 **TITLE V—DRUG AND BIOLOGI-**  
 20 **CAL PRODUCTS REGULATORY**  
 21 **REFORM**

22 **SEC. 501. SHORT TITLE.**

23 This title may be cited as the “Drug and Biological  
 24 Product Regulatory Reform Act of 1996”.

1 **SEC. 502. NEW DRUG APPROVAL STANDARD.**

2       Section 505(d) (21 U.S.C. 355(d)) is amended by add-  
3 ing at the end thereof the following new sentence: “Substan-  
4 tial evidence may consist of data from 1 well-controlled  
5 clinical investigation and confirmatory evidence obtained  
6 prior to, or after, such investigation.”.

7 **SEC. 503. PILOT AND SMALL SCALE MANUFACTURE.**

8       Section 505(c) (21 U.S.C. 355(c)) is amended by add-  
9 ing at the end thereof the following new paragraph:  
10       “(4) A new drug or biological product manufactured  
11 in a pilot or other small facility may be used to demonstrate  
12 the safety and effectiveness of the drug or product and to  
13 obtain approval prior to scaling up to a larger facility, un-  
14 less the Secretary demonstrates in writing and specifies in  
15 detail the reasons, after an informal hearing, that a full  
16 scale production facility is necessary to ensure the safety  
17 or effectiveness of the drug or product.”.

18 **SEC. 504. MANUFACTURING CHANGES.**

19       Chapter VII (21 U.S.C. 371 et seq.), as amended by  
20 section 406, is further amended by adding at the end thereof  
21 the following new section:

22 **“SEC. 746. MANUFACTURING CHANGES.**

23       “(a) *IN GENERAL.*—A change in the manufacture of  
24 a new drug, biological product, or new animal drug, may  
25 be made in accordance with this section.



1       “(b) *DRUG AND BIOLOGICAL PRODUCT.*—A change in  
2 *the manufacture of a new drug, a biological product that*  
3 *is the subject of a monograph in an official compendium,*  
4 *a biological product that can be adequately characterized*  
5 *by chemical, physical, or biological means, or a new animal*  
6 *drug—*

7               “(1) *shall require validation; and*

8               “(2)(A) *if there is no change in the approved*  
9 *qualitative and quantitative formulation relating to*  
10 *the new drug, biological product, or new animal drug*  
11 *or in the approved release specifications relating to*  
12 *the new drug, biological product, or new animal drug,*  
13 *or if there is a change in the approved qualitative or*  
14 *quantitative formula or in the approved release speci-*  
15 *fications of a type permitted by the Secretary by reg-*  
16 *ulation, may be made at any time so long as the*  
17 *change is reported annually to the Secretary; or*

18               “(B) *in the case of a change other than a change*  
19 *described in subparagraph (A), shall require comple-*  
20 *tion of an appropriate study demonstrating equiva-*  
21 *lence according to criteria established by the Sec-*  
22 *retary (unless such requirement is waived by the Sec-*  
23 *retary), may be made at any time, and shall be re-*  
24 *ported to the Secretary through a supplement or*  
25 *amendment submitted at the time the change is made.*

1       “(c) *BIOLOGICAL PRODUCT NOT SUBJECT TO A MONO-*  
 2 *GRAPH.*—A change in the manufacture of a biological prod-  
 3 uct that is not the subject of a monograph in an official  
 4 compendium and cannot be adequately characterized by  
 5 chemical, physical, or biological means—

6               “(1) shall require validation; and

7               “(2)(A) if the change relates solely to a modifica-  
 8 tion of the manufacturing facility or change in per-  
 9 sonnel, with no change in the approved manufactur-  
 10 ing process or release specifications, may be made at  
 11 any time so long as the change is reported annually  
 12 to the Secretary; or

13               “(B) in the case of a change other than a change  
 14 described in subparagraph (A), shall require comple-  
 15 tion of a bioassay or other appropriate study dem-  
 16 onstrating equivalence according to criteria estab-  
 17 lished by the Secretary (unless such requirement is  
 18 waived by the Secretary), may be made at any time,  
 19 and shall be reported to the Secretary through an  
 20 amendment submitted at the time the change is made.

21       “(d) *SPECIAL DETERMINATION FOR A BIOLOGICAL*  
 22 *PRODUCT.*—A determination shall be made, prior to the ap-  
 23 proval of a biological product under section 351(a) of the  
 24 Public Health Service Act (42 U.S.C. 262(a)), whether the  
 25 product can be adequately characterized for purposes of this

1 *section. With respect to biological products approved prior*  
 2 *to the date of enactment of the Food and Drug Administra-*  
 3 *tion Performance and Accountability Act of 1996, the deter-*  
 4 *mination shall be made not later than 90 days after the*  
 5 *date of enactment of such Act. Any determination made*  
 6 *under this subsection is subject to change based upon new*  
 7 *scientific information.”.*

8 **SEC. 505. INSULIN AND ANTIBIOTICS.**

9       (a) *CERTIFICATION OF DRUGS CONTAINING INSU-*  
 10 *LIN.—Section 506 (21 U.S.C. 356) is repealed.*

11       (b) *CERTIFICATION OF ANTIBIOTICS.—Section 507 (21*  
 12 *U.S.C. 357) is repealed.*

13       (c) *EXPORTATION.—Section 802 (21 U.S.C. 382) is*  
 14 *amended—*

15               (1) *by redesignating subsection (h) as subsection*  
 16 *(i); and*

17               (2) *by inserting after subsection (g) the following*  
 18 *new subsection:*

19       “(h) *EXPORTATION OF UNAPPROVED PRODUCTS.—In-*  
 20 *sulin and antibiotics may be exported without regard to*  
 21 *the requirements in this section if the insulin and anti-*  
 22 *biotics meet the requirements of section 801(e)(1).”.*

1 **SEC. 506. MODERNIZATION OF REGULATION OF BIOLOGI-**  
 2 **CAL PRODUCTS.**

3 (a) *IN GENERAL.*—Section 351 of the Public Health  
 4 Service Act (42 U.S.C. 262) is amended by striking “SEC.  
 5 351. (a)” and all that follows through “barter, or exchange  
 6 the same.” and inserting the following:

7 “SEC. 351. (a)(1) *Except as provided in paragraph*  
 8 *(6), no person shall introduce or deliver for introduction*  
 9 *into interstate commerce any biological product unless—*

10 “(A) *a license is in effect for the biological prod-*  
 11 *uct; and*

12 “(B) *each package of the biological product is*  
 13 *plainly marked with the proper name of the biological*  
 14 *product contained therein, the name, address, and ap-*  
 15 *plicable license number of the manufacturer of the bi-*  
 16 *ological product, and the expiration date of the bio-*  
 17 *logical product.*

18 “(2) *The license required under paragraph (1)(A)*  
 19 *shall, as determined by the Secretary, cover the biological*  
 20 *product, any facility in which the biological product is*  
 21 *manufactured, processed, packed, or held, or both the prod-*  
 22 *uct and facility.*

23 “(3)(A) *The Secretary shall establish, by regulation,*  
 24 *requirements for license applications for biological prod-*  
 25 *ucts.*

1       “(B) *Except as provided in subparagraph (D), a li-*  
2 *cense application that covers a biological product shall be*  
3 *approved based upon a demonstration that—*

4               “(i) *the product that is the subject of the applica-*  
5 *tion is safe and effective in accordance with sections*  
6 *505(c) and 505(d) of the Federal Food, Drug, and*  
7 *Cosmetic Act (21 U.S.C. 355 (c) and (d)), or meets*  
8 *standards designed to ensure that the product is safe,*  
9 *pure, and where appropriate, potent; and*

10              “(ii) *the methods used in, and the facilities and*  
11 *control used for, the manufacture, processing, pack-*  
12 *ing, and holding of such product meet standards de-*  
13 *signed to ensure that the product meets the require-*  
14 *ments of clause (i).*

15       “(C) *A license application that covers a facility shall*  
16 *ensure that the product and the facility meet standards de-*  
17 *signed to ensure that the product meets applicable require-*  
18 *ments of subparagraph (B).*

19       “(D) *A license application for blood or a blood compo-*  
20 *nent (including plasma) shall be approved based on a dem-*  
21 *onstration that the product is safe, pure, and where appro-*  
22 *priate, potent, and that the facility in which the product*  
23 *is manufactured, processed, packed, or held meets standards*  
24 *designed to ensure that such product is safe, pure, and*  
25 *where appropriate, potent.*

1       “(4)(A) *Requirements prescribed under paragraph (3)*  
2 *shall include a requirement for preapproval inspection*  
3 *under subsection (c).*

4       “(B) *A license shall be approved only on condition that*  
5 *the licensee agrees to permit inspection of the facility of the*  
6 *licensee in accordance with subsection (c).*

7       “(5)(A) *Except as provided in subparagraph (C), an*  
8 *approved license for a biological product may be revoked*  
9 *if the Secretary determines, on the record after providing*  
10 *an opportunity for a hearing in accordance with section*  
11 *554 of title 5, United States Code, that the requirements*  
12 *for approval as specified in paragraph (3) are no longer*  
13 *met with respect to such product, or that other public health*  
14 *reasons, prescribed by regulation, exist. No action to revoke*  
15 *a license based on the findings of an inspection shall be*  
16 *initiated prior to the submission and review by the Sec-*  
17 *retary of a written response submitted by the licensee to*  
18 *a notice of inspectional findings so long as such written*  
19 *response is received within 30 days after the date of receipt*  
20 *by the licensee of the findings. The revocation of any prod-*  
21 *uct license shall not prevent the continued use of any li-*  
22 *censed biological product that has been sold and delivered*  
23 *by the licensee unless the biological product is subject to*  
24 *recall under subsection (d).*

1       “(B) If at any time before the Secretary has taken  
2 final action to revoke a license, the licensee requests an in-  
3 spection by the Secretary to determine whether the licensee  
4 is in compliance with applicable standards, the Secretary  
5 shall conduct an inspection within 30 days after the date  
6 of the request. If the inspection confirms that the licensee  
7 is not in compliance with applicable standards, the 30-day  
8 requirement for inspection shall not apply to any subse-  
9 quent request by the licensee under this subparagraph for  
10 inspection. If the inspection confirms that the licensee is  
11 in compliance with all applicable requirements, the Sec-  
12 retary shall withdraw any proposed action within 30 days  
13 after the inspection.

14       “(C) If the Secretary determines that conditions exist  
15 that constitute a danger to health, the Secretary shall sus-  
16 pend the license, notify the licensee that the licensee’s license  
17 is suspended, and require notification of the suspension to  
18 any consignee. Within 30 days thereafter, the Secretary  
19 shall initiate the hearing process under subparagraph (A).

20       “(6) The requirements of paragraph (1) do not apply  
21 to a biological product for which there is in effect an inves-  
22 tigational new drug application under section 505(i) of the  
23 Federal Food, Drug, and Cosmetic Act.”.

1       (b) *DELETION OF ELA REQUIREMENT.*—Section  
 2   351(d) of the Public Health Service Act (42 U.S.C. 262(d))  
 3   is amended—

4           (1) by striking “(d)(1)” and all that follows  
 5   through “of this section.”;

6           (2) by redesignating paragraph (2)(A) as sub-  
 7   section (d)(1);

8           (3) by redesignating subparagraph (B) as para-  
 9   graph (2); and

10          (4) in paragraph (2) (as so redesignated), by  
 11   striking “subparagraph (A)” and inserting “para-  
 12   graph (1)”.

13       (c) *LABELING.*—Section 351(b) of the Public Health  
 14   Service Act (42 U.S.C. 262(b)) is amended to read as fol-  
 15   lows:

16       “(b) No person shall falsely label or mark any package  
 17   or container of any biological product or alter any label  
 18   or mark on the package so as to falsify the label or mark.”.

19       (d) *INSPECTION.*—Section 351(c) of the Public Health  
 20   Service Act (42 U.S.C. 262(c)) is amended by striking  
 21   “virus, serum,” and all that follows through “other product  
 22   aforesaid” and inserting “biological product”.

23       (e) *DEFINITION; APPLICATION.*—Section 351 of the  
 24   Public Health Service Act (42 U.S.C. 262) is amended by  
 25   adding at the end thereof the following new subsections:



1       “(i) *For purposes of this section, the term ‘biological*  
 2 *product’ means a virus, therapeutic serum, toxin, antitoxin,*  
 3 *vaccine, blood, blood component or derivative, allergenic*  
 4 *biologic product, or arsphenamine or its derivative (or any*  
 5 *other analogous biological product) applicable to the pre-*  
 6 *vention, treatment, or cure of diseases or conditions of*  
 7 *human beings.*

8       “(j)(1) *Sections 505(i), 903, and 904 of the Federal*  
 9 *Food, Drug, and Cosmetic Act shall apply to all biological*  
 10 *products, and references in such sections to new drug appli-*  
 11 *cations shall be deemed to include product license applica-*  
 12 *tions for biological products.*

13       “(2) *Requirements involving labeling or advertising*  
 14 *for biological products shall be established in accordance*  
 15 *with sections 201(m) and 502(n) of the Federal Food, Drug,*  
 16 *and Cosmetic Act.”.*

17 **SEC. 507. EFFECTIVE MEDICATION GUIDES.**

18       *Chapter IX (21 U.S.C. 391 et seq.), as amended by*  
 19 *section 108, is further amended by adding at the end thereof*  
 20 *the following new section:*

21 **“SEC. 908. EFFECTIVE MEDICATION GUIDES.**

22       “(a) *IN GENERAL.—Not later than 30 days after the*  
 23 *date of enactment of this section, the Secretary shall request*  
 24 *that national organizations representing health care profes-*  
 25 *sionals, consumer organizations, voluntary health agencies,*

1 *the pharmaceutical industry, drug wholesalers, patient*  
 2 *drug information database companies, and other relevant*  
 3 *parties collaborate to develop a long-range comprehensive*  
 4 *action plan to achieve goals consistent with the goals of the*  
 5 *proposed rule of the Food and Drug Administration on*  
 6 *‘Prescription Drug Product Labeling: Medication Guide*  
 7 *Requirements (60 Fed. Reg. 44182; relating to the provision*  
 8 *of oral and written prescription information to consumers).*

9       “(b) *PLAN.*—*The plan described in subsection (a)*  
 10 *shall—*

11               “(1) *identify the plan goals;*

12               “(2) *assess the effectiveness of the current pri-*  
 13 *vate-sector approaches used to provide oral and writ-*  
 14 *ten prescription information to consumers;*

15               “(3) *develop guidelines for providing effective*  
 16 *oral and written prescription information consistent*  
 17 *with the findings of any such assessment;*

18               “(4) *develop a mechanism to assess periodically*  
 19 *the quality of the oral and written prescription infor-*  
 20 *mation and the frequency with which the information*  
 21 *is provided to consumers; and*

22               “(5) *provide for compliance with relevant State*  
 23 *board regulations.*

24       “(c) *LIMITATION ON THE AUTHORITY OF THE SEC-*  
 25 *RETARY.*—*The Secretary shall have no authority to imple-*

1 ment the proposed rule described in subsection (a), or to  
 2 develop any similar regulation, policy statement, or other  
 3 guideline specifying a uniform content or format for writ-  
 4 ten information voluntarily provided to consumers about  
 5 prescription drugs if, not later than 120 days after the date  
 6 of enactment of this section, the national organizations de-  
 7 scribed in subsection (a) develop and begin to implement  
 8 a comprehensive, long-range action plan (as described in  
 9 subsection (a)) regarding the provision of oral and written  
 10 prescription information.

11 “(d) *SECRETARY REVIEW.*—Not later than January 1,  
 12 2001, the Secretary shall review the status of private-sector  
 13 initiatives designed to achieve the goals of the plan de-  
 14 scribed in subsection (a), and if such goals are not achieved,  
 15 the limitation in subsection (c) shall not apply, and the  
 16 Secretary shall seek public comment on other initiatives  
 17 that may be carried out to meet such goals. The Secretary  
 18 shall not delegate such review authority to the Commis-  
 19 sioner.”.

20 **SEC. 508. STATE AND LOCAL REQUIREMENTS RESPECTING**  
 21 **NONPRESCRIPTION DRUGS INTENDED FOR**  
 22 **HUMAN USE.**

23 Subchapter A of chapter V (21 U.S.C. 351 et seq.) is  
 24 amended by inserting after section 522 the following new  
 25 section:

1 **“SEC. 523. STATE AND LOCAL REQUIREMENTS RESPECTING**  
2 **NONPRESCRIPTION DRUGS INTENDED FOR**  
3 **HUMAN USE.**

4 “(a) *LIMITATION.*—

5 “(1) *IN GENERAL.*—*Except as provided in sub-*  
6 *section (b), no State or political subdivision thereof*  
7 *may establish or continue in effect any requirement—*

8 “(A) *that relates to the regulation of a drug*  
9 *intended for human use that is not subject to the*  
10 *requirements of section 503(b)(1); and*

11 “(B) *that is different from or in addition*  
12 *to, or that is otherwise not identical with, a re-*  
13 *quirement of this Act or the Fair Packaging and*  
14 *Labeling Act (15 U.S.C. 1451 et seq.), and the*  
15 *administrative implementation of such Act.*

16 “(2) *SPECIAL RULE.*—*For purposes of this sec-*  
17 *tion, a requirement relating to the regulation of a*  
18 *drug described in paragraph (1) shall be deemed to*  
19 *include any requirement relating to the subject matter*  
20 *in any provision of this Act, the Fair Packaging and*  
21 *Labeling Act (15 U.S.C. 1451 et seq.), and any re-*  
22 *quirement relating to the dissemination of informa-*  
23 *tion in any manner about such drug, but shall not*  
24 *include any requirement relating to the dispensing of*  
25 *a drug only upon prescription of a practitioner li-*  
26 *censed by law to administer such drug.*

1       “(b) *EXEMPTION.*—Upon application of a State, the  
 2       Secretary may by regulation, after providing notice and an  
 3       opportunity for written and oral presentation of views, ex-  
 4       empt from the provisions of subsection (a), under such con-  
 5       ditions as the Secretary may impose, a proposed require-  
 6       ment relating to the regulation of a drug intended for  
 7       human use—

8               “(1) that is justified by compelling local condi-  
 9       tions or protects an important public interest that  
 10       would otherwise be unprotected;

11              “(2) that would not cause any drug intended for  
 12       human use that is not subject to the requirements of  
 13       section 503(b)(1) to be in violation of any applicable  
 14       requirement or prohibition under Federal law; and

15              “(3) that would not unduly burden interstate  
 16       commerce.”.

17   **SEC. 509. REQUIREMENT OF RADIOPHARMACEUTICALS.**

18       (a) *REQUIREMENTS.*—

19              (1) *REGULATIONS.*—Not later than 180 days  
 20       after the date of enactment of this Act, the Secretary  
 21       of Health and Human Services, after consultation  
 22       with patient advocacy groups, associations, physi-  
 23       cians licensed to use radiopharmaceuticals, and the  
 24       regulated industry, shall establish proposed regula-  
 25       tions governing the approval of a

1        *radiopharmaceutical designed for diagnosis and mon-*  
2        *itoring that shall assess the safety and effectiveness of*  
3        *the radiopharmaceutical taking into account the ap-*  
4        *propriate use of the radiopharmaceutical in the prac-*  
5        *tice of medicine, the pharmacological and toxi-*  
6        *cological activity of the radiopharmaceutical, and the*  
7        *estimated absorbed radiation dose of the*  
8        *radiopharmaceutical. Not later than 1 year after the*  
9        *date of enactment of this Act, the Secretary shall issue*  
10       *final regulations.*

11            (2) *SPECIAL RULE.—In the case of a*  
12        *radiopharmaceutical intended to be used for diag-*  
13        *nostic purposes, the indications for which such*  
14        *radiopharmaceutical is approved under this section*  
15        *may refer to manifestations of disease (such as bio-*  
16        *chemical, physiological, anatomic, or pathological*  
17        *processes) common to or present in 1 or more disease*  
18        *states, or may refer to a diagnostic procedure used in*  
19        *the diagnosis of 1 or more diseases or conditions.*

20            (b) *APPROVAL.—All applications or petitions request-*  
21        *ing approval of a radiopharmaceutical and all other mat-*  
22        *ters relating to such radiopharmaceutical shall be reviewed*  
23        *and acted upon by a single office in the Center for Drug*  
24        *Evaluation and Research, and that office shall report di-*  
25        *rectly to the director of the Center for Drug Evaluation and*

1 *Research. A single scientific review group may provide con-*  
2 *clusions and recommendations regarding any such matter*  
3 *relating to the approval of a radiopharmaceutical. Such*  
4 *group shall be appointed and administered pursuant to sec-*  
5 *tion 904 of the Federal Food, Drug, and Cosmetic Act (21*  
6 *U.S.C. 394), as amended by section 107.*

7 (c) *DEFINITION.—As used in this section, the term*  
8 *“radiopharmaceutical” means—*

9 (1) *an article that is intended for use in vivo in*  
10 *the diagnosis, cure, mitigation, treatment, or preven-*  
11 *tion of a disease or a manifestation of disease in*  
12 *man, and that exerts its primary effect by the sponta-*  
13 *neous disintegration of unstable nuclei with the emis-*  
14 *sion of ionizing radiation; or*

15 (2) *a reagent kit or nuclide generator that is in-*  
16 *tended to be used in the preparation of any such arti-*  
17 *cle.*

18 (d) *APPROVAL ASSESSED UNDER PERFORMANCE*  
19 *STANDARDS.—The approval of radiopharmaceuticals shall*  
20 *be assessed under quantifiable performance standards estab-*  
21 *lished by the Secretary under section 903(b)(3) of the Fed-*  
22 *eral Food, Drug, and Cosmetic Act, as added by section 103.*

1   ***TITLE VI—DEVICE REGULATORY***  
 2                   ***REFORM***

3   ***SEC. 601. SHORT TITLE.***

4           *This title may be cited as the “Medical Device Reform*  
 5 *Act of 1996”.*

6   ***SEC. 602. PREMARKET NOTIFICATION.***

7           *(a) EXEMPTION OF CERTAIN DEVICES.—Section 510*  
 8 *(21 U.S.C. 360) is amended—*

9                   *(1) in subsection (k), by striking “intended for*  
 10 *human use” and inserting “intended for human use*  
 11 *(except a device that is classified into class I under*  
 12 *section 513 or 520 and is not identified in a list*  
 13 *under subsection (n), or a device that is classified into*  
 14 *class II under section 513 or 520 and is exempt from*  
 15 *the requirements of this subsection under subsection*  
 16 *(l))”;*

17                   *(2) by adding at the end of subsection (k) the fol-*  
 18 *lowing flush sentence:*

19 *“The Secretary shall review the notification required by this*  
 20 *subsection and make a determination under section*  
 21 *513(f)(1)(A) within 90 days of receiving the notification.”;*  
 22 *and*

23                   *(3) by adding at the end thereof the following*  
 24 *new subsections:*



1       “(l) Not later than 30 days after the date of enactment  
2 of this subsection, the Secretary shall publish in the Federal  
3 Register a list of each type of class II device that does not  
4 require a notification under subsection (k) to provide rea-  
5 sonable assurance of safety and effectiveness. Each type of  
6 class II device so identified by the Secretary not to require  
7 the notification shall be exempt from the requirement to  
8 provide notification under subsection (k) as of the date of  
9 the publication of the list in the Federal Register. Begin-  
10 ning on the date that is 1 day after the date of the publica-  
11 tion of a list under this subsection, any person may petition  
12 the Secretary to exempt a type of class II device from the  
13 notification requirement of subsection (k). The Secretary  
14 shall respond to the petition within 120 days of the receipt  
15 of the petition and determine whether or not to grant the  
16 petition in whole or in part.

17       “(m) The Secretary may not withhold a determination  
18 of the initial classification of a device under section  
19 513(f)(1) because of a failure to comply with any provision  
20 of this Act unrelated to a substantial equivalence decision,  
21 including a failure to comply with good manufacturing  
22 practices under section 520(f).

23       “(n) Not later than 15 days after the date of enactment  
24 of this subsection, the Secretary shall publish in the Federal  
25 Register a list of each type of class I device that shall not

1 *be considered exempt from the notification requirement of*  
 2 *section 510(k) because such notification is necessary to pro-*  
 3 *tect the public health. If the Secretary fails to publish the*  
 4 *list within 15 days after the date of enactment of this sub-*  
 5 *section, all types of class I devices shall be exempt from the*  
 6 *requirement to provide notification under section 510(k).”.*

7       **(b) INITIAL CLASSIFICATION.**—Section 513(f)(1) (21  
 8 *U.S.C. 360c(f)(1)) is amended in the second sentence, by*  
 9 *striking the period at the end thereof and inserting the fol-*  
 10 *lowing: “, unless within 30 days of receiving an order*  
 11 *classifying the device into class III, the individual who sub-*  
 12 *mits a notification under section 510(k) requests an advi-*  
 13 *sory committee review and recommendation with respect to*  
 14 *the classification of the device and a final order of classi-*  
 15 *fication from the Secretary. After the request, a device clas-*  
 16 *sified into class III under this paragraph shall not be*  
 17 *deemed to be finally classified until an advisory committee*  
 18 *established under subsection (b) reviews the request with re-*  
 19 *spect to the classification of the device and, within 60 days*  
 20 *of the date of receiving the request, recommends to the Sec-*  
 21 *retary a classification for the device based on the classifica-*  
 22 *tion criteria set forth in subparagraphs (A) through (C) of*  
 23 *subsection(a)(1). Thereafter, the Secretary shall have 10*  
 24 *days after the date of receiving the recommendation of the*  
 25 *advisory committee to determine by order the final classi-*

1 *fication of the device by applying the classification criteria*  
 2 *set forth in subparagraphs (A) through (C) of*  
 3 *subsection(a)(1).”.*

4       (c)       *SUBSTANTIAL       EQUIVALENCE.—Section*  
 5 *513(i)(1)(A) (21 U.S.C. 360c(i)(1)(A)) is amended by in-*  
 6 *serting after “intended use” the following: “, which, as de-*  
 7 *termined by the Secretary, shall include each use reasonably*  
 8 *included within a general use,”.*

9       (d)       *DEVICE MODIFICATION.—Section 513(i) (21*  
 10 *U.S.C. 360c(i)) is amended by adding at the end thereof*  
 11 *the following new paragraph:*

12       “(4)(A) *Any change or modification to a device ini-*  
 13 *tially classified under section 513(f), other than a major*  
 14 *change (including any major modification) in the intended*  
 15 *use or a change or modification in design that is significant*  
 16 *and significantly affects safety or effectiveness, shall not re-*  
 17 *quire an additional notification under section 510(k) if,*  
 18 *prior to the commercial distribution of the device—*

19               *“(i) the change or modification is supported by*  
 20 *appropriate data or information, (including data or*  
 21 *information demonstrating compliance with good*  
 22 *manufacturing practice regulations promulgated*  
 23 *under section 520(f)); and*

1           “(ii) the change or modification is shown by  
2           such data or information to not adversely affect the  
3           safety or effectiveness of the device.

4           “(B) All data or information relied upon to document  
5           that a change to (including any modification of) the device  
6           does not require an additional notification under section  
7           510(k) shall be made available to the Secretary upon request  
8           and shall be maintained, at least for a period of time equal  
9           to the expected life of the device or 2 years after the date  
10          of commercial distribution of the device by the manufac-  
11          turer, whichever is greater.”.

12   **SEC. 603. MEDICAL DEVICE APPROVAL STANDARDS.**

13          (a) *DEVICE CLASSES*.—Section 513(a)(3)(A) (21  
14   U.S.C. 360c(a)(3)(A)) is amended—

15               (1) by striking “well-controlled” and inserting  
16               “one or more well-controlled”; and

17               (2) by striking “clinical investigations” and in-  
18               serting “one or more clinical investigations”.

19          (b) *SUPPLEMENT TO APPLICATION*.—Section 513(a)(3)  
20   (21 U.S.C. 360c(a)(3)) is amended by adding at the end  
21   thereof the following new subparagraphs:

22               “(C) The Secretary shall accept, for the purpose of fa-  
23               cilitating a review of a premarket application, a supple-  
24               ment to a premarket application, or a premarket notifica-  
25               tion of a device, retrospective or historical clinical data as

1 a control, or for use, in determining whether there is a rea-  
 2 sonable assurance of effectiveness of a device if sufficient  
 3 valid data are available and the effects of the device on the  
 4 cure, mitigation, treatment, or prevention of a disease are  
 5 clearly defined and well understood.

6 “(D) The Secretary may not require a person intend-  
 7 ing to conduct clinical trials to conduct clinical trials using  
 8 prospective concurrent controls in determining whether  
 9 there is a reasonable assurance of effectiveness for a device  
 10 or whether a device is substantially equivalent to a predi-  
 11 cate device unless—

12 “(i) the effects of the device on the cure, mitiga-  
 13 tion, treatment, or prevention of a disease or condi-  
 14 tion are not clearly defined and well understood as  
 15 determined by the Secretary;

16 “(ii) retrospective or historical data are not  
 17 available that meet the standards of the Secretary for  
 18 quality and completeness; or

19 “(iii) there is a compelling public health reason  
 20 to not rely on retrospective or historical data as a  
 21 control.”.

22 **SEC. 604. TRACKING.**

23 Section 519(e) (21 U.S.C. 360i(e)) is amended to read  
 24 as follows:

1                                   *“Device Tracking*

2                   *“(e) The Secretary may by regulation require a manu-*  
 3 *facturer to adopt a method of tracking a class II or class*  
 4 *III device—*

5                           *“(1) the failure of which would be reasonably*  
 6 *likely to be life-threatening or have serious adverse*  
 7 *health consequences; and*

8                           *“(2) which is—*

9                                   *“(A) permanently implantable; or*

10                                   *“(B) life sustaining or life supporting and*  
 11 *used outside a device user facility.*

12 *Any patient receiving a device subject to tracking under*  
 13 *this section may refuse to release, or refuse permission to*  
 14 *release, the patient’s name, address, social security number,*  
 15 *or other identifying information for the purpose of track-*  
 16 *ing.”.*

17 **SEC. 605. POSTMARKET SURVEILLANCE.**

18           *Section 522 (21 U.S.C. 360l) is amended to read as*  
 19 *follows:*

20 **“SEC. 522. POSTMARKET SURVEILLANCE.**

21           *“(a) IN GENERAL.—The Secretary may require a*  
 22 *manufacturer to conduct postmarket surveillance for any*  
 23 *device of the manufacturer that—*

1           “(1) is a permanent implant the failure of which  
2           may cause serious, adverse health consequences or  
3           death;

4           “(2) is intended for a use in supporting or sus-  
5           taining human life; or

6           “(3) potentially presents a serious risk to human  
7           health or creates public health concerns that justify  
8           surveillance under this section.

9           “(b) *SURVEILLANCE APPROVAL.*—Each manufacturer  
10          required to conduct a surveillance of a device under sub-  
11          section (a) shall, within 30 days of receiving notice from  
12          the Secretary that the manufacturer is required under this  
13          section to conduct the surveillance, submit for the approval  
14          of the Secretary, a protocol for the required surveillance.  
15          The Secretary, within 60 days of the date of the receipt  
16          of the protocol, shall determine if the principal investigator  
17          proposed to be used in the surveillance has sufficient quali-  
18          fications and experience to conduct the surveillance and if  
19          the protocol will result in collection of useful data or other  
20          information necessary to protect the public health and to  
21          provide safety and effectiveness information for the device.  
22          The Secretary may not approve the protocol until the proto-  
23          col has been reviewed by a qualified scientific and technical  
24          review committee established by the Secretary.”.

1 **SEC. 606. DEVICE DISTRIBUTOR REPORTING.**

2 *Section 519 (21 U.S.C. 360i) is amended—*

3 *(1) by striking “, importer, or distributor” each*  
 4 *place it appears and inserting “or importer”;*

5 *(2) in subsection (a)—*

6 *(A) in paragraph (7), by striking the semi-*  
 7 *colon at the end thereof and inserting “; and”;*

8 *(B) in paragraph (8), by striking “; and”*  
 9 *and inserting a period; and*

10 *(C) by striking paragraph (9); and*

11 *(3) in subsection (d), by striking “, importer,*  
 12 *and distributor” and inserting “and importer”.*

13 **SEC. 607. PREMARKET APPROVAL.**

14 *(a) ACTION ON APPLICATION.—Section 515(d) (21*  
 15 *U.S.C. 360e(d)) is amended—*

16 *(1) in paragraph (1)(A), by striking “paragraph*  
 17 *(2) of this subsection” each place it appears and in-*  
 18 *serting “paragraph (4)”;*

19 *(2) in paragraph (1)(B), by adding at the end*  
 20 *thereof the following new clause:*

21 *“(iii) The Secretary shall accept and review data and*  
 22 *any other information from investigations conducted under*  
 23 *the authority of regulations required by section 520(g) to*  
 24 *make a determination of whether there is a reasonable as-*  
 25 *surance of safety and effectiveness of a device subject to a*  
 26 *pending application under this section if—*



1           “(I) the data or information is derived from in-  
2           vestigations of an earlier version of the device, the de-  
3           vice has been modified during or after the investiga-  
4           tions, and the modification of the device does not con-  
5           stitute a significant change in the design or in the  
6           basic principles of operation of the device that would  
7           invalidate the data or information; or

8           “(II) the data or information on a device ap-  
9           proved under this section is available for use under  
10          this Act and is relevant to the design and intended  
11          use of the device subject to the pending application.”;

12          (3) by redesignating paragraphs (2) and (3) as  
13          paragraphs (4) and (5), respectively; and

14          (4) by inserting after paragraph (1) the follow-  
15          ing new paragraphs:

16          “(2) Each application received under section 515(c)  
17          shall be reviewed in the following manner to achieve final  
18          action on the application within 180 days of the receipt  
19          of the application:

20                 “(A) The Secretary shall meet with an applicant  
21                 within 90 days of the receipt of the application to  
22                 discuss the review status of the application. If the ap-  
23                 plication does not appear in a form that would re-  
24                 quire an approval under this subsection, the Sec-  
25                 retary shall in writing, and prior to the meeting,

1     *present to the applicant a description of any defi-*  
2     *ciencies in the application and what information is*  
3     *required to bring the application into a form that*  
4     *would require an approval.*

5             *“(B) The Secretary shall refer an application to*  
6     *a panel established under section 513 for review and*  
7     *an approval recommendation (unless a panel is not*  
8     *required under subsection (c)(2)) within 30 days of*  
9     *the date of the meeting referred to in subparagraph*  
10    *(A) or at the next scheduled panel meeting following*  
11    *the meeting referred to in subparagraph (A), which-*  
12    *ever occurs first.*

13            *“(C) The Secretary shall meet with the applicant*  
14    *within 15 days of the date of the panel review to dis-*  
15    *cuss the status of the application, including a discus-*  
16    *sion on what action is necessary to bring the applica-*  
17    *tion into a form that would require approval under*  
18    *this subsection. Prior to the meeting, the Secretary*  
19    *shall in writing, set forth an agenda for the meeting*  
20    *(including a complete description of the subject mat-*  
21    *ter to be discussed at the meeting), and a full descrip-*  
22    *tion of the additional information required to bring*  
23    *the application into a form that would require an ap-*  
24    *proval under this subsection. Participation of the ap-*

1     *plicant at such a meeting shall be at the discretion*  
2     *of the applicant.*

3             *“(D) The Secretary shall meet with the applicant*  
4     *not later than 135 days after the receipt of an appli-*  
5     *cation under subsection (c), if an advisory panel is*  
6     *not required under subsection (c)(2), and inform the*  
7     *applicant whether or not the application is in a form*  
8     *that would require approval under this subsection. If*  
9     *the application is in such form, the Secretary shall,*  
10    *at or prior to the meeting, present in writing to the*  
11    *applicant a description of all additional information*  
12    *necessary to require an approval of the application*  
13    *under this subsection. If the application is not in*  
14    *such form, the Secretary shall deny approval of the*  
15    *application and prior to the meeting, present in writ-*  
16    *ing to the applicant each basis for denying approval*  
17    *of the application and the additional information re-*  
18    *quired to bring the application into a form that*  
19    *would require approval.*

20            *“(E) The Secretary shall issue an order approv-*  
21    *ing or denying an application within 180 days of the*  
22    *receipt of the application under subsection (c).*

23            *“(3) The time for the review of an application by the*  
24    *Secretary under this subsection shall not take more than*

1 180 days and such time may not be extended if the applica-  
2 tion is amended.”.

3 (b) *REVISIONS OF REGULATIONS.*—

4 (1) *PREMARKET APPROVAL OF APPLICATIONS.*—

5 *The Secretary of Health and Human Services shall*  
6 *revise, through notice and comment procedures, the*  
7 *regulations set forth in part 814 of title 21 of the*  
8 *Code of Federal Regulations, to conform to the*  
9 *amendment made by subsection (a).*

10 (2) *PREMARKET APPROVAL OF SUPPLEMENTS.*—

11 *The Secretary of Health and Human Services shall*  
12 *revise regulations relating to premarket approval of*  
13 *devices to eliminate premarket approval of supple-*  
14 *ments that relate to manufacturing or product*  
15 *changes (excluding changes in intended use) of a de-*  
16 *vice that have been demonstrated through appropriate*  
17 *data or information to not adversely affect safety or*  
18 *effectiveness. The Secretary of Health and Human*  
19 *Services shall require the manufacturer of a device to*  
20 *notify the Secretary of Health and Human Services*  
21 *of significant manufacturing changes or other changes*  
22 *not subject to a supplement under section 515 within*  
23 *10 days of implementing such changes. All informa-*  
24 *tion relied upon in making such changes shall be*  
25 *made a part of the device master record. The informa-*

7           (a) *ALTERNATIVE PROCEDURE.*—Section 514 (21  
8 *U.S.C. 360d)* is amended by adding at the end thereof the  
9 *following new subsection:*

“(c)(1) For the purpose of facilitating a review of a device under section 510(k), 513(f), 515, or 520, the Secretary shall recognize appropriate device performance standards developed by any standard-setting organization accredited by the American National Standards Institute (ANSI), the International Standards Organization (ISO), or the International Electrotechnical Commission (IEC).

19 “(2)(A) For any standard-setting organization not  
20 identified in paragraph (1), and for the purpose of facilitat-  
21 ing a review of devices under section 510(k), 513(f), 515,  
22 or 520, the Secretary shall establish a procedure governing  
23 the certification by the Food and Drug Administration of  
24 the competence of such an organization to develop standards  
25 for devices.

1       “(B) A certification of a standard-setting organization  
2 not identified in paragraph (1) shall be based on formal,  
3 written criteria that include requirements with respect to  
4 the role of the organization in the scientific community, sci-  
5 entific or medical expertise, standard-writing experience,  
6 conflict of interest considerations, and the openness of the  
7 standard-setting process of the organization.

8       “(C) The Secretary may impose a reasonable one-time  
9 fee on the standard-setting organization for certification  
10 pursuant to this paragraph.

11       “(3)(A) Upon being notified by a standard-setting or-  
12 ganization described in paragraph (1) that a standard has  
13 been adopted by the organization, the Secretary shall recog-  
14 nize the standard by publishing a notice in the Federal Reg-  
15 ister listing the name of the standard.

16       “(B) Upon being notified by a standard-setting orga-  
17 nization certified under paragraph (2) that a standard has  
18 been adopted by the organization, the Secretary shall review  
19 and may recognize the standard by publishing a notice in  
20 the Federal Register listing the name of the standard.

21       “(4) The Secretary may withdraw recognition of a  
22 performance standard adopted by a standard-setting orga-  
23 nization described in paragraph (1) or a standard-setting  
24 organization certified under paragraph (2) if the Secretary  
25 determines that the standard is insufficient to facilitate a

1 review of a device. The Secretary shall notify the standard-  
2 setting organization and specify the basis for the with-  
3 drawal.

4 “(5) The Secretary shall promulgate regulations under  
5 which the Secretary may withdraw the certification of a  
6 standard-setting organization described in paragraph (2),  
7 or may no longer rely upon standards adopted by a stand-  
8 ard-setting organization described in paragraph (1), if the  
9 Secretary determines that such organization no longer pos-  
10 sesses the appropriate scientific or medical expertise, con-  
11 flict of interest practices, standard-writing experience, or  
12 any other qualification necessary to the development of de-  
13 vice standards.

14 “(6) As provided for in this section, the Secretary may  
15 promulgate performance standards for a device that differs  
16 from or is not established by, an organization described in  
17 paragraph (1) or an organization certified under para-  
18 graph (2).

19 “(7) The Secretary shall not require, as a condition  
20 for approving an application under section 515 or 520 or  
21 classifying a device under sections 510(k) and 513(f), con-  
22 formity with a device standard recognized under this sub-  
23 section if the person requesting such approval or classifica-  
24 tion submits evidence to demonstrate a reasonable assur-  
25 ance that the device is substantially equivalent to a legally

1 *marketed predicate device or provides reasonable assurance*  
2 *that the device is safe and effective.*

3 “(8) *A performance standard recognized pursuant to*  
4 *this subsection for a device—*

5 “(A) *shall include provisions to provide reason-*  
6 *able assurance of the safe and effective performance of*  
7 *the device;*

8 “(B) *shall, where necessary to provide reasonable*  
9 *assurances of the safe and effective performance of the*  
10 *device, include—*

11 “(i) *provisions with respect to the construc-*  
12 *tion, components, ingredients, and properties of*  
13 *the device and the compatibility of the device*  
14 *with power systems and connections to the sys-*  
15 *tems;*

16 “(ii) *provisions for the testing (on a sample*  
17 *basis or, if necessary, on an individual basis) of*  
18 *the device or, if it is determined that no other*  
19 *more practicable means are available to the Sec-*  
20 *retary to assure the conformity of a device to the*  
21 *standard, provisions for the testing (on a sample*  
22 *basis or, if necessary, on an individual basis) of*  
23 *the device by the Secretary or by another person*  
24 *at the direction of the Secretary;*



1           “(iii) provisions for the measurement of the  
2           performance characteristics of the device; and

3           “(iv) provisions requiring that the results of  
4           each or certain of the tests of the device required  
5           to be made under clause (ii) demonstrate that the  
6           device is in conformity with those portions of the  
7           standard for which the test or tests were re-  
8           quired; and

9           “(C) shall, where appropriate, require the proce-  
10          dures, for the proper installation, maintenance, oper-  
11          ation, and use of the device.

12          “(9) The Secretary shall accept a certification by a  
13          person who has made a submission pursuant to section  
14          510(k), 515, or 520 that the device conforms with each  
15          standard identified in the certification. The Secretary may,  
16          where appropriate, require data demonstrating conformity  
17          with a standard recognized under this subsection.

18          “(10) The Secretary shall require a person who makes  
19          a certification under paragraph (9) that a device conforms  
20          to an applicable performance standard recognized under  
21          this subsection or who makes a certification that a device  
22          conforms to a standard established under subsection (a) or  
23          (b) to maintain data demonstrating conformity of the de-  
24          vice to the standard for a period of time equal to the period  
25          of time for the design and expected life of the device. Such

1 *data shall be made available to the Secretary upon re-*  
 2 *quest.”.*

3 (b) *ADULTERATED DEVICE.*—Section 501(e) (21  
 4 *U.S.C. 351(e)) is amended—*

5 (1) *by striking “(e)” and inserting “(e)(1)”;*

6 (2) *by striking “section 514” and inserting “sec-*  
 7 *tion 514(b)”;* and

8 (3) *by inserting at the end thereof the following:*

9 “(2) *If it is, or purports to be or is represented as,*  
 10 *a device which is certified to be in compliance with any*  
 11 *voluntary standard recognized under section 514(c), unless*  
 12 *such a device is in all respects in conformity with such a*  
 13 *standard.”.*

14 **SEC. 609. ACCREDITED-PARTY PARTICIPATION.**

15 *Subchapter A of chapter V (21 U.S.C. 351 et seq.), as*  
 16 *amended by section 508, is further amended by adding at*  
 17 *the end the following new section:*

18 **“SEC. 523A. ACCREDITED-PARTY PARTICIPATION.**

19 “(a) *IN GENERAL.*—*Not later than 1 year after the*  
 20 *date of enactment of this section, the Secretary shall ac-*  
 21 *credit persons, including any entity or any individual who*  
 22 *is not an employee of the Department to review and ini-*  
 23 *tially classify devices under section 513(f)(1) that are sub-*  
 24 *ject to a report under section 510(k) and to review and rec-*

1 *commend to the Secretary approval or denial of applications*  
2 *submitted under section 515(c)(1).*

3       “(b) *ACCREDITATION.*—*Not later than 6 months after*  
4 *the date of enactment of this section, the Secretary shall*  
5 *establish and publish in the Federal Register requirements*  
6 *to accredit or deny accreditation to a person who makes*  
7 *a request for accreditation to carry out the activities de-*  
8 *scribed in subsection (a). The requirements shall, at a mini-*  
9 *imum, advise such person how to become accredited, and set*  
10 *forth criteria for accreditation including criteria to avoid*  
11 *conflicts of interest and to ensure that persons to be accred-*  
12 *ited are capable of maintaining the confidentiality of sub-*  
13 *missions consistent with section 552 of title 5, United States*  
14 *Code, and the regulations of the Food and Drug Adminis-*  
15 *tration. The Secretary shall respond to a request for accred-*  
16 *itation not later than 60 days after the receipt of the re-*  
17 *quest. The accreditation of a person shall specify the activi-*  
18 *ties under subsection (a) which such person is authorized*  
19 *to carry out in the place of the Secretary.*

20       “(c) *WITHDRAWAL OF ACCREDITATION.*—*The Sec-*  
21 *retary may suspend or withdraw the accreditation of any*  
22 *person accredited under this section, after providing notice*  
23 *and an opportunity for an informal hearing, if such person*  
24 *acts in a manner that is substantially inconsistent with the*  
25 *purposes of this section, including the failure to avoid con-*

1 *flicts of interest, the failure to protect confidentiality of in-*  
 2 *formation, or the failure to competently review premarket*  
 3 *submissions for devices.*

4       “(d) *SELECTION AND COMPENSATION.*—A person who  
 5 *submits a premarket submission for a device to the Sec-*  
 6 *retary for review and classification, or approval of a device,*  
 7 *shall have the option to select an accredited person to review*  
 8 *such submission. The Secretary shall identify for the person*  
 9 *no less than 2 accredited persons from whom the selection*  
 10 *may be made. Compensation for an accredited person shall*  
 11 *be determined by agreement between the accredited person*  
 12 *and the person who engages the services of the accredited*  
 13 *person.*

14       “(e) *REVIEW BY SECRETARY.*—

15               “(1) *IN GENERAL.*—If a person exercises the op-  
 16 *tion to obtain review of a premarket submission that*  
 17 *is an application or a notification by an accredited*  
 18 *person, the Secretary shall complete a filing review*  
 19 *for a premarket approval application under section*  
 20 *515(c)(1) not later than 30 days after the receipt of*  
 21 *such application, or shall ensure the completeness of*  
 22 *a premarket notification submission under section*  
 23 *510(k) not later than 15 days after the receipt of such*  
 24 *submission, prior to referring the premarket submis-*

1       sion for review by the accredited person selected by  
2       the person submitting the premarket submission.

3               “(2) *REPORT ON CLASSIFICATION, APPROVAL, OR*  
4       *DENIAL.*—The Secretary shall require an accredited  
5       person, upon recommending a classification of a de-  
6       vice or approval or disapproval of an application for  
7       a device, to report to the Secretary the reasons of the  
8       accredited person for such classification or approval  
9       or disapproval. For devices reviewed and initially  
10      classified under section 513(f)(1) and subject to a re-  
11      port under section 510(k), the Secretary shall have  
12      not more than 15 days to review the submission. For  
13      applications submitted under section 515(c)(1), the  
14      Secretary shall have not more than 45 days to review  
15      the application. The Secretary may change the classi-  
16      fication under section 513(f)(1), or the approval or  
17      disapproval of the application under section 515(d),  
18      that is recommended by the accredited person, and in  
19      such case shall notify the person making the submis-  
20      sion of the detailed reasons for the change.

21           “(f) *DURATION.*—This section shall remain in force for  
22      a period of 3 years from the date on which the Secretary  
23      accredits the first person to conduct initial classifications  
24      under section 513(f)(1) and to conduct premarket approval  
25      reviews under section 515.

1 “(g) *REPORTS.*—

2 “(1) *IMPLEMENTATION OF ACCREDITATION PROC-*  
 3 *ESS.*—*Not later than 1 year after the date of enact-*  
 4 *ment of this section, the Secretary shall prepare and*  
 5 *submit to the committees of Congress with oversight*  
 6 *authority over the Food and Drug Administration a*  
 7 *report concerning each action the Secretary has taken*  
 8 *to implement the accreditation of persons to under-*  
 9 *take the activities described in subsection (a).*

10 “(2) *EXAMINATION OF THE USE OF ACCREDITED*  
 11 *PERSONS.*—

12 “(A) *IN GENERAL.*—*Not later than 2 years*  
 13 *after the date on which the Secretary accredits*  
 14 *the first person to conduct initial classifications*  
 15 *under section 513(f)(1) and to conduct pre-*  
 16 *market approval reviews under section 515, the*  
 17 *Secretary shall contract with an independent re-*  
 18 *search organization to prepare and submit to the*  
 19 *Secretary a written report examining the use of*  
 20 *accredited persons under this section. The Sec-*  
 21 *retary shall submit the report to the committees*  
 22 *described in paragraph (1) not later than 30*  
 23 *months after the date on which the Secretary ac-*  
 24 *credits the first person to conduct initial classi-*

fications under section 513(f)(1) and to conduct  
premarket approval reviews under section 515.

“(B) CONTENTS.—The report by the independent research organization described in subparagraph (A) shall identify the benefits or detriments to public and patient health of using accredited persons to conduct such reviews, and shall summarize all relevant data, including data on the review of accredited persons (including review times, recommendations, and compensation), and data on the review of the Secretary (including review times, changes, and reasons for changes).”.

## **TITLE VII—ANIMAL DRUG REGULATORY REFORM**

### **SEC. 701. SHORT TITLE.**

This title may be cited as the “Animal Drug Regulatory Reform Act of 1996”.

### **SEC. 702. EVIDENCE OF EFFECTIVENESS.**

(a) SUBSTANTIAL EVIDENCE.—Section 512(d) (21 U.S.C. 360b(d)) is amended—

(1) by striking paragraph (3); and

(2) by adding at the end thereof the following

new paragraph:

1       “(4)(A) *As used in this subsection and subsections*  
 2 *(c)(2)(F)(iii) and (e)(1)(C), the term ‘substantial evidence’*  
 3 *means evidence from 1 or more scientifically sound studies,*  
 4 *including as appropriate in vitro studies, studies in labora-*  
 5 *tory animals (including a target species), bioequivalence*  
 6 *studies, and any studies voluntarily undertaken by or for*  
 7 *the applicant, that taken together provide reasonable assur-*  
 8 *ance that the drug will have the claimed or intended effect*  
 9 *of the drug.*

10       “(B) *For purposes of subparagraph (A), a study shall*  
 11 *be considered to be scientifically sound if the study is de-*  
 12 *signed and conducted in a manner that is consistent with*  
 13 *generally recognized scientific procedures and principles.”.*

14       (b) *COMBINATION OF DRUGS.—Section 512(d) (21*  
 15 *U.S.C. 360b(d)) is amended by inserting before paragraph*  
 16 *(4) (as added by subsection (a)) the following new para-*  
 17 *graph:*

18       “(3) *In a case in which a new animal drug contains*  
 19 *more than 1 active ingredient, or the labeling of the drug*  
 20 *prescribes, recommends, or suggests use of the drug in com-*  
 21 *bination with another animal drug, and the active ingredi-*  
 22 *ents or drugs in the combination have been separately ap-*  
 23 *proved for particular uses and species prior to the approval*  
 24 *of the application for the same uses and species in combina-*  
 25 *tion (or, in the absence of such approvals, after evaluating*



1 *the safety and efficacy of the combination itself), the Sec-*  
 2 *retary may only consider with respect to the combination*  
 3 *whether any of the active ingredients or any of the drugs*  
 4 *in the combination, respectively, at the longest withdrawal*  
 5 *time of any of the active ingredients or drugs in the com-*  
 6 *bination, respectively—*

7           “(A) is above its safe concentration (such as ex-  
 8           ceeding its established tolerance, as measured by its  
 9           marker residue); or

10           “(B) interferes with the methods of analysis for  
 11           another of the active ingredients or drugs in the com-  
 12           bination, respectively.”.

13       (c)       *SUPPLEMENTAL       APPLICATIONS.—Section*  
 14 *512(c)(2)(F)(iii) (21 U.S.C. 360b(c)(2)(F)(iii)) is amend-*  
 15 *ed—*

16           (1) by striking “reports of new clinical or field  
 17           investigations (other than bioequivalence or residue  
 18           studies) and” and inserting “substantial evidence of  
 19           effectiveness as defined in subsection (d)(4), any study  
 20           of animal safety, or”; and

21           (2) by striking “essential to” and inserting “, re-  
 22           quired for”.

23       (d) *MINOR SPECIES AND USES.—Section 512(d)(1)*  
 24 *(21 U.S.C. 360b(d)(1)) is amended by adding at the end*  
 25 *the following new sentence: “Subparagraph (E) shall not*

1 *apply to a claim for use of the drug described in subpara-*  
 2 *graph (E) in a minor species, or for a minor use of the*  
 3 *drug, as the terms ‘minor species’ and ‘minor use’ are de-*  
 4 *fin ed in regulations issued by the Secretary, if there is an*  
 5 *application filed under subsection (b) for the drug, and the*  
 6 *application is approved, prior to the submission of the*  
 7 *claim.”.*

8       (e)       WITHDRAWAL       OF       APPROVAL.—Section  
 9 512(e)(1)(C) (21 U.S.C. 360b(e)(1)(C)) is amended by in-  
 10 serting after “substantial evidence” the following: “(as de-  
 11 fin ed in subsection (d)(4))”.

12       (f) IMPLEMENTATION.—

13               (1) IN GENERAL.—Not later than 6 months after  
 14 the date of enactment of this Act, the Secretary shall  
 15 issue proposed regulations implementing the amend-  
 16 ments made by this section. Not later than 18 months  
 17 after the date of enactment of this Act, the Secretary  
 18 shall issue final regulations implementing the amend-  
 19 ments.

20               (2) CONTENTS.—In issuing regulations imple-  
 21 menting the amendments made by this section, and in  
 22 taking an action to review an application for ap-  
 23 proval of a new animal drug under section 512 of the  
 24 Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
 25 360b), or a request for an investigational exemption

1     *for a new animal drug under subsection (j) of such*  
2     *section, that is pending or has been submitted prior*  
3     *to the effective date of the regulations, the Secretary*  
4     *shall—*

5             *(A) further define the term “substantial evi-*  
6             *dence”, as defined in subsection (d)(4) of such*  
7             *section, in a manner that encourages the submis-*  
8             *sion of applications for production drugs that*  
9             *conserve food resources, of applications for veteri-*  
10            *nary prescription drugs whose use is designed to*  
11            *rely on the experience and training of practi-*  
12            *tioners in establishing effective doses for such*  
13            *drugs, and of supplemental applications, includ-*  
14            *ing applications seeking approval for uses of*  
15            *animal drugs in minor species, for minor uses of*  
16            *such drugs, and for permitted unlabeled uses of*  
17            *such drugs;*

18            *(B) take into account the proposals con-*  
19            *tained in the citizen petition (FDA Docket No.*  
20            *91P–0434/CP) jointly submitted by the Amer-*  
21            *ican Veterinary Medical Association and the*  
22            *Animal Health Institute, dated October 21, 1991;*  
23            *and*

24            *(C)(i) provide for the opportunity for a con-*  
25            *ference prior to the submission of an application*

1       for approval of a new animal drug under such  
 2       section, and prior to the submission of a request  
 3       for an investigational exemption under sub-  
 4       section (j) of such section, to make a decision es-  
 5       tablishing any submission or investigational re-  
 6       quirement relating to the application or request  
 7       (which decision shall bind the Secretary and the  
 8       applicant or requester unless the Secretary by  
 9       order determines that a documented scientific  
 10      issue that occurred subsequent to the conference  
 11      requires the decision to be modified in order to  
 12      ensure that an appropriate determination can be  
 13      made with respect to the safety or effectiveness of  
 14      the animal drug involved); and

15               (ii) not later than 10 days after each such  
 16      conference, by written order, provide a scientific  
 17      justification specific to the animal drug and in-  
 18      tended uses under consideration for requiring  
 19      studies of types other than the types of studies  
 20      specified in subsection (d)(4) of such section, as  
 21      being essential to provide substantial evidence of  
 22      effectiveness for the intended uses of the drug.

23   **SEC. 703. LIMITATION OF RESIDUES.**

24       Section 512(d)(1)(F) (21 U.S.C. 360b(d)(1)(F)) is  
 25   amended to read as follows:

1           “(F) on the basis of information submitted to the  
 2       Secretary as part of the application or any other in-  
 3       formation before the Secretary with respect to such  
 4       drug, any use prescribed, recommended, or suggested  
 5       in labeling proposed for such drug will result in a  
 6       residue of such drug in excess of a tolerance found by  
 7       the Secretary to be safe for such drug;”.

8   **SEC. 704. ADULTERATED DRUGS.**

9       Section 501(a)(2) (21 U.S.C. 351(a)(2)) is amended—  
 10       (1) in subparagraph (A), by striking “health; or”  
 11       and inserting “health;”; and  
 12       (2) in subparagraph (B), by striking “possess;”  
 13       and inserting the following: “possess; or (C) if it is  
 14       a drug intended for use by animals other than man  
 15       and the methods used in, or the facilities or controls  
 16       used for, its manufacture, processing, packing, or  
 17       holding do not conform to or are not operated or ad-  
 18       ministered in conformity with current good manufac-  
 19       turing practice requirements (appropriate for animal  
 20       drugs) adopted pursuant to regulations issued by the  
 21       Secretary to ensure that such drug meets the require-  
 22       ments of this Act as to safety and has the identity  
 23       and strength, and meets the quality and purity char-  
 24       acteristics, which it purports or is represented to pos-  
 25       sess for use in animals other than man;”.

1 **SEC. 705. VETERINARY FEED DIRECTIVES.**

2 (a) WRITTEN OR ORAL ORDERS.—Section  
 3 503(f)(1)(A) (21 U.S.C. 353(f)(1)(A)) is amended by strik-  
 4 ing “other than man” and inserting the following: “other  
 5 than man, other than a veterinary feed directive drug in-  
 6 tended for use in animal feed or an animal feed bearing  
 7 or containing a veterinary feed directive drug,”.

8 (b) GENERAL REQUIREMENTS.—Chapter V (21 U.S.C.  
 9 351 et seq.) is amended by inserting after section 503 the  
 10 following new section:

11 “VETERINARY FEED DIRECTIVES DRUGS

12 “SEC. 504. (a)(1) A drug intended for use in or on  
 13 animal feed that is limited by an approved application  
 14 filed pursuant to section 512(b) to use under the profes-  
 15 sional supervision of a licensed veterinarian is a veterinary  
 16 feed directive drug. Any animal feed bearing or containing  
 17 a veterinary feed directive drug shall be fed to animals only  
 18 by or upon the lawful veterinary feed directive issued by  
 19 a licensed veterinarian in the course of the professional  
 20 practice of the veterinarian. When labeled, distributed, held,  
 21 and used in accordance with this section, a veterinary feed  
 22 directive drug and any animal feed bearing or containing  
 23 a veterinary feed directive drug shall be exempt from section  
 24 502(f).

25 “(2) A veterinary feed directive is lawful if it—

1           “(A) contains such information as the Secretary  
2           may, by general regulation or by order, require; and

3           “(B) is in compliance with the conditions and  
4           indications for use of the drug set forth in the notice  
5           published pursuant to section 512(i).

6           “(3)(A) Any persons involved in the distribution or use  
7           of animal feed bearing or containing a veterinary feed di-  
8           rective drug, and the licensed veterinarian issuing the vet-  
9           erinary feed directive, shall maintain a copy of the veteri-  
10          nary feed directive applicable to each such feed, except in  
11          the case of a person distributing such feed to another person  
12          for further distribution, such person distributing the feed  
13          shall maintain a written acknowledgment from the person  
14          to whom the feed is shipped stating that that person shall  
15          not ship or move such feed to an animal production facility  
16          without a veterinary feed directive or ship such feed to an-  
17          other person for further distribution unless that person has  
18          provided the same written acknowledgment to the imme-  
19          diate supplier of that person.

20          “(B) Every person required under subparagraph (A)  
21          to maintain records, and every person in charge or custody  
22          thereof, shall, upon request of an officer or employee des-  
23          ignated by the Secretary, permit such officer or employee  
24          at all reasonable times to have access to and copy and verify  
25          such records.

1       “(C) Any person who distributes animal feed bearing  
 2 or containing a veterinary feed directive drug shall upon  
 3 first engaging in such distribution notify the Secretary of  
 4 the name and place of business of that person. The failure  
 5 to provide such notification shall be deemed to be an act  
 6 which results in the drug being misbranded.

7       “(b) A veterinary feed directive drug and any feed  
 8 bearing or containing a veterinary feed directive drug shall  
 9 be deemed to be misbranded if the drug and feed labeling  
 10 fails to bear such cautionary statement and such other in-  
 11 formation as the Secretary may, by general regulation or  
 12 by order, prescribe, or the drug and feed advertising fails  
 13 to conform to the conditions and indications for use pub-  
 14 lished pursuant to section 512(i) or fails to contain the gen-  
 15 eral cautionary statement prescribed by the Secretary.

16       “(c) Neither a drug subject to this section, nor animal  
 17 feed bearing or containing such a drug, shall be deemed to  
 18 be a prescription article under any Federal or State law.”.

19       (c) CONFORMING AMENDMENTS.—Section 512 (21  
 20 U.S.C. 360b) is amended—

21               (1) in subsection (a)(2)(C), by striking “its label-  
 22 ing” and inserting “its labeling, its distribution, its  
 23 holding,”;

24               (2) in subsection (i), by striking “requirements)”  
 25 and inserting “requirements and any requirement



1        *that an animal feed bearing or containing the new*  
 2        *animal drug be limited to use under the professional*  
 3        *supervision of a licensed veterinarian)”; and*

4                *(3) in subsection (m)(4)(B)(i)—*

5                        *(A) by striking “paragraph (5)(A) of this*  
 6                        *subsection” and inserting “paragraph (5)(A) or*  
 7                        *under section 504(a)(3)(A)”; and*

8                        *(B) by striking “subparagraph (B) of such*  
 9                        *paragraph” and inserting “paragraph (5)(B) or*  
 10                        *section 504(a)(3)(B)”.*

11        *(d) PROHIBITED ACTS.—Section 301(e) (21 U.S.C.*  
 12        *331(e)) is amended—*

13                        *(1) by striking “section 412” and inserting “sec-*  
 14        *tion 412, 504,”; and*

15                        *(2) by striking “under section 412,” and insert-*  
 16        *ing “under section 412, 504,”.*

17        **SEC. 706. TIMEFRAMES FOR APPROVAL.**

18        *The first sentence of section 512(c)(1) (21 U.S.C.*  
 19        *360b(c)(1)) is amended by striking “one hundred and*  
 20        *eighty” and inserting “90”.*

21        **TITLE VIII—FOOD REGULATORY**  
 22                        **REFORM**

23        **SEC. 801. SHORT TITLE.**

24        *This title may be cited as the “Food Regulatory Re-*  
 25        *form Act of 1996”.*

1 **SEC. 802. INDIRECT FOOD ADDITIVES.**

2       (a) *APPROVAL.*—Section 409 (21 U.S.C. 348) is  
3 amended by adding at the end thereof the following new  
4 subsection:

5                   *“Alternative Approval Procedure*

6           “(j)(1) *As an alternative to the approval procedure es-*  
7 *tablished under subsection (b), any person may submit a*  
8 *notification for an indirect food additive under this sub-*  
9 *section.*

10          “(2) *Any person who proposes to begin the introduc-*  
11 *tion or delivery for introduction into interstate commerce*  
12 *of an article intended for use as an indirect food additive*  
13 *may submit to the Secretary, at least 90 days prior to mak-*  
14 *ing such introduction or delivery, a notification containing*  
15 *information demonstrating that the labeled use of the article*  
16 *is safe.*

17          “(3) *Within 90 days after the receipt of the notification*  
18 *by the Secretary, the Secretary shall—*

19                   “(A) *either—*

20                           “(i) *approve the notification if the article is*  
21 *safe for its intended use; or*

22                           “(ii) *disapprove the notification if the arti-*  
23 *cle has not been shown to be safe for its intended*  
24 *use; and*

25                   “(B) *publish a notice of this determination in*  
26 *the Federal Register and, if the notification is ap-*

1       proved, promulgate an appropriate regulation pursu-  
2       ant to subsection (c).”.

3       (b) *DEFINITION.*—Section 201 (21 U.S.C. 321), as  
4       amended by section 408, is further amended by adding at  
5       the end thereof the following new paragraph:

6       “(hh) The term ‘indirect food additive’ means a food  
7       additive that is intended to contact food but that is not  
8       intended for consumption as a food ingredient.”.

9       **SEC. 803. HEALTH CLAIMS OF FOOD PRODUCTS.**

10       Section 403(r)(3) (21 U.S.C. 343(r)(3)) is amended by  
11       adding at the end thereof the following new subparagraph:

12       “(C) Notwithstanding the provisions of subparagraphs  
13       (A)(i) and (B), a claim of the type described in paragraph  
14       (1)(B) which is not authorized by the Secretary in a regula-  
15       tion promulgated in accordance with subparagraph (B)  
16       shall be authorized and may be made if—

17       “(i) an authoritative scientific body of the  
18       United States Government with official responsibility  
19       for public health protection or research directly relat-  
20       ing to human nutrition (such as the National Insti-  
21       tutes of Health or the Centers for Disease Control and  
22       Prevention), the National Academy of Sciences, or  
23       subdivisions of the scientific body or the National  
24       Academy of Sciences, has published statements, con-  
25       clusions, or recommendations in effect recognizing

1        *that the relationship between the nutrient and disease*  
 2        *or health-related condition to which the claim refers*  
 3        *is supported by pertinent scientific evidence; and*

4                *“(ii) the manufacturer or distributor of the food*  
 5        *for which such claim is made has submitted to the*  
 6        *Secretary at least 90 days before the first introduction*  
 7        *of such food into interstate commerce a notice of*  
 8        *claim, including a concise description of the basis*  
 9        *upon which such manufacturer or distributor relied*  
 10       *for determining that the requirements of clause (i)*  
 11       *have been satisfied.”.*

12    ***TITLE IX—ESTABLISHMENT OF***  
 13       ***CENTERS FOR EDUCATION***  
 14       ***AND RESEARCH ON DRUGS,***  
 15       ***DEVICES, AND BIOLOGICAL***  
 16       ***PRODUCTS***

17    ***SEC. 901. CENTERS FOR EDUCATION AND RESEARCH ON***  
 18                ***DRUGS, DEVICES, AND BIOLOGICAL PROD-***  
 19                ***UCTS.***

20        *Chapter IX (21 U.S.C. 391 et seq.), as amended by*  
 21        *section 507, is further amended by adding at the end thereof*  
 22        *the following new section:*

1 **“SEC. 909. CENTERS FOR EDUCATION AND RESEARCH ON**  
 2 **DRUGS, DEVICES, AND BIOLOGICAL PROD-**  
 3 **UCTS.**

4 “(a) *IN GENERAL.*—The Secretary, acting through the  
 5 Commissioner, shall establish a consortium of 3 or more  
 6 centers for research and education on drugs, devices, and  
 7 biological products in accordance with subsection (b).

8 “(b) *GRANT AUTHORITY.*—The Secretary, acting  
 9 through the Commissioner, shall make grants to 3 or more  
 10 private entities to assist each of the entities in the establish-  
 11 ment and operation of a center for research and education  
 12 on drugs, devices, and biological products. In awarding a  
 13 grant under this subsection, the Secretary shall use a peer-  
 14 review selection procedure.

15 “(c) *AUTHORIZED GRANT ACTIVITIES.*—

16 “(1) *REQUIRED ACTIVITIES.*—A grant awarded  
 17 under subsection (b) shall be used to—

18 “(A) *conduct state-of-the-art clinical and*  
 19 *laboratory research that—*

20 “(i) *increases awareness of new uses of*  
 21 *drugs, devices, or biological products and*  
 22 *the unforeseen risks of new uses of drugs,*  
 23 *devices, or biological products;*

24 “(ii) *provides objective clinical infor-*  
 25 *mation to—*

1                   “(I) health care practitioners or  
2                   other providers of health care goods or  
3                   services;

4                   “(II) pharmacy benefit managers;

5                   “(III) health maintenance organi-  
6                   zations or other managed health care  
7                   organizations; and

8                   “(IV) health care insurers or gov-  
9                   ernmental agencies; and

10                  “(iii) improves the quality of health  
11                  care while reducing the cost of health care  
12                  through the prevention of adverse effects of  
13                  drugs, devices, or biological products and  
14                  the consequences of such effects, such as un-  
15                  necessary hospitalizations; and

16                  “(B) conduct research on the comparative  
17                  effectiveness and safety of drugs, devices, or bio-  
18                  logical products.

19                  “(2) *DISCRETIONARY ACTIVITIES*.—A grant  
20                  awarded under subsection (b) may be used to con-  
21                  duct—

22                         “(A) surveillance of the adverse effects of  
23                         drugs, devices, or biological products;

1                   “(B) a study of new or unapproved uses for  
 2                   marketed drugs, devices, or biological products;  
 3                   or

4                   “(C) a study of the therapeutic characteris-  
 5                   tics of clinically special populations, such as  
 6                   children, women, and elderly individuals.

7                   “(3) *LIMITATION.*—A grant awarded under sub-  
 8                   section (b) may not be used to assist the Secretary in  
 9                   the review of new drugs.

10                  “(d) *APPLICATION.*—An entity that desires to receive  
 11 a grant under this section shall submit to the Secretary an  
 12 application at such time, in such manner, and accom-  
 13 panied by such information as the Secretary may require.

14                  “(e) *ESTABLISHMENT OF AN OVERSIGHT COMMIT-*  
 15 *TEE.*—The Secretary shall establish within the Food and  
 16 Drug Administration a committee to provide oversight of  
 17 the research and educational activities of the consortium of  
 18 centers described in subsection (a). The committee shall be  
 19 composed of—

20                   “(1) a representative from each of the centers;

21                   “(2) a representative from the Food and Drug  
 22 Administration;

23                   “(3) a representative from consumer advocacy  
 24 groups; and

1           “(4) a representative from the pharmaceutical,  
2           device, or biological products industry.

3           “(f) *REPORT*.—Not later than September 30, 1999, the  
4           Secretary shall prepare and submit to the Chairmen and  
5           Ranking Members of the Committee on Labor and Human  
6           Resources of the Senate and the Committee on Commerce  
7           of the House of Representatives a report on the activities  
8           of the consortium of centers established pursuant to this sec-  
9           tion. The report shall include an analysis on the impact  
10          of the centers on the safe use of drugs, devices, and biological  
11          products and recommendations on whether the funding for  
12          the centers should be extended and increased.

13          “(g) *AUTHORIZATION OF APPROPRIATIONS*.—There  
14          are authorized to be appropriated to carry out this section  
15          \$9,000,000 for fiscal year 1997, \$12,000,000 for fiscal year  
16          1998, \$15,000,000 for fiscal year 1999, and \$15,000,000 for  
17          fiscal year 2000.”.

18       ***TITLE X—PROGRAM IN CLINICAL***  
19                       ***PHARMACOLOGY***

20       ***SEC. 1001. REAUTHORIZATION OF CLINICAL PHARMACOL-***  
21                       ***OGY PROGRAM.***

22          Section 2(b) of Public Law 102–222 (105 Stat. 1677)  
23          is amended by striking “to carry out this section” and in-  
24          serting “, and fiscal years 1997 and 1998, \$1,900,000 for  
25          each fiscal year, to carry out this section”.