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104TH CONGRESS
2D SESSION

H. R. 3201

To amend the Federal Food, Drug, and Cosmetic Act to facilitate the development, clearance, and use of devices to maintain and improve the public health and quality of life of the citizens of the United States.

IN THE HOUSE OF REPRESENTATIVES

MARCH 29, 1996

Mr. BARTON of Texas (for himself, Mr. GREENWOOD, Mr. RICHARDSON, Mr. BILIRAKIS, Mr. HALL of Texas, Mr. GORDON, Mr. BURR, Ms. ESHOO, Mr. COBURN, Mr. BREWSTER, Mr. KLUG, Mr. DOOLEY of California, Mr. GANSKE, Mr. MCHALE, Mr. BILBRAY, Mr. PAYNE of Virginia, Mr. OXLEY, Mr. HOLDEN, Mr. FIELDS of Texas, Mr. PAXON, Mr. SCHAEFER, Mr. TAUZIN, Mr. FOX of Pennsylvania, Mr. UPTON, Mr. CAMPBELL, Mr. MCINTOSH, Mr. COX of California, Mr. DREIER, Mr. HEINEMAN, Mr. FUNDERBURK, Mr. WELDON of Florida, Mr. HOSTETTLER, Mr. SHAYS, Mr. HASTERT, Mr. NORWOOD, Mr. BURTON of Indiana, Mr. FRAZER, Mr. STEARNS, Mr. FRISA, Mr. RAMSTAD, Mr. MARTINI, and Ms. DUNN of Washington) introduced the following bill; which was referred to the Committee on Commerce

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A BILL

To amend the Federal Food, Drug, and Cosmetic Act to facilitate the development, clearance, and use of devices to maintain and improve the public health and quality of life of the citizens of the United States.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE; REFERENCE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the ''Medical Device Reform Act of 1996''.

(b) REFERENCE.—Whenever in this Act an amendment or repeal is expressed in terms of an amendment to, or repeal of, a section or other provision, the reference shall be considered to be made to a section or other provision of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

(c) TABLE OF CONTENTS.—The table of contents is as follows:

SEC. 2. FDA MISSION AND ANNUAL REPORT.

(a) MISSION.—Section 903 (21 U.S.C. 393) is amended by redesignating subsections (b) and (c) as subsections (c) and (d), respectively, and by adding after subsection (a) the following:

''(b) MISSION.—The Food and Drug Administration shall protect the public health and safety and promptly and efficiently review and approve clinical research and marketing of products in a manner that does not unduly impede innovation or product availability. The Food and Drug Administration shall participate with other countries to reduce the burden of regulation, harmonize regulatory requirements, and achieve appropriate reciprocal arrangements.''

(b) ANNUAL REPORT.—Section 903 (21 U.S.C. 393), as amended by subsection (a), is amended by adding at the end the following:

''(e) ANNUAL REPORT.—The Secretary shall, simultaneously with the submission each year of the budget for the Food and Drug Administration, submit to the Committee on Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate an annual report which shall—

''(1) review the performance of the Food and Drug Administration in meeting its mission and the

development of Food and Drug Administration policies to implement such mission;

''(2) review the performance of the Food and Drug Administration in meeting its own performance standards, including its own outcome measurements and statutory deadlines for the approval of products or for other purposes contained in this Act;

''(3) describe the staffing and resources of the Food and Drug Administration and list those persons and organizations accredited to conduct investigations under section 505(1), product approvals under sections 505 and 506, and to perform good manufacturing practice reviews under section 505(d)(3) and 520(f);

''(4) describe the goals, activities, and accomplishments of the Food and Drug Administration in bilateral and multinational meetings that addressed methods and approaches to reduce the burden of regulation, harmonize regulation, and to seek appropriate reciprocal arrangements, list each such meeting, and list pending issues specifying those that are not consistent with or are contrary to the provisions of this Act; and

''(5) compare the performance of the Food and Drug Administration in approving innovative prod-

ucts with that of the most successful agencies performing similar functions in other countries and compare the resources used by such agencies.''.

SEC. 3. DISPUTE RESOLUTION.

Chapter V is amended by adding after section 522 the following:

''DISPUTE RESOLUTION

''SEC. 523. (a) At any time before the issuance of the notice under section 510(k) or an exemption for investigational use under section 520(g) for a device, the applicant may, in writing, notify the Secretary that an impasse exists in the review of the application for a device under section 515 or the submission for such an exemption with respect to a specifically identified issue.

''(b) On receipt of the notification from the applicant, the Secretary shall refer the disputed issue—

''(1) to an existing (as of the date of the notification) scientific advisory panel having expertise related to the issue;

''(2) to a special Government employee, as defined in section 202(a) of title 18, United States Code, or to a non-governmental person qualified to mediate or arbitrate the substance of such impasse who is acceptable to the Secretary and the applicant.

''(c) The applicant and representatives of the Secretary may consult with the panel, special Government em-

ployee, or non-governmental person on the matter referred. The panel, special Governmental employee, or non-governmental person shall submit to the Secretary and the applicant a report containing recommendations (including a statement of reasons for the recommendations) regarding the matter not later than 60 days after the date of the referral, or not later than 90 days after the date of the referral if the panel, special Governmental employee, or non-governmental person considers the additional 30 days to be necessary. Not later than 30 days after the date of receiving the report, the Secretary shall, in writing, confirm or modify the recommendations received, providing reasons and reference to data before the panel, special Governmental employee, or non-governmental person for any modification. If the Secretary fails to act on such a recommendation within 30 days of its receipt, the recommendation of the panel, special Government employee, or non-governmental person shall be deemed to be the recommendation of the Secretary.

''(d) The Federal Advisory Committee Act shall not apply to any scientific advisory panel acting under this section.''.

SEC. 4. INVESTIGATIONAL DEVICE EXEMPTIONS.

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

''(6) The Secretary shall, by regulation and within 120 days of the date of the enactment of this paragraph, update the procedures and conditions under which devices intended for human use may upon application be granted an exemption from certain requirements of this Act. Such regulation shall—

''(A) permit the use of investigational devices, outside of an investigational protocol, in the diagnosis or treatment of diseases or conditions that are life-threatening or could be irreversibly debilitating when the risk of not using the investigational device exceeds the probable risk of using such device as determined by the treating physician;

''(B) ensure that prior to submitting an application to the Secretary or to an institutional review board, any person intending to investigate the safety or effectiveness of a class III device or an implant device will have the opportunity to submit an investigational plan, including a clinical protocol, to the Secretary for review;

''(C) within 30 days of receipt of an investigational plan under subparagraph (B), require the Secretary to respond in writing to the submitter identifying each deficiency with the plan and such other

information that will facilitate the review and approval of an application;

''(D) provide a submitter who disputes the Secretary's response under subparagraph (C) a right to appear before a classification panel constituted under section 513(b), at the next scheduled panel meeting, and obtain the review by the panel of the investigational plan and the Secretary's evaluation of such plan;

''(E) permit developmental changes in devices in response to information gathered during the course of an investigation without requiring an additional approval of an application for an investigational device exemption, or the approval of a supplement to such an application, if such changes do not constitute a significant change in design or a significant change in basic principles of operation; and

''(F) without additional approval of an application for an investigational device exemption, or the approval of a supplement to such an application, permit changes or modifications to clinical protocols that do not affect the validity of data or information resulting from the completion of an approved protocol and do not alter the relationship of likely patient risk to benefit relied upon to approve a protocol.''.

SEC. 5. SPECIAL REVIEW FOR CERTAIN DEVICES.

Section 515(d) is amended by adding at the end the following:

''(4) In order to better treat or diagnose life-threatening or irreversibly debilitating diseases or conditions of man, the Secretary shall promulgate a regulation to create review priority for devices—

''(A) representing breakthrough technologies,

''(B) for which no approved alternatives exist,

''(C) which offer significant advantages over existing approved alternatives, or

''(D) the availability of which is in the best interest of the public health.

Such regulation shall include, among other things, criteria identifying devices which merit preferential review, specifying procedures for implementing such reviews, and identifying substantive review criteria appropriate to making prompt and efficient review of such devices. The Secretary shall publish in the Federal Register a proposed regulation to create such review priority no later than 6 month after the date of the enactment of this paragraph, allowing 60 days for comment. The Secretary will publish a final regulation no later than 60 days after the last day of the comment period.''.

SEC. 6. EXPANDING HUMANITARIAN USE OF DEVICES.

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

(1) in paragraph (2), by inserting after and below subparagraph (C) the following: ''The request shall be in the form of an application to the Secretary. Within 30 days of the date of the receipt of an application, the Secretary shall issue an order approving or denying the application.''; and

(2) by striking paragraphs (5) and (6).

SEC. 7. PERFORMANCE STANDARDS.

Section 514 (21 U.S.C. 360d) is amended to read as follows:

''STANDARDS

''SEC. 514. (a) The Secretary shall, through publication in the Federal Register, issue notices recognizing applicable nationally or internationally recognized consensus standards in any determination as to whether there is a reasonable assurance that a device is safe or effective or to determine compliance with any requirement of this Act. Any person may elect to utilize data other than that required by such standards to demonstrate a reasonable assurance of device safety or effectiveness or compliance with the requirements of this Act.

''(b) The Secretary shall accept certifications that devices conform with each type of standard referenced in subsection (a) and identified in each such certification.''.

SEC. 8. EFFECTIVENESS DETERMINATION.

Section 513(a)(3) (21 U.S.C. 360c(a)(3)) is amended—

(1) in subparagraph (A), by inserting ''one or more'' after ''on the basis of'' and by striking ''clinical investigations'' and inserting ''a clinical investigation''; and

(2) by adding at the end of subparagraph (A) the following: ''A well-controlled clinical investigation—

''(i) shall not be considered appropriate unless the Secretary determines, after consultation with a classification panel established under subsection (b), that such investigation is necessary to demonstrate that the device will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling of the device; and

''(ii) shall only include methods of control that are appropriate to the disease or condition for which a device is intended as prescribed, recommended, or suggested in the labeling of the device.

Any person may submit a well-controlled clinical investigation to the Secretary to demonstrate that a device will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or sug-

gested in the labeling of the device and, without reliance on a classification panel, the Secretary may determine that such studies are appropriate for such purpose.''; and

(3) by adding at the end the following:

''(C) For purposes of this paragraph, the determination of effectiveness shall not include any of the following:

''(i) The evaluation of clinical outcomes if the use of a device provides a medical contribution to the diagnosis or treatment of the persons for whom the device is intended unless the labeling of the device represents that it provides a therapeutic effect to the persons for whom the device is intended.

''(ii) The evaluation of relative effectiveness unless the performance of a device is compared to that of another device through labeling or other representations by the person legally responsible for the labeling of the device.

''(iii) The evaluation of cost effectiveness representations unless the labeling specifically includes a statement about the cost effectiveness.

''(iv) The evaluation of any indication for use not included in the labeling of a device unless the person legally responsible for the labeling of the device promotes such indications for use.''.

SEC. 9. PREMARKET NOTIFICATION.

(a) SECTION 510.—Section 510 (21 U.S.C. 360) is amended—

(1) in subsection (k), by inserting after ''a device intended for human use'' the following: ''(other than any device classified into class I under section 513 or 520 or any device classified into class II under section 513 or 520 if such class II device has been exempted from the requirements of this subsection under subsection (l))'';

(2) in subsection (k), by striking ''report to the Secretary'' and inserting ''have the option of reporting to the Secretary or any person who is not an employee of the United States and who is accredited under section 712(a)''; and

(3) by adding the following after subsection (k):

''(l) Within 30 days after the date of the enactment of this subsection, the Secretary shall publish in the Federal Register a list of each type of class II device that does not require a report under subsection (k) to provide reasonable assurance of safety and effectiveness. Each type of class II device listed by the Secretary shall be exempt from the requirement to file a report under subsection (k) as of the date of the publication of the list in the Federal Register. Beginning on the date that is 1 day after the date of the publication of the list, any person

may petition the Secretary to exempt a type of class II device from the reporting requirement of subsection (k). If the Secretary fails to respond to a petition within 120 days of receiving it, the petition shall be deemed to be granted.''.

(b) INITIAL CLASSIFICATION.—Section 513(f) (21 U.S.C. 360c(f)) is amended—

(1) in the second sentence of paragraph (1) by striking the period at the end and inserting the following: ''unless within 30 days of receiving an order classifying the device into class III the individual who submits a report under section 510(k) for such device requests review and recommendation with respect to the classification of the device by a classification panel established under subsection (b) and a final order of classification from the Secretary. After the request, a device classified into class III under this paragraph shall not be deemed to be finally classified until a classification panel established under subsection (b) reviews the request with respect to the classification of the device and, within 60 days of the date of receiving the request, recommends to the Secretary a classification for the device based on the classification criteria set forth in subparagraphs (A) through (C) of subsection (a)(1).

Thereafter, the Secretary shall have 10 days to determine by order the final classification of the device by applying such criteria. If the Secretary fails to issue such an order within such 10 days, the recommendation of the classification panel shall be deemed to be the order of final classification of the device issued by the Secretary.''.

(2) by adding at the end the following:

''(4)(A) Within 90 days of receiving a report required under section 510(k) for devices identified as being substantially equivalent to a class II device, a person accredited under section 712 to conduct reviews of such report shall determine the initial classification under paragraph (1)(A) of any such device which was not introduced or delivered for introduction into interstate commerce for commercial distribution before the date of the enactment of this subparagraph and shall submit such determination to the Secretary. The accredited person shall immediately, by registered mail, provide to the submitter of such report a copy of the recommendation to the Secretary for an order classifying the device. Such determination shall be considered to be an order of the Secretary initially classifying the device. If the accredited person determines that the device should be classified into class III, such per-

son shall, immediately upon making such determination, refer the report to the Secretary.

''(B) Within 60 days of receiving a report required under section 510(k) for a device identified as being substantially equivalent to a class III device, a person accredited under section 712 to conduct reviews of such report shall make a determination of the initial classification under paragraph (1)(A) of any such device which was not introduced or delivered for introduction into interstate commerce for commercial distribution before the date of the enactment of this subparagraph, and within such time period submit a recommendation to the Secretary and to the submitter of the report which contains such determination. The recommendation by such person of initial classification of a device shall be considered to be an order of the Secretary unless the Secretary, within 30 calendar days of receipt of the recommendation, finds that the device is not substantially equivalent to a predicate device and issues an order under this subsection initially classifying the device. Such order shall be based on the criteria in this subsection and subsection (i) and provide a detailed explanation and justification for the basis of the Secretary's disagreement, if any, with the accredited person's recommendation. If, within 90 days from the date of receipt of the report, the Secretary does not issue an

order that differs from the recommendation of the accredited person, the Secretary shall promptly send by registered mail to the submitter of the report such recommendation as the Secretary's order of initial classification. If the Secretary does not provide the submitter such recommendation by registered mail as specified, the recommendation of classification provided to the submitter of the report shall become the Secretary's order of initial classification of the device. Such classification may only be changed pursuant to the procedures specified in paragraph (2) of this subsection.

''(5) the Secretary may not withhold a determination of the initial classification of a device under paragraph (1) because of a failure to comply with any provision of this Act unrelated to a substantial equivalence decision, including a finding that the facility in which the device is manufactured is not in compliance with good manufacturing requirements as set forth in regulations of the Secretary under section 520(f).''.

(c) SECTION 513(i).—Section 513(i) (21 U.S.C. 360c(i)) is amended—

(1) in paragraph (1)(A)(ii)(I), by striking ''clinical data'' and inserting ''either appropriate clinical or scientific data'' and by inserting ''or a person accredited under section 712'' after ''Secretary'';

(2) in paragraph (1)(A)(ii)(II), by striking ''efficacy'' and inserting ''effectiveness''; and

(3) by adding at the end of paragraph (1) the following:

''(C) For purposes of subparagraph (A), the term 'legally marketed device' includes any device introduced into interstate commerce for commercial distribution before May 28, 1976, and any device found substantially equivalent to such device, which has not been removed from the market by an order of the Secretary or a judicial order because it is unsafe or ineffective.

''(D) Any change or modification to a device, other than a major change (including any major modification) in the intended use, shall not require an additional submission under section 510(k) if such change or modification is supported by appropriate data or information and the change or modification can be shown to not adversely affect the safety or effectiveness of the device which was introduced in interstate commerce before May 28, 1976 or initially classified under subsection (f). All data or information relied upon to document that a change to (including any modification of) such a device does not require an additional report under section 510(k) shall be made available to the Secretary upon request and maintained

for a period of time equal to at least the commercial life of the device.

''(E) For the purpose of determining the intended use of a predicate device under subparagraph (A), each use reasonably included within a general use for the predicate device shall be deemed a legally marketed use of the predicate device and shall be available for use in premarket reports required under section 510(k).

''(F) For the purpose of determining substantial equivalence, the Secretary shall not consider any uses or indications for use of a device that are not specifically identified in a premarket market notification under section 510(k).

''(G) For the purpose of determining substantial equivalence the Secretary shall accept certification of compliance with nationally or internationally recognized consensus standards to resolve any substantial equivalence issue which such standards address. To the extent that a substantial equivalence issue is resolved by such standards, additional information shall not be required to further address such an issue.''.

SEC. 10. CLASSIFICATION PANELS.

Section 513(b) (21 U.S.C. 360c(b)) is amended by adding at the end the following:

''(5) Classification panels covering each type of device shall be scheduled to meet at least 6 times each calendar year to consider, among other things, the approval of applications submitted to the Secretary under section 515. Such meetings shall, to the extent possible, be scheduled at equal intervals throughout the year. Such meetings shall be held with the physical presence of panel members at least 3 times each calendar year. Other meetings of the panel may be held using electronic communication to convene the meeting.

''(6) Each member of a panel shall publically disclose all conflicts of interest that member may have with the work to be undertaken by the panel. No member of a panel may vote on any matter where the member could gain financially from the advice given to the Secretary. The Secretary may grant a waiver of any conflict of interest upon public disclosure of such conflict of interest if such waiver contributes to the ability of a panel to contribute to the public health, except that the Secretary may not grant a waiver for a member of a panel when the member's own scientific work is involved.

''(7) The Secretary shall provide education and training to each new panel member before such member participates in a panel's activities. Such education and training shall include a familiarization with certain requirements

under this Act and any related regulation of the Secretary and the administrative process and procedures related to panel meetings.

''(8) The Secretary shall take whatever action is necessary to ensure that regular meetings are held by scientific advisory panels, at appropriate intervals and for a sufficient length of time, so that any matter to be reviewed by any such panel shall be presented to the panel not more than 60 days after the matter is ready for review by the panel. The meetings shall occur not less than 6 times each year unless there are compelling reasons for fewer meetings. Such meetings shall be held with the physical presence of panel members at least 3 times each calendar year. Other meetings of the panel may be held using electronic communication to convene the meeting.

''(9)(A) All persons, including employees of the Secretary, shall have the same rights and responsibilities regarding—

''(i) the submission of data and information to, and contact and discussion with, a classification panel;

''(ii) the participation of the persons at meetings of the panel; and

''(iii) access to data and information submitted to a classification panel (except for data and infor-

mation that are not available for public disclosure under section 552 of title 5, United States Code).

''(B) In a case in which a classification panel reviews a submission under section 510(k), all related data and information that are not available for public disclosure under section 552 of title 5, United States Code, shall be exchanged between the person who submitted such notice and the Food and Drug Administration at the time the data and information are submitted to such panel but shall not otherwise be publicly disclosed.

''(C) Any meetings of a classification panel shall provide adequate time for initial presentations and for response to any differing views and shall encourage free and open participation by all interested persons.

''(10) Within 30 days after the date a classification panel makes its conclusions and recommendations on any matter under review by the panel, the Food and Drug Administration official responsible for the matter shall review the conclusions and recommendations of the panel, shall make a final decision on the matter, and shall notify the affected persons of the decision in writing and, if the decision differs from the conclusions and recommendations of the panel, shall include the reasons for the difference.

''(11) A scientific advisory panel under this subsection shall not be subject to the annual chartering and

annual report requirements of the Federal Advisory Committee Act. Such a panel shall make an annual report of its activities to the Secretary.''.

SEC. 11. PREMARKET APPROVAL.

(a) SECTION 515(c).—Section 515(c) (21 U.S.C. 360e(c)) is amended—

(1) in the first sentence of paragraph (1), by inserting immediately before the period the following: ''or may file such application with a person authorized to review applications for premarket approval under section 712''; and

(2) by adding after paragraph (2) the following:

''(3)(A) The scope of review responsibilities of accredited persons authorized to conduct reviews of premarket approval applications under section 712 shall include—

''(i) the receipt and filing of applications for substantive review;

''(ii) the review of applications to determine whether there is a reasonable assurance that a device is safe and effective for its labeled uses;

''(iii) the review of applications in accordance with the schedule for review identified in subsection (d)(2) unless such organization or person by contract with an applicant alters such schedule or elimi-

nates any item of review but not the review by a classification panel under paragraph (2);

''(iv) the presentation, when appropriate, of such applications to a classification panel constituted under section 513(b); and

''(v) the evaluation of classification panel recommendations and premarket approval applications and the formulation of reports and recommendations to be submitted to the Secretary no later than 30 days after receipt of a classification panel's recommendation.

Recommendations to the Secretary shall specify whether an application should be approved or denied and shall state the basis for the recommendation.

''(B) The recommendation of an accredited person to approve or deny an application shall be considered to be an order of the Secretary unless the Secretary finds that there is a reasonable probability that the device is not safe or effective. In the event that the Secretary makes such a finding, the Secretary shall provide a detailed explanation of the basis of the finding.''.

(b) SECTION 515(d).—Section 515(d) (21 U.S.C. 360e(d)) is amended by redesignating paragraphs (2) and (3) as paragraphs (5) and (6), respectively, by adding before the semicolon at the end of paragraph (5)(B) (as so

redesignated) the following: ''and for purposes of this subparagraph, the determination of a reasonable assurance that a device is effective under the conditions of use prescribed, recommended, or suggested in proposed labeling shall not include uses or indications for use not identified in the application'', and by adding after paragraph (1) the following:

''(2) Each application received under subsection (c) shall be reviewed in the following manner to achieve final action on such applications within 180 days of its receipt:

''(A) The Secretary shall determine, within 30 days of the receipt of an application submitted under subsection (c), whether the application satisfies the content requirements of subsection (c)(1) and applicable regulations.

''(B) The Secretary shall meet with an applicant on request within 90 days of receipt of an application that has been accepted for filing to discuss the review status of the application. If the application does not appear in a form that would necessitate an approval under this subsection, the Secretary shall, in writing and prior to the meeting, present to the applicant a description of any deficiencies with the application and what information

would be necessary to bring the application into a form that would require an approval.

''(C) The Secretary shall refer an application to a classification panel established under section 513 for review and an approval recommendation, unless a panel is not required under subsection (c)(2), within 30 days of the meeting referred to in subparagraph (B). The application shall be reviewed at the next scheduled panel meeting.

''(D) The Secretary shall, within 15 days before the date of a panel review, provide to an applicant a statement of each view or position the Secretary has communicated or intends to communicate to a classification panel constituted under section 513(b) or any panel member regarding a premarket approval application scheduled for a panel review. Additionally, at this time the Secretary shall provide to the applicant all information provided by the Secretary to such panel regarding the review of a premarket application.

''(E) The Secretary shall meet not later than 10 days after the panel review to present to an applicant a description of all additional information necessary to require an approval of an application under paragraph (1)(A) if the Secretary has deter-

mined that the application appears to be in a form that would receive approval within 180 days of receipt of such application. The applicant may waive such meeting and instead receive in writing from the Secretary such information within 30 days of the panel review.

''(F) The Secretary shall meet with the applicant not later than 15 days after the panel review if the Secretary has determined that the application is not in a form that would require approval under paragraph (1)(A). Prior to the meeting, the Secretary shall in writing present to the applicant each basis for denying approval of the application and the additional information necessary to bring the application into a form that would require an approval.

''(G) When the Secretary reviews an application and a classification panel review and recommendation is not required under subsection (c)(2), the Secretary shall meet with the applicant no later than 135 days after receipt of an application which has been accepted for filing under subsection (c)(1) and inform the applicant whether or not the application is in a form that would require approval under paragraph (1)(A). If the application is in such form, the Secretary shall, at or prior to the meeting, present

in writing a description of all additional information necessary to require an approval of an application under paragraph (1)(A). If the application is not in such form, the Secretary shall, prior to the meeting, present in writing to the applicant each basis for denying approval of the application and the additional information necessary to bring the application into a form that would require approval.

''(H) When an application is reviewed by an accredited person and a classification panel is not required under subsection (c)(2) to review a premarket approval application, the accredited person shall, no later than 120 days after filing, or at such other designated time determined by the applicant and the accredited person, provide the Secretary with a report and recommendation.

''(I) The Secretary shall approve or deny an application reviewed by an accredited person within 180 days of receipt of an application which has been accepted for filing under paragraph (1) unless the accredited person submits its report and recommendation to the Secretary later than 150 days after such receipt. If the report and recommendation of an accredited person is submitted to the Secretary later than 150 days after receipt of an application

which has been accepted for filing under paragraph (1), the Secretary shall have 30 days from the date of receipt to approve or deny the application.

''(3)(A) The time for the Secretary's review of an application under this subsection shall not be enlarged by any amendment to the application and shall take no more than 180 days.

''(B) The Secretary shall ensure that each time frame under paragraph (2) is met. For each instance in which a review requirement under paragraph (2) is not met, a report to the Commissioner and the Secretary is required no later than 10 days after the date of the scheduled event set forth in paragraph (2) fully explaining the reason that the scheduled time frame was not met. Within 10 days after receipt of such report, the Commissioner shall provide an explanation to the applicant regarding the failure to comply with paragraph (2) and set the date for satisfying the scheduled review program obligation.

''(C) On January 1 of each calendar year, the Secretary shall submit to the committees of Congress with substantive oversight responsibility for the Food and Drug Administration a report summarizing each instance in the previous fiscal year in which the requirements of paragraph (2) were not met. This report shall include reasons for the failures to meet the requirements of paragraph (2)

and proposals to ensure that such requirements will be met.''.

(c) REGULATIONS.—The Secretary of Health and Human Services shall revise, through notice and comment procedures, the regulations appearing in part 814 of title 21 of the Code of Federal Regulations to conform to this section's amendment of section 515 of the Federal Food, Drug, and Cosmetic Act and to eliminate premarket approval of supplements which relate to manufacturing changes and other changes which do not actually affect device safety or effectiveness. The Secretary shall publish in the Federal Register such proposed regulation no later than 6 months after the date of the enactment of this Act, allowing 60 days for comment. The Secretary shall publish a final regulation no later than 60 days after the last day for the comment period.

SEC. 12. ACCREDITATION OF THIRD PARTIES.

(a) AMENDMENT.—Subchapter A of chapter VII is amended by adding at the end the following:

''ACCREDITED PERSONS

''(a) SEC. 712. IN GENERAL.—The Secretary shall, within 180 days of the date of the enactment of this section, by regulation establish procedures for the accreditation of third parties for the purposes of—

''(1) reviewing applications under section 515, providing written reviews to the Secretary for the

Secretary's consideration, and making recommendations on whether or not such applications should be approved; and

''(2) conducting good manufacturing practice inspections to determine the conformance of a facility with regulations promulgated under section 520(f).

''(b) ACCREDITATION.—

''(1) PROGRAMS.—The Secretary shall provide for such accreditation through programs administered by government agencies or by other qualified organizations.

''(2) IMPLEMENTATION.—The Secretary may designate one or more qualified non-government organizations to implement such programs. Such organizations shall implement such programs from fees charged to applicants for accreditation.

''(3) QUALIFICATIONS.—An accredited person shall meet the following requirements:

''(A) Such person shall be an independent organization which is not owned or controlled by manufacturer, supplier, or vendor of devices and which has no organizational, material, or financial affiliation with such a manufacturer, supplier, or vendor.

''(B) Such person shall be a legally constituted entity permitted to conduct the activities for which it seeks accreditation.

''(C) Such person shall not engage in the design, manufacture, promotion, or sale of devices.

''(D) Such person shall be operated in accordance with generally accepted professional and ethical business practices and shall agree in writing that as a minimum it will—

''(i) certify that reported information accurately reflects data reviewed;

''(ii) limit work to that for which competence and capacity are available;

''(iii) treat information received, records, reports, and recommendations as proprietary information; and

''(iv) promptly respond and attempt to resolve complaints regarding its activities for which it is accredited.''.

(b) CONFORMING AMENDMENT.—Section 301 (21 U.S.C. 321) is amended by redesignating the second paragraph (u) as paragraph (v) and by adding after that paragraph the following:

''(w) in the case of a drug, device, or food—

''(A) the submission of a report or recommendation by a person accredited under section 712 that is false or misleading in any material respect;

''(B) the disclosure by a person accredited under section 712 of confidential commercial information or any trade secret without the express written consent of the person who submitted such information or secret to such person; or

''(C) the receipt by a person accredited under section 712 of a bribe in any form or the doing of any corrupt act by such person associated with a responsibility delegated to such person under this Act.''.

SEC. 13. RECLASSIFICATION OF PREAMENDMENT DEVICES.

Section 515 (21 U.S.C. 360e) is amended by adding at the end the following:

''(j) The Secretary shall, within 18 months of the date of enactment of this subsection, publish in the Federal Register a proposed regulation reclassifying all devices identified in subsection (i)(2) into class II except a device for which the Secretary has already published a proposed regulation required under subsection (i)(2). The Secretary shall provide 60 days for comment on such proposed regulation required by this subsection and shall pub-

lish a final regulation in the Federal Register within 60 days after the last day for comment reclassifying into class II each such device not included in a proposed regulation required under subsection (i)(2) or maintaining, where appropriate, the original classification of such device.''.

SEC. 14. DEVICE TRACKING.

Subsection (e) of section 519 (21 U.S.C. 360i) is amended to read as follows:

''(e) DEVICE TRACKING.—The Secretary may by order require a manufacturer to adopt a method of tracking a class II or class III device—

''(1) the failure of which would be life threatening or have permanently debilitating effects; and

''(2) which is—

''(A) a permanently implantable device, or

''(B) a life sustaining or life supporting device used outside a device user facility.''.

SEC. 15. POSTMARKET SURVEILLANCE.

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

''POSTMARKET SURVEILLANCE

''SEC. 522. (a) IN GENERAL.—The Secretary may by order require a manufacturer to conduct postmarket surveillance for any device of the manufacturer first introduced or delivered for introduction into interstate commerce after January 1, 1991, which is a class II or class

III device the failure of which would be reasonably likely to have serious adverse health consequences and which is—

''(1) a permanently implantable device, or

''(2) a life-sustaining or life-supporting device used outside a device user facility.

''(b) SURVEILLANCE APPROVAL.—Each manufacturer required to conduct a surveillance of a device shall, within 30 days of receiving notice from the Secretary that the manufacturer is required under this section to conduct such surveillance, submit, for the approval of the Secretary, a proposal for the required surveillance. The Secretary, within 60 days of the receipt of such proposal, shall determine if the person designated to conduct the surveillance has appropriate qualifications and experience to undertake such surveillance and if such proposal will result in information necessary to determine the occurrence of unforeseen events. Any order requiring a prospective postmarket surveillance shall not require a surveillance period greater than 18 months.''.

SEC. 16. HARMONIZATION.

(a) SECTION 520(f).—Section 520(f)(1)(B) (21 U.S.C. 360j(f)(1)(B)) is amended by striking ''and'' at the end of clause (i), by striking the period at the end of

clause (ii) and inserting ''; and'' and by adding after clause (ii) the following:

''(iii) ensure that such regulation conforms, to the extent practicable, with the international standards organization standards defining quality systems, or parts thereof, for medical devices.''.

(b) SECTION 803.—Section 803 (21 U.S.C. 383) is amended by adding at the end the following:

''(c)(1) The Secretary shall regularly and continuously participate in meetings with other countries to discuss methods and approaches to reduce the burden of regulation, harmonize regulatory requirements, and seek appropriate reciprocal arrangements. The Secretary shall, within 180 days of the date of enactment of this subsection, make public a plan that establishes a framework for achieving mutual recognition of good manufacturing practices.

''(2) The Secretary shall report to the Committee on Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate at least 60 days before executing any bilateral or multilateral agreement under paragraph (1).''.

SEC. 17. GOOD MANUFACTURING PRACTICE INSPECTIONS.

(a) Section 704 (21 U.S.C. 374) is amended—

(1) in subsection (a)(1), by inserting ‘‘, or an accredited person to conduct good manufacturing practice inspections under section 712’’ after ‘‘Secretary’’;

(2) in subsection (a)(3), by inserting ‘‘, or an accredited organization or individual under section 712,’’ after ‘‘employee’’;

(3) in subsection (b), by inserting ‘‘, or an accredited person under section 712,’’ after ‘‘employee’’;

(4) in subsection (b), by inserting ‘‘(1)’’ after ‘‘(b)’’, by redesignating clauses (1) and (2) as clauses (A) and (B), respectively, and by adding at the end the following:

‘‘(2) The Secretary shall provide, at least 10 days from the date of presentation of the report of conditions or practices identified in paragraph (1), for the person receiving such report to respond. The Secretary shall take no regulatory action against a person or article identified in such a report until completing a review of such response which is timely submitted to the Secretary, except the Secretary may take immediate action when the Secretary finds that there is a reasonable probability that a device intended for human use would cause serious, adverse health consequences or death or that any regulated article

could present an unreasonable and substantial risk of injury or illness to the public health. The Secretary shall provide to the regulated person, within 30 days of receiving a response to the report identified in paragraph (1), a written detailed assessment of the response.

''(3) At the time an accredited person completes an inspection under the authority of this section and section 712, such person shall identify in writing to the person subject to the inspection each condition or practice observed during such inspection which suggests a deviation from requirements of this Act. However, such accredited person shall immediately submit to the Secretary the findings of the inspection when the device to which such findings relate is intended for human use and presents a reasonable probability that such device would cause serious, adverse health consequences or death or that such device could present an unreasonable and substantial risk of injury or illness to the public unless the person subject to the inspection—

''(A) immediately ceases distribution of the device;

''(B) immediately notifies health professionals and device user facilities to instruct such professionals and facilities to cease use of the device; and

''(C) immediately undertakes all corrections identified by the accredited person.

When such compliance is complete, the accredited person shall provide the inspected person a certification of compliance which includes the dates of inspections, a statement that the inspected facility is in compliance with the requirements of section 520(f), the date the compliance was achieved at the facility, and the signature of the accredited person attesting to the finding that the inspected facility is in good manufacturing practices compliance as defined by such section. When an accredited person has certified compliance with good manufacturing practices requirements and provided the Secretary with a copy of the certification within 10 days of its being made, the Secretary may not perform a good manufacturing practices inspection of the person subject to an inspection for a period of 2 years after the date of the certification unless justified by good cause.''; and

(5) in subsection (c), by striking ''or employee'' and inserting '', employee, or accredited person'';

(6) in subsection (e), by striking ''or employee'' each place it occurs and inserting '', employee, or accredited person''; and

(7) by adding at the end the following:

''(f) Persons duly designated by the Secretary to conduct inspections under this section shall not request any information not permitted under subsections (a) and (e) unless such person states with specificity and in writing the identification of the information subject to the request, the reason for the request, and that the written request seeks to obtain information not required to be produced under this section. Such request shall not include information related to sales (other than distribution), personnel, or pricing data.''.

SEC. 18. USE OF SCIENTIFIC AND MEDICAL INFORMATION.

Section 502(f) (21 U.S.C. 352(f)) is amended by adding at the end the following: ''The dissemination of medical texts, articles from peer-reviewed scientific publications, information from Federal Government agencies, and presentations at medical and scientific meetings shall not form a basis to require adequate directions for use under clause (1) or information for use (or the equivalent thereof) under any exemption to clause (1) and shall not form a basis to require the filing of a report required under section 510(k) or the filing of an application under section 505 or 515 unless such person, in addition to disseminating the above-referenced information, encourages the unapproved use of a legally marketed device through labeling, advertising, or other means of promotion. Mere

knowledge that a legally available device is used by licensed practitioners for the treatment or diagnosis of diseases or conditions in individual patients shall not form a basis to require adequate directions for use under clause (1), or information for use (or the equivalent thereof) under any exemption to clause (1), and shall not form a basis to require either the filing of a notification required under section 510(k) or an application under section 515. The Secretary shall not consider the dissemination of medical texts, articles from peer review scientific publications, information from Federal Government agencies, presentations at medical and scientific meetings, and displays at trade shows relating to a device which is investigational within the meaning of section 520(g) to be activities prohibited under published regulations of the Secretary unless the sponsor of an investigation for the device, or an agent of such sponsor, in addition to the aforementioned activities encourages the use of a device.''.

SEC. 19. REPORTS.

(a) EXCLUSION OF REPORTS BY DISTRIBUTORS.—Section 519 (21 U.S.C. 360i) is amended—

(1) in subsection (a), by striking ''manufacturer, importer, or distributor'' and inserting ''manufacturer or importer'';

(2) in paragraph (4) of subsection (a), by striking ''manufacturer, importer, or distributor'' and inserting ''manufacturer or importer'';

(3) in paragraph (8) of subsection (a), by striking ''manufacturer, importer, or distributor'' each place it occurs and inserting ''manufacturer or importer'';

(4) in paragraph (8)(B)(i) of subsection (a), by striking ''manufacturer, importer, or distributor'' and inserting ''manufacturer or importer''; and

(5) in subsection (a), by inserting ''and'' at the end of paragraph (7), by striking ''; and'' at the end of paragraph (8) and inserting a period, by striking paragraph (9).

(b) LIMITATION ON MALFUNCTION REPORTING.—Section 519(a)(1)(B) (21 U.S.C. 360i(a)(1)(B)) is amended by inserting before the semicolon the following: '', except that information that a device failed to perform as labeled or in an acceptable manner shall not constitute a malfunction within the meaning of this subparagraph when the available information clearly shows that the device failure was caused by improper servicing or maintenance to the device as determined exclusively by the device labeling which was provided to the user''.

(c) REGULATIONS.—Within 120 days after the date of enactment of this section, the Secretary of Health and Human Services shall delete the regulations of the Secretary appearing in part 800 of title 21 of the Code of Federal Regulations, requiring distributors, other than importers, to make reports of deaths, serious injuries or illness, and malfunctions related to devices and shall amend the regulations of the Secretary to conform to the change in malfunction reporting in section 519(a)(1)(B) of the Federal Food, Drug, and Cosmetic Act.

(d) USER REPORTS, CERTIFICATIONS, AND REPORTS OF REMOVALS AND CORRECTIONS.—Section 519 (21 U.S.C. 360i) is amended by repealing subsections (b), (d), and (f).

SEC. 20. G.M.P. AND DEVICE REPORTS.

Section 303(c) is amended by inserting before the period at the end the following: ''; or (6) for having violated subsection (a), (b), (c), or (k) of section 301 by failure to comply with either section 502(t)(2) or 501(h), or for having violated section 301(g)(1)(B) by failing to furnish material or information required under section 519(a), if such person acted in good faith, had no reason to believe that the person's acts violated the law, and had no prior notice from the Secretary that the acts constituted violations of the Act''.

SEC. 21. CIVIL PENALTIES.

Section 303 (21 U.S.C. 333) is amended—

(1) in subsection (g)(2)(C), by adding at the end the following: ''Additionally, the Secretary may direct a person subject to a civil penalty under paragraph (1) to apply the monetary amount of the penalty to the correction of the violation that resulted in the penalty assessment in lieu of paying such moneys into the United States Treasury. Any person who undertakes correction of violations under this subparagraph must submit an independent audit of the corrections to the Secretary within a time specified in the civil penalty order. A failure to submit such independent audit in a timely manner shall be deemed to be a violation of this Act.''; and

(2) in subsection (f)(2), by adding at the end ''The person accused of a violation under this subsection shall be entitled to reasonable discovery in accordance with the Federal Rules of Civil Procedure.''.

SEC. 22. INFORMATION SYSTEM.

Chapter IX, as amended by section 9, is amended by adding at the end the following:

''SEC. 907. INFORMATION SYSTEM.

''The Secretary shall establish and maintain an information system to track the status and progress of each

application or submission (including a petition, notification, or other similar form of request) submitted to the Food and Drug Administration requesting agency action. The system shall permit access by the applicant.''.

SEC. 23. ENVIRONMENTAL IMPACT REVIEW.

Chapter VII, as amended by section 13, is amended by adding at the end the following:

''SUBCHAPTER E—ENVIRONMENTAL IMPACT REVIEW

''SEC. 745. ENVIRONMENTAL IMPACT REVIEW.

''No action by the Secretary pursuant to this Act shall require, with respect to an action to be taken by the Secretary, the preparation of an environmental impact statement under the National Environmental Policy Act of 1969 or an environmental assessment unless the Secretary demonstrates that—

''(1) because of extraordinary circumstances the action will have a significant effect on the human environment; and

''(2) the consideration of such significant effect on the human environment will directly affect the Secretary's decision on the action.''

SEC. 24. INFORMAL AGENCY STATEMENTS.

Section 701 (21 U.S.C. 371) is amended by adding at the end the following:

''(h)(1) The Secretary shall not rely upon informal agency statements, including guidance documents, policy statements, points to consider documents, or any other statements that have not been promulgated in accordance with the rulemaking requirements of chapter V of title 5, United States Code, to require any action be taken to satisfy a requirement of this Act.

''(2) The Secretary shall publish notice in the Federal Register of the availability to the public of each type of statement identified in paragraph (1). Additionally, the Secretary shall undertake to make available all such statements by electronic or other similar means.

SEC. 25. EDUCATION AND RESEARCH; PRACTICE OF MEDICINE.

Chapter IX, as amended by section 23, is amended by adding at the end the following:

''SEC. 908. EDUCATION AND RESEARCH.

''(a) EDUCATION.—The Secretary shall conduct training and education programs for the employees of the Food and Drug Administration relating to the regulatory responsibilities and policies established by this Act, including programs for scientific training, administrative process and procedure, and integrity issues.

''(b) RESEARCH.—The Secretary, acting through the Food and Drug Administration, may conduct or contract

for scientific research only if it is directly related to the implementation of this Act.

"SEC. 909. PRACTICE OF MEDICINE.

"Nothing in this Act shall be construed to limit or interfere with the authority of a health care practitioner, licensed by law to administer drugs and devices, to prescribe or administer any legally marketed drug or device to a patient for any condition or disease within a legitimate health care practitioner-patient relationship.".

SEC. 26. PUBLICATION OF NOTICE OF DEVIATION.

Section 705 (21 U.S.C 375) is amended by adding at the end the following:

"(c) The Secretary may make public or communicate to any person outside the Food and Drug Administration any information regarding a notice which informs a regulated person of a purported deviation from a requirement of this Act only after the Secretary has completed the investigation of such deviation.".

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