

104TH CONGRESS
1ST SESSION

S. 1477

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.

IN THE SENATE OF THE UNITED STATES

DECEMBER 13, 1995

Mrs. KASSEBAUM introduced the following bill; which was read twice and referred to the Committee on Labor and Human Resources

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,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Food and Drug Ad-
5 ministration Performance and Accountability Act of
6 1995”.

1 **TITLE I—MISSION AND**
 2 **ACCOUNTABILITY**

3 **SEC. 101. SHORT TITLE.**

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

6 **SEC. 102. THE MISSION OF THE FOOD AND DRUG ADMINIS-**
 7 **TRATION.**

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

12 “(1) facilitating the rapid and efficient develop-
 13 ment and availability of products subject to its regu-
 14 lation;

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

17 “(3) enforcing the applicable statutes and regu-
 18 lations in a timely, fair, consistent, and decisive
 19 manner.”.

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

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

23 “(3) PERFORMANCE STANDARDS AND RE-
 24 VIEW.—Within 180 days after the date of enactment
 25 of this paragraph, the Commissioner, after consulta-

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

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

22 “(i) for a serious, life-threatening, or
23 seriously debilitating disease or condition;
24 or

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

3 “(I) provides therapy not avail-
4 able from other approved therapy; or

5 “(II) offers significant improve-
6 ment over other approved therapy;

7 “(B) reduce backlogs on all applications
8 with the objective of eliminating all backlogs by
9 January 1, 2000; and

10 “(C) establish a schedule to bring the Ad-
11 ministration into full compliance by July 1,
12 1998, with the time periods specified in this Act
13 for action on all applications.

14 For applications for which there is no statutory time
15 period, the applicable time period for action shall be
16 180 days. The Commissioner shall prepare and pub-
17 lish in the Federal Register for public comment an
18 annual report comparing the performance of the Ad-
19 ministration with the applicable performance stand-
20 ards, analyzing any failure to achieve any of the
21 standards, and setting forth a plan to achieve com-
22 pliance with the standards that have not been met.”.

23 **SEC. 104. INFORMATION SYSTEM.**

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

1 **“SEC. 906. INFORMATION SYSTEM.**

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

8 **SEC. 105. POLICY STATEMENTS.**

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

10 (1) by striking “(a) The” and inserting “(a)(1)
11 The”; and

12 (2) by adding at the end thereof the following
13 new paragraph:

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

24 “(B) The Secretary shall establish a procedure for
25 the formal publication and compilation of all policy state-
26 ments of general applicability (including any guideline,

1 points-to-consider, protocol, recommendation, or similar
2 document regardless of the form or designation) that are
3 not promulgated as regulations.”.

4 **SEC. 106. ADVISORY COMMITTEES.**

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

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

8 (2) by adding at the end thereof the following
9 new subsections:

10 “(b) DELEGATION OF APPOINTMENT AUTHORITY.—

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

17 “(c) MEMBERSHIP AND MEETING REQUIREMENTS.—

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

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

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

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

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

19 “(6) FREQUENCY OF MEETINGS.—The Sec-
20 retary shall take whatever action is necessary to en-
21 sure that regular meetings are held by scientific re-
22 view groups, at appropriate intervals and for a suffi-
23 cient length of time, so that any matter to be re-
24 viewed by any scientific review group shall be pre-
25 sented to the group not more than 90 days after the

1 matter is ready for review by the group. The meet-
2 ings shall occur not less than 6 times each year un-
3 less there are compelling reasons for fewer meetings.

4 “(d) PERSONS INVOLVEMENT WITH REVIEW
5 GROUPS.—

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

9 “(A) the submission of data and informa-
10 tion to, and contact and discussion with, a sci-
11 entific review group;

12 “(B) the participation of the persons at
13 meetings of the group; and

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

19 “(2) SUBMISSION OF INFORMATION TO FDA.—
20 In a case in which a scientific review group reviews
21 an application (including a petition, notification, or
22 other similar request), all related data and informa-
23 tion that are not available for public disclosure
24 under section 552 of title 5, United States Code,
25 shall be exchanged between the applicant and the

1 Food and Drug Administration at the time the data
2 and information are submitted to the scientific re-
3 view group but shall not otherwise be publicly dis-
4 closed.

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

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

20 “(f) DEFINITION.—For purposes of this section, the
21 term ‘center director’ means a director of a center within
22 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 II—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(c)(1) (21 U.S.C.
15 355(c)(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 (c). 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 “(c) 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 organization 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 “(c) 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 “(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 (e)(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(e)(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
13 reimportation of the exported drug or device would
14 present an imminent hazard to the public health and
15 safety of the United States and the only means of
16 limiting the hazard is to prohibit the export of the
17 drug or device; 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:’, 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-

1 proved application under paragraph (2) is ex-
2 porting a drug to a country for which the Sec-
3 retary cannot make a finding under paragraph
4 (1)(A), and that the export of the drug presents
5 an imminent hazard, the Secretary shall imme-
6 diately prohibit the export of the drug to such
7 country, provide the holder prompt notice of the
8 determination, and afford the holder an oppor-
9 tunity for an expedited hearing. A determina-
10 tion by the Secretary under this subparagraph
11 may not be stayed pending final action by a re-
12 viewing court. The authority conferred by this
13 subparagraph shall not be delegated by the Sec-
14 retary.

15 “(D) LIMITATION ON THE EXPORTATION
16 OF OTHER DRUGS BY A HOLDER.—If the Sec-
17 retary receives credible evidence that the holder
18 of an application approved under paragraph (2)
19 is exporting a drug to a country for which the
20 Secretary cannot make a finding under para-
21 graph (1)(A), the Secretary shall give the hold-
22 er 60 days to provide information to the Sec-
23 retary respecting such evidence and shall pro-
24 vide the holder an opportunity for an informal
25 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(c) (21 U.S.C. 355(c)) 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 (e)(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 351 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 (1) ensure the safety and effectiveness of the
2 products under section 351 of the Public Health
3 Service Act (42 U.S.C. 262 et seq.); and

4 (2) take in account whether regulation of facili-
5 ties in which the products are manufactured or proc-
6 essed is sufficient to ensure safety and effectiveness
7 of the products.

8 **TITLE VII—DEVICE** 9 **REGULATORY REFORM**

10 **SEC. 701. SHORT TITLE.**

11 This title may be cited as the “Medical Device Re-
12 form Act of 1995”.

13 **SEC. 702. PREMARKET NOTIFICATION.**

14 (a) EXEMPTION OF CERTAIN DEVICES.—Section 510
15 (21 U.S.C. 360) is amended—

16 (1) in subsection (k), by striking “intended for
17 human use” and inserting “intended for human use
18 (except a device that is classified into class I under
19 section 513 or 520 or a device that is classified into
20 class II under section 513 or 520, and is exempt
21 from the requirements of this subsection under sub-
22 section (l))”;

23 (2) by adding at the end of subsection (k) (as
24 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. 360c(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 sserting “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 (c).

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.”.

○

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