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H. R. 1165

To amend the Federal Food, Drug, and Cosmetic Act to establish additional authorities to ensure the safe and effective use of drugs, to establish whistleblower protections for certain individuals, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 16, 2007

Mr. MARKEY introduced the following bill; which was referred to the
Committee on Energy and Commerce

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to establish additional authorities to ensure the safe and effective use of drugs, to establish whistleblower protections for certain individuals, 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,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Swift Approval, Full
5 Evaluation Drug Act” or the “SAFE Drug Act”.

1 **SEC. 2. POSTMARKET STUDIES REGARDING DRUG SAFETY;**
2 **POSTMARKET LABELING CHANGES.**

3 (a) POSTMARKET ORDERS REGARDING STUDIES.—
4 Chapter V of the Federal Food, Drug, and Cosmetic Act
5 (21 U.S.C. 351 et seq.) is amended by inserting after sec-
6 tion 505B the following section:

7 **“SEC. 505C. POSTMARKET STUDIES REGARDING DRUG**
8 **SAFETY.**

9 “(a) POSTMARKET ORDERS.—Within 30 days after
10 receiving evidence of a significant issue regarding the safe-
11 ty or lack of effectiveness of an approved drug, including
12 reports of adverse events, studies conducted or reports re-
13 leased by the Food and Drug Administration, the National
14 Institutes of Health, the Agency for Healthcare Research
15 and Quality, or another relevant agency, actions or reports
16 by regulatory agencies in foreign countries, or studies or
17 case reports published in scientific or academic journals,
18 the Secretary, after providing public notice of the signifi-
19 cant safety or effectiveness issue, may order the holder
20 of the approved application to conduct a study or studies
21 to address the issues involved. Each such notice and order
22 shall be published in the Federal Register.

23 “(b) RESTRICTIONS ON USE.—

24 “(1) IN GENERAL.—An order under subsection
25 (a) with respect to an approved drug may, during
26 the period in which the study involved is conducted,

1 establish restrictions on the distribution or use of
2 the drug if the Secretary determines that such re-
3 strictions are necessary to ensure the safe and effec-
4 tive use of the drug during such period.

5 “(2) CERTAIN AUTHORITIES.—Restrictions that
6 may be established by the Secretary under para-
7 graph (1) with respect to a drug include the fol-
8 lowing:

9 “(A) Restricting distribution to certain fa-
10 cilities or physicians with special training or ex-
11 perience.

12 “(B) Conditioning distribution on the per-
13 formance of specified medical procedures.

14 “(C) Restricting direct-to-consumer adver-
15 tisements for the drug.

16 “(3) TERMINATION.—The Secretary may, on
17 the basis of the results of a study ordered pursuant
18 to subsection (a) or other evidence, continue the re-
19 strictions under paragraph (1), terminate restric-
20 tions established, or establish different restrictions,
21 as necessary to ensure the safe use of the drug. The
22 Secretary shall notify the sponsor of the decision to
23 extend, terminate, or change the restrictions no later
24 than 30 days after the date on which the results of
25 the study involved are submitted to the Secretary.

1 “(c) DEFINITION.—For purposes of this section, the
2 term ‘approved drug’ means a drug for which an approved
3 application under section 505 is in effect or for which a
4 biologics license under section 351 of the Public Health
5 Service Act is in effect.”.

6 (b) NEW DRUG APPLICATIONS; POSTMARKET STUD-
7 IES PURSUANT TO ACCELERATED APPROVAL.—Section
8 505 of the Federal Food, Drug, and Cosmetic Act (21
9 U.S.C. 355) is amended by adding at the end the following
10 subsection:

11 “(o)(1) The Secretary shall amend subpart H of part
12 314 of title 21, Code of Federal Regulations, to establish
13 the following policies:

14 “(A) As a condition of the approval under such
15 subpart of a new drug on or after the date of the
16 enactment of the SAFE Drug Act, the Secretary
17 shall require that one or more postmarket studies of
18 the drug be conducted.

19 “(B) The Secretary may not approve the appli-
20 cation involved unless—

21 “(i) the sponsor has submitted to the Sec-
22 retary the protocols for each such study;

23 “(ii) the Secretary has approved the proto-
24 cols; and

1 “(iii) the Secretary and the sponsor have
2 agreed on a timeframe, including designated
3 milestones, for the prompt completion of the
4 study, which timeframe assumes due diligence
5 by the sponsor in conducting the study.

6 “(C) The Secretary shall require that, after the
7 application is approved under such subpart and the
8 drug enters commercial distribution, the drug be
9 marketed in accordance with the following:

10 “(i) The distribution and use of the drug
11 shall be restricted in accordance with such sub-
12 part.

13 “(ii) Until the Secretary determines that
14 the sponsor has fulfilled its commitments under
15 subparagraphs (A) and (B), the labeling of the
16 drug shall bear—

17 “(I) a statement that the Food and
18 Drug Administration is requiring a study
19 or studies to confirm the safety and effec-
20 tiveness of the drug; and

21 “(II) a statement providing a clear
22 and concise summary of the outstanding
23 issues or questions to be addressed in such
24 required studies.

1 “(iii) Until the Secretary determines that
2 the sponsor has fulfilled its commitments under
3 subparagraphs (A) and (B), the labeling of the
4 drug shall bear a statement providing as fol-
5 lows: ‘This product received conditional ap-
6 proval from the FDA under its accelerated ap-
7 proval process. It will not receive full approval
8 until completion of further testing to confirm
9 safety and/or efficacy. For further information
10 please contact your physician.’.

11 “(iv) Direct-to-consumer advertisements
12 for the drug shall be restricted until—

13 “(I) the Secretary determines that the
14 sponsor has fulfilled its commitments
15 under subparagraphs (A) and (B); and

16 “(II) the drug has been approved
17 under such part 314 independently of sub-
18 part H of such part.

19 “(2) The Secretary shall amend part 314 of title 21,
20 Code of Federal Regulations, to establish the following
21 policies regarding postmarket studies that, on or after the
22 date of the enactment of the SAFE Drug Act, are required
23 pursuant to approval of a new drug under subpart H of
24 such part or under section 506(b)(2) of this Act:

1 “(A) If a required study is not completed by
2 two years after the date on which the new drug was
3 so approved, the Secretary shall, promptly after the
4 expiration of such period, convene a public meeting
5 of the appropriate advisory committee to review the
6 progress of the study. Such review shall include the
7 assessment of compliance with the timeframe for
8 prompt completion of the study as agreed to by the
9 company and the Secretary under paragraph
10 (1)(B)(iii) or under section 506(b)(2) (as the case
11 may be), the quality of study conduct, rates of en-
12 rollment overall and by institution, the barriers to
13 progress, and whether the sponsor is acting with due
14 diligence. At the meeting, the advisory committee
15 shall determine whether it is in the best interest of
16 the public to allow the sponsor to continue mar-
17 keting the drug until the study is completed or
18 whether it is in the best interest of the public to sus-
19 pend the commercial marketing of the drug until the
20 study is completed.

21 “(B) If the drug was approved on the basis of
22 animal efficacy data because human efficacy studies
23 are not ethical or feasible, the holder of the ap-
24 proved application shall conduct studies when ethical

1 and feasible to verify and describe clinical benefit
2 and to assess the product’s safety and effectiveness.

3 “(C) If the results of a completed study that
4 was so required are inconclusive or the risk-to-ben-
5 efit profile cannot be positively established, the Sec-
6 retary shall withdraw the product for commercial
7 distribution. If a required study is not completed by
8 five years after the date of approval, the results of
9 the study are presumed to be inconclusive. The prod-
10 uct may only be made available to a patient who—

11 “(i) according to a health care professional
12 has previously benefitted from the product; and

13 “(ii) has signed a statement of informed
14 consent that—

15 “(I) states that the patient has re-
16 ceived notice from the sponsor that the re-
17 sults of completed studies on the product
18 have proven to be inconclusive or the risk-
19 to-benefit profile cannot be positively es-
20 tablished; and

21 “(II) identifies the risks of continuing
22 the product.

23 Otherwise the product shall be unavailable except in
24 a research setting until the product can meet the

1 same standard of safety and effectiveness that exists
2 for full approval.”.

3 (c) ENFORCEMENT REGARDING POSTMARKET STUD-
4 IES.—

5 (1) MISBRANDING.—Section 502 of the Federal
6 Food, Drug, and Cosmetic Act (21 U.S.C. 352) is
7 amended by adding at the end the following:

8 “(y) If it is a drug with respect to which there is
9 a failure to comply with a requirement under section
10 505(o)(1), an order under section 505C, or a requirement
11 under section 506(b)(2).”.

12 (2) CIVIL PENALTIES.—Section 303 of the Fed-
13 eral Food, Drug, and Cosmetic Act (21 U.S.C. 331)
14 is amended by adding at the end the following:

15 “(g)(1)(A) Any person who violates section 301(a),
16 301(b), or 301(c) by reason of section 502(y) shall be sub-
17 ject to a civil penalty of not more than 100 percent of
18 the gross profits received by the sponsor from sales of the
19 drug, or \$1,000,000, whichever is greater, subject to sub-
20 paragraph (B).

21 “(B) If any harm to a consumer occurs as a result
22 of a violation referred to in subparagraph (A), the person
23 involved may be subject to a civil penalty of not more than
24 an amount equal to 300 percent of the gross profits re-
25 ceived by the person, or \$3,000,000, whichever is greater.

1 “(2) Any person who fails to act with due diligence
2 to complete a postmarket study required under section
3 506(b)(2), or under subpart H of part 314 of title 21,
4 Code of Federal Regulations, shall be subject to a civil
5 penalty of not more than the amount that applies under
6 subparagraph (A) or subparagraph (B) of paragraph (1)
7 (as the case may be) for a violation referred to in such
8 paragraph. The Secretary shall by regulation define the
9 term ‘due diligence’ for purposes of this paragraph.

10 “(3) The provisions of paragraphs (3) through (5)
11 of subsection (f) apply to a civil penalty under subpara-
12 graph (A) or (B) of paragraph (1) or under paragraph
13 (2) to the same extent and in the same manner as such
14 provisions apply to a civil penalty under paragraph (1) or
15 (2) of such subsection.”.

16 (d) POSTMARKET LABELING CHANGES.—Section
17 502 of the Federal Food, Drug, and Cosmetic Act, as
18 amended by subsection (c)(1) of this section, is amended
19 by adding at the end the following:

20 “(z) If it is a drug and the manufacturer of the
21 drug or product fails to make changes to a product’s
22 labeling in compliance with an order of the Sec-
23 retary, issued on the basis of clinical evidence (in-
24 cluding studies submitted to the Secretary, an anal-
25 ysis of adverse events reports, studies conducted or

1 reports released by the Food and Drug Administra-
2 tion, the National Institutes of Health, the Agency
3 for Healthcare Research and Quality, or another rel-
4 evant agency, actions or reports by regulatory agen-
5 cies in foreign countries, or studies published in sci-
6 entific or academic journals), that the labeling of the
7 drug be modified to include specific wording re-
8 quired by the Secretary to ensure the safe and effec-
9 tive use of the drug.”.

10 (e) **RULE OF CONSTRUCTION REGARDING CERTAIN**
11 **PEDIATRIC STUDIES.**—The amendments made by this
12 section establish authorities in addition to, and not in lieu
13 of—

14 (1) the program under section 505A of the
15 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
16 355a); and

17 (2) authorities under section 505B of such Act
18 (21 U.S.C. 355b).

19 **SEC. 3. WHISTLEBLOWER PROTECTIONS.**

20 (a) **PROHIBITION.**—It shall be unlawful for any per-
21 son to discharge, demote, suspend, reprimand, investigate,
22 or take or fail to take any other personnel action that in
23 any manner discriminates against any covered individual,
24 or in any other manner discriminate against any covered
25 individual (including by a denial, suspension, or revocation

1 of a security clearance or by any other security access de-
2 termination, or by denial of award of a Federal contract
3 or subcontract), or to threaten or recommend the dis-
4 charge, demotion, suspension, reprimand, investigation,
5 other personnel action (or rejection of such action) that
6 in any manner discriminates against any covered indi-
7 vidual, or other manner of discrimination if such action,
8 discrimination, or recommendation is due, in whole or in
9 part, to any lawful act done, perceived to have been done,
10 or intended to be done by the covered individual—

11 (1) to provide information, cause information to
12 be provided, or otherwise assist in an investigation
13 or proceeding regarding any conduct which the cov-
14 ered individual reasonably believes constitutes evi-
15 dence of a violation of any law, rule, or regulation,
16 a substantial and specific threat to public health or
17 safety, an abuse of authority, fraud, waste, or mis-
18 management of public funds, censorship, distortion,
19 or suppression of scientific information, research, or
20 analysis, or the willful disclosure of false, mis-
21 leading, or incomplete scientific information, if the
22 information or assistance is provided to or the inves-
23 tigation or proceeding is conducted by—

24 (A) a Federal, State, or local regulatory or
25 law enforcement agency (including an office of

1 Inspector General under the Inspector General
2 Act of 1978);

3 (B) any Member of Congress, any com-
4 mittee of Congress, or the Government Ac-
5 countability Office;

6 (C) any person with supervisory or mana-
7 gerial authority over the covered individual (or
8 any other person who has the authority to in-
9 vestigate, discover, or terminate misconduct); or

10 (D) a potential witness to or other person
11 affected by or aware of the conduct described in
12 this section who has the authority to inves-
13 tigate, discover, or terminate misconduct;

14 (2) to file, cause to be filed, testify, participate
15 in, or otherwise assist in a proceeding or action filed
16 or about to be filed relating to an alleged violation
17 of any law, rule, or regulation; or

18 (3) to refuse to violate or assist in the violation
19 of any law, rule, or regulation.

20 (b) ENFORCEMENT ACTION.—

21 (1) IN GENERAL.—A covered individual who al-
22 leges discharge or other discrimination by any per-
23 son in violation of subsection (a) may seek relief
24 under paragraph (3) by—

1 (A) filing a complaint with the Secretary of
2 Labor; or

3 (B) if the Secretary has not issued a final
4 decision within 180 days after the filing of the
5 complaint and there is no showing that such
6 delay is due to the bad faith of the claimant,
7 bringing an action at law or equity for de novo
8 review in the appropriate district court of the
9 United States, which shall have jurisdiction
10 over such an action without regard to the
11 amount in controversy.

12 (2) PROCEDURE.—

13 (A) IN GENERAL.—An action under para-
14 graph (1)(A) shall be governed under the rules
15 and procedures set forth in section 42121(b) of
16 title 49, United States Code.

17 (B) EXCEPTION.—Notification made under
18 section 42121(b)(1) of title 49, United States
19 Code, shall be made—

20 (i) to the person named in the com-
21 plaint; and

22 (ii) to the person's employer.

23 (C) BURDENS OF PROOF.—An action
24 brought under paragraph (1)(B) shall be gov-
25 erned by the legal burdens of proof set forth in

1 section 42121(b) of title 49, United States
2 Code.

3 (D) STATUTE OF LIMITATIONS.—An action
4 under paragraph (1) shall be commenced not
5 later than 6 years after the date on which the
6 violation occurs.

7 (3) REMEDIES.—

8 (A) IN GENERAL.—A covered individual
9 prevailing in any action under this subsection
10 shall be entitled to all relief appropriate to
11 make the covered individual whole.

12 (B) DAMAGES.—Relief for any action
13 under this subsection shall include—

14 (i) reinstatement with the same se-
15 niority status and employment grade or
16 pay level (or the equivalent) that the cov-
17 ered individual would have had, but for the
18 discrimination;

19 (ii) compensatory damages, including
20 the amount of any back pay, with interest;

21 (iii) compensation for any special
22 damages sustained as a result of the dis-
23 crimination, including litigation costs, ex-
24 pert witness fees, and reasonable attorney
25 fees; and

1 (iv) punitive damages in an amount
2 not to exceed the greater of 3 times the
3 amount of any monetary damages awarded
4 under this section (apart from this para-
5 graph) or \$5,000,000.

6 (c) CRIMINAL PENALTIES.—

7 (1) IN GENERAL.—Any person who violates
8 subsection (a) shall be fined under title 18 of the
9 United States Code, imprisoned not more than 10
10 years, or both.

11 (2) REPORTING REQUIREMENTS.—The Attor-
12 ney General of the United States shall (based on
13 such periodic reports and other information from the
14 Department of Labor as the Attorney General may
15 require) submit to the Congress an annual report on
16 the enforcement of paragraph (1). Each such report
17 shall—

18 (A) identify each case in which formal
19 charges under paragraph (1) were brought;

20 (B) describe the status or disposition of
21 each such case; and

22 (C) in any action under subsection (b) in
23 which the covered individual was the prevailing
24 party or the substantially prevailing party, indi-
25 cate whether or not any formal charges under

1 paragraph (1) have been brought and, if not,
2 the reasons therefor.

3 (d) RIGHTS RETAINED BY COVERED INDIVIDUAL.—

4 Nothing in this section shall be deemed to diminish the
5 rights, privileges, or remedies of any covered individual
6 under any Federal or State law, or under any collective
7 bargaining agreement. The rights and remedies in this
8 section may not be waived by any agreement, policy, form,
9 or condition of employment.

10 (e) NOTIFICATION.—The provisions of this section
11 shall be prominently posted in any place of employment
12 to which this section applies.

13 (f) DEFINITIONS.—For purposes of this section:

14 (1) The term “covered individual” means an
15 employee or a contractor or subcontractor of the
16 Food and Drug Administration.

17 (2) The term “lawful” means not specifically
18 prohibited by law.

19 **SEC. 4. RIGHT TO PUBLISH.**

20 Subchapter E of chapter V of the Federal Food,
21 Drug, and Cosmetic Act (21 U.S.C. 360bbb et seq.) is
22 amended by adding at the end the following section:

23 **“SEC. 565. RIGHT TO PUBLISH.**

24 “Officers and employees of the Food and Drug Ad-
25 ministration, and individuals sponsored by such Adminis-

1 tration, may publish in peer-reviewed journals and other
2 scientific publications, and make oral presentations at pro-
3 fessional society meetings and other meetings of their
4 peers, unless publication or presentation of the data is
5 subject to Federal export control or national security laws
6 or regulations, or is proprietary information. The right to
7 publish or present such data cannot be waived by any
8 agreement, policy, form, or condition of employment.”.

9 **SEC. 5. PROVIDING FDA ADVISORY COMMITTEES WITH**
10 **COMPLETE INFORMATION.**

11 Subchapter E of chapter V of the Federal Food,
12 Drug, and Cosmetic Act, as amended by section 4 of this
13 Act, is amended by adding at the end the following section:

14 **“SEC. 566. PROVIDING ADVISORY COMMITTEES WITH COM-**
15 **plete INFORMATION.**

16 “(a) IN GENERAL.—In conjunction with any hearing
17 of an advisory committee of the Food and Drug Adminis-
18 tration, the Secretary shall, at the request of any officer
19 or employee of the Administration whose employment du-
20 ties relate to the topic of the hearing, allow the officer
21 or employee a reasonable amount of time to present to
22 the advisory committee information on such topic.

23 “(b) TIMING OF PRESENTATION.—An advisory com-
24 mittee shall provide a period of time to an officer or em-
25 ployee for a presentation under subsection (a) that is sepa-

1 rate from the period of time allotted to the public for the
2 hearing involved.”.

3 **SEC. 6. PRESERVING SCIENTIFIC INTEGRITY.**

4 Subchapter E of chapter V of the Federal Food,
5 Drug, and Cosmetic Act, as amended by section 5 of this
6 Act, is amended by adding at the end the following section:

7 **“SEC. 567. PRESERVING SCIENTIFIC INTEGRITY.**

8 “(a) PROHIBITION.—An officer or employee of the
9 Food and Drug Administration shall not direct any other
10 officer or employee of the Administration—

11 “(1) to censor, distort, or suppress any sci-
12 entific research, analysis, opinion, or recommenda-
13 tion; or

14 “(2) to willfully disclose scientific information
15 that is false, misleading, or incomplete.

16 “(b) APPROPRIATE DISCIPLINARY ACTION.—The
17 Secretary shall subject any officer or employee who vio-
18 lates subsection (a) to appropriate disciplinary action
19 (which may include dismissal).

20 “(c) REPORTING BY IG.—Not less than 1 year after
21 the date of the enactment of this section, and annually
22 thereafter, the Inspector General of the Department of
23 Health and Human Services shall submit a report to the
24 Congress—

1 “(1) identifying each disciplinary action under
2 subsection (b) during the preceding 12 months; and

3 “(2) describing the circumstances of each such
4 disciplinary action.”.

5 **SEC. 7. TRANSPARENCY OF APPROVAL DECISIONS.**

6 Section 505 of the Federal Food, Drug, and Cosmetic
7 Act, as amended by section 2(b) of this Act, is further
8 amended by adding at the end the following:

9 “(p) **TRANSPARENCY OF APPROVAL DECISIONS.—**

10 “(1) **SUMMARY STATEMENT.—**Not later than
11 48 hours after the approval of an application filed
12 under subsection (b) or (j), the Secretary shall pub-
13 lish a summary statement of the scientific basis for
14 such approval and how the final decision balanced
15 the risks and benefits.

16 “(2) **CONTENTS.—**A summary statement under
17 paragraph (1) shall be dated and shall include the
18 following:

19 “(A) A summary of the factual, scientific,
20 and related issues considered during the ap-
21 proval process, including—

22 “(i) an explanation of the risks and
23 the benefits of the drug involved; and

24 “(ii) the scientific rationale for the
25 final decision.

1 “(B) Identification by name of each officer
2 or employee of the Food and Drug Administra-
3 tion who participated in the decision to approve
4 the application.

5 “(C) A description of—

6 “(i) any significant controversy or dif-
7 ference of opinion between two or more of-
8 ficers or employees described in subpara-
9 graph (B) relating to the decision to ap-
10 prove the application; and

11 “(ii) the resolution of each such con-
12 troversy or difference of opinion.

13 “(3) DISSENTING AND OTHER VIEWS.—Any of-
14 ficer or employee of the Food and Drug Administra-
15 tion who participates in the decision to approve an
16 application filed under subsection (b) or (j) may sub-
17 mit a statement of views on the matter for inclusion
18 in the applicable summary statement. Upon receipt
19 of such a statement of views, the Secretary shall at-
20 tach the statement of views, without alteration, as
21 an addendum to the summary statement.

22 “(4) SUBSEQUENT CHANGES.—After publica-
23 tion of a summary statement under this subsection,
24 the Secretary—

1 “(A) shall not alter the text of the sum-
2 mary statement; and

3 “(B) may prepare a description of changes
4 to the summary statement in a separate docu-
5 ment and attach the document as an addendum
6 to the summary statement.

7 “(5) CONFIDENTIAL INFORMATION.—This sub-
8 section does not authorize the disclosure of any
9 trade secret or privileged or confidential commercial
10 or financial information described in section
11 552(b)(4) of title 5, United States Code, unless the
12 Secretary determines that such disclosure is nec-
13 essary to protect the public health.”.

14 **SEC. 8. BIENNIAL REPORTS ON APPROVED APPLICATIONS**
15 **SUPPORTED BY NON-INFERIORITY STUDIES.**

16 Section 505 of the Federal Food, Drug, and Cosmetic
17 Act, as amended by section 7 of this Act, is amended by
18 adding at the end the following subsection:

19 “(q) BIENNIAL REPORTS ON APPROVED APPLICA-
20 TIONS SUPPORTED BY NON-INFERIORITY STUDIES.—The
21 Secretary shall submit to the Congress biennial reports on
22 approved applications under subsection (b) (including sup-
23 plemental applications) that have been supported by data
24 from one or more non-inferiurity studies. For each such

1 application, the report shall include the following informa-
2 tion:

3 “(1) The name of the drug listed in application.

4 “(2) The name of the sponsor.

5 “(3) The date of the approval.

6 “(4) The name of each drug used as an active
7 control in the non-inferiority studies used to support
8 the application.

9 “(5) The indication studied.

10 “(6) The primary and secondary endpoints of
11 the non-inferiority studies.

12 “(7) The margins used in such studies.

13 “(8) The explanation required by section
14 314.126(b)(2)(iv) of title 21, Code of Federal Regu-
15 lations, as to why the drugs should be considered ef-
16 fective in the study.”.

17 **SEC. 9. BIENNIAL REPORTS REGARDING POSTMARKET**
18 **STUDIES.**

19 Section 505 of the Federal Food, Drug, and Cosmetic
20 Act, as amended by section 8 of this Act, is amended by
21 adding at the end the following subsection:

22 “(r) BIENNIAL REPORTS REGARDING POSTMARKET
23 STUDIES.—The Secretary shall submit to the Congress bi-
24 annual reports that provide the following information:

1 “(1) The number of enforcement actions taken
2 to ensure that sponsors are complying with the re-
3 quirements to complete postmarketing studies under
4 subsection (o) and sections 505C and 506(b)(2), to-
5 gether with a description of each such action.

6 “(2) The measures taken by the Secretary to
7 establish a system to ensure effective monitoring of
8 the status of all such postmarketing studies, to-
9 gether with a description of the status of that sys-
10 tem.

11 “(3) The measures taken by the Secretary to
12 develop a system to track information about ongoing
13 postmarketing safety issues, together with a descrip-
14 tion of the status of that system.”.

○