

104TH CONGRESS
2D SESSION

H. R. 3199

To amend the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act to facilitate the development and approval of new drugs and biological products, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

MARCH 29, 1996

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

A BILL

To amend the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act to facilitate the development and approval of new drugs and biological products, and for other purposes.

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

1 **SECTION 1. SHORT TITLE, REFERENCE, AND TABLE OF**
2 **CONTENTS.**

3 (a) **SHORT TITLE.**—This Act may be cited as the
4 “Drug and Biological Products Reform Act of 1996”.

5 (b) **REFERENCE.**—Whenever in this Act (other than
6 in sections 13 and 24) an amendment is expressed in
7 terms of an amendment to a section or other provision,
8 the reference shall be considered to be made to a section
9 or other provision of the Federal Food, Drug, and Cos-
10 metic Act (21 U.S.C. 321) et seq.) except as otherwise
11 specified.

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

- Sec. 1. Short title, reference, and table of contents.
- Sec. 2. FDA mission and annual report.
- Sec. 3. Streamlining clinical research on drugs and biological products.
- Sec. 4. The content and review of a new drug application.
- Sec. 5. Effectiveness determination.
- Sec. 6. Scientific review groups.
- Sec. 7. Marketing approval.
- Sec. 8. Accreditation of third parties.
- Sec. 9. Dispute resolution.
- Sec. 10. Good manufacturing practice inspections.
- Sec. 11. Good manufacturing practices.
- Sec. 12. Pilot and small scale manufacture.
- Sec. 13. Manufacturing changes.
- Sec. 14. Insulin and antibiotics.
- Sec. 15. Nonprescription drugs.
- Sec. 16. Information system.
- Sec. 17. Environmental impact review.
- Sec. 18. Application of State and Federal law to the practice of pharmacy
compounding.
- Sec. 19. Harmonization.
- Sec. 20. Use of scientific and medical information.
- Sec. 21. Informal agency statements.
- Sec. 22. Research and education; practice of medicine.
- Sec. 23. Delegation of authority.
- Sec. 24. Judicial review.
- Sec. 25. Publication of notice of deviation.
- Sec. 26. Biological products.

1 **SEC. 2. FDA MISSION AND ANNUAL REPORT.**

2 (a) MISSION.—Section 903 (21 U.S.C. 393) is
3 amended by redesignating subsections (b) and (c) as sub-
4 sections (c) and (d), respectively, and by adding after sub-
5 section (a) the following:

6 “(b) MISSION.—The Food and Drug Administration
7 shall protect the public health and safety and promptly
8 and efficiently review and approve clinical research and
9 marketing of products in a manner that does not unduly
10 impede innovation or product availability. The Food and
11 Drug Administration shall participate with other countries
12 to reduce the burden of regulation, harmonize regulatory
13 requirements, and achieve appropriate reciprocal arrange-
14 ments.”.

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

18 “(e) ANNUAL REPORT.—The Secretary shall, simul-
19 taneously with the submission each year of the budget for
20 the Food and Drug Administration, submit to the Com-
21 mittee on Commerce of the House of Representatives and
22 the Committee on Labor and Human Resources of the
23 Senate an annual report which shall—

24 “(1) review the performance of the Food and
25 Drug Administration in meeting its mission and the

1 development of Food and Drug Administration poli-
2 cies to implement such mission;

3 “(2) review the performance of the Food and
4 Drug Administration in meeting its own perform-
5 ance standards, including its own outcome measure-
6 ments and statutory deadlines for the approval of
7 products or for other purposes contained in this Act;

8 “(3) describe the staffing and resources of the
9 Food and Drug Administration and list those per-
10 sons and organizations accredited to conduct inves-
11 tigations under section 505(i), product approvals
12 under sections 505 and 506, and to perform good
13 manufacturing practice reviews under sections
14 505(d)(3) and 520(f);

15 “(4) describe the goals, activities, and accom-
16 plishments of the Food and Drug Administration in
17 bilateral and multinational meetings that addressed
18 methods and approaches to reduce the burden of
19 regulation, harmonize regulation, and to seek appro-
20 priate reciprocal arrangements, list each such meet-
21 ing, and list pending issues specifying those that are
22 not consistent with or are contrary to the provisions
23 of this Act; and

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

1 ucts with that of the most successful agencies per-
2 forming similar functions in other countries and
3 compare the resources used by such agencies.”.

4 **SEC. 3. STREAMLINING CLINICAL RESEARCH ON DRUGS**
5 **AND BIOLOGICAL PRODUCTS.**

6 Section 505(i) (21 U.S.C. 355(i)) is amended by add-
7 ing “(1)” prior to the first sentence, by redesignating
8 paragraphs (1), (2), and (3) as subparagraphs (A), (B),
9 and (C), respectively, and by adding the following new
10 paragraphs at the end thereof:

11 “(2) A clinical investigation of a new drug may begin
12 21 days after the Secretary has received from the sponsor
13 of the investigation a submission containing information
14 about the drug and the clinical investigation as follows:
15 The submission shall contain—

16 “(A) adequate reports of basic information, cer-
17 tified by the applicant to be accurate reports, nec-
18 essary to assess the safety of the drug for use in
19 clinical investigation; and

20 “(B) adequate information on the chemistry of
21 the drug, manufacturing of the drug, controls avail-
22 able for the drug, and primary data tabulations for
23 the drug from animal or human studies, except that
24 for phase I or phase II clinical investigations de-
25 tailed information shall not be required unless the

1 director of the office responsible for the review of
2 the drug makes a request within 21 days after the
3 submission regarding such detailed information in
4 writing and specifies the reasons for the request.

5 “(3)(A) At any time, the Secretary may issue to the
6 sponsor of an investigation a clinical hold in writing pro-
7 hibiting the sponsor from conducting the investigation and
8 specifying the basis for the clinical hold. The Secretary
9 may issue a clinical hold upon a demonstration, based on
10 specific information available to the Secretary, that the
11 drug to be investigated represents an unreasonable risk
12 to the safety of the persons who are the subject of the
13 clinical investigation, taking into account the design of the
14 clinical investigation, the condition for which the drug is
15 to be investigated, and the health status of the subjects
16 involved.

17 “(B) Any response from the sponsor of an investiga-
18 tion to the Secretary requesting that a clinical hold be re-
19 moved shall receive a decision, in writing and specifying
20 the reasons therefor, within 15 days after receipt of such
21 response or the clinical hold shall be deemed to be with-
22 drawn.

23 “(4) As an alternative to the procedure established
24 in paragraph (2), a Phase I or Phase II clinical investiga-
25 tion may begin after an accredited institution has ap-

1 proved the investigation and the sponsor of the investiga-
2 tion has submitted to the Secretary a notification setting
3 forth the name and address of the sponsor, the identity
4 of the drug, and the uses of the drug that the sponsor
5 intends to investigate. Data and information developed
6 through such an investigation may be submitted in sup-
7 port of an application for approval of a new drug and shall
8 be considered by the Secretary to the same extent as data
9 and information developed through an investigation under
10 paragraph (2). Paragraph (3) shall apply to such an inves-
11 tigation. The Secretary shall establish by regulation the
12 requirements and qualifications that an accredited institu-
13 tion shall meet to be eligible to approve an investigation
14 for purposes of this paragraph.

15 “(5) The Food and Drug Administration shall have
16 exclusive regulatory jurisdiction in the Department of
17 Health and Human Services over the use of a new drug
18 in any clinical investigation.”.

19 **SEC. 4. THE CONTENT AND REVIEW OF A NEW DRUG APPLI-**
20 **CATION.**

21 (a) SECTION 505(b).—Section 505(b) (21 U.S.C.
22 355(b)) is amended by adding at the end the following:

23 “(4)(A) An application submitted under paragraph
24 (1) shall include adequate reports of clinical and pre-
25 clinical investigations on safety and effectiveness certified

1 by the applicant to be accurate and supported by tables
2 of the relevant data, and forms and tabulations related
3 to deaths and dropouts due to adverse reactions. The di-
4 rector of the office responsible for review of the drug may
5 request, in writing and specifying the reasons for the re-
6 quest for a particular application, the submission of spe-
7 cific primary data tabulations or case report forms or tab-
8 ulations for a specific investigation.

9 “(B) The Secretary shall establish standards for the
10 review of applications submitted under paragraph (1) re-
11 lating to promptness, technical excellence, lack of bias and
12 conflict of interest, and a knowledge of regulatory and sci-
13 entific standards which shall apply equally to outside re-
14 viewers and to employees of the Secretary who review such
15 applications.

16 “(C) Food and Drug Administration employees shall
17 meet with a sponsor of an investigation or an applicant
18 under an application submitted under paragraph (1) with-
19 in 30 days of any reasonable request for a meeting by the
20 sponsor or applicant for the purpose of reaching agree-
21 ment on the design and size of clinical trials. Minutes of
22 any such meeting shall be exchanged. Advice provided to
23 a sponsor or applicant at its request by a Food and Drug
24 Administration employee, which is reduced to writing and
25 made part of the administrative record by the sponsor or

1 applicant or by the Food and Drug Administration, re-
2 garding appropriate testing of a new drug shall not be
3 changed after such testing begins, except with the written
4 agreement of the sponsor or applicant or by a decision
5 in writing, after an informal hearing, by the director of
6 the office in which the drug is reviewed where such change
7 is needed because there is a demonstrated need to protect
8 the public health.

9 “(D) The written decisions of the office responsible
10 for the review of a drug on all aspects of scientific and
11 medical matters relating to a new drug shall be binding
12 upon, and may not directly or indirectly be changed by,
13 the field personnel or the offices of compliance of the office
14 responsible for the review.

15 “(E) No action by the office responsible for the re-
16 view of a drug on any matter relating to a new drug for
17 which an application has been submitted under paragraph
18 (1) may at any time, or under any circumstance other
19 than a demonstrable extraordinary circumstance, be de-
20 layed because of the unavailability of information from or
21 action by field personnel.”.

22 (b) SECTION 735(7).—Section 735(7) is amended—
23 (1) by striking “applications for” and inserting
24 “applications” and by inserting “for” after “(A)”,
25 “(B)”, and “(C)”;

1 (2) by striking “and” at the end of subpara-
2 graph (C),

3 (3) by striking the period at the end of sub-
4 paragraph (D) and inserting “, and”, and

5 (4) by inserting the following after subpara-
6 graph (D):

7 “(E) by outside organizations and individ-
8 uals.”.

9 **SEC. 5. EFFECTIVENESS DETERMINATION.**

10 Section 505(d) (21 U.S.C. 355(d)) is amended—

11 (1) in the last sentence, by adding “one or
12 more” before “clinical investigations”;

13 (2) by adding at the end the following: “For
14 purposes of the preceding sentence, a well-controlled
15 investigation shall only include methods of control
16 that are appropriate to the disease or condition for
17 which a drug is intended as prescribed, rec-
18 ommended, or suggested in its labeling. The Sec-
19 retary may waive the requirement to conduct any
20 well-controlled investigation, as defined in the pre-
21 ceding sentence.”; and

22 (3) by inserting “(1)” after “(d)”, by redesign-
23 ating clauses (1) through (6) as clauses (A)
24 through (F), by striking “(1) through (6)” and in-

1 serting “(A) through (F)”, and by adding at the end
2 the following:

3 “(2) For purposes of clause (E) of paragraph (1)—

4 “(A) an application for a new drug for a serious
5 or life-threatening condition shall be considered to
6 have substantial evidence if it could be fairly and re-
7 sponsibly concluded by the experts referred to in
8 paragraph (1) that there is a reasonable likelihood
9 that the drug will be effective in a significant num-
10 ber of patients and that the risk from the drug is
11 no greater than the risk from the condition; and

12 “(B) if an application has been submitted for a
13 new use of a previously approved new drug, such
14 drug shall be considered to have substantial evidence
15 by a demonstration that the new use is common
16 among clinicians experienced in the field and rep-
17 resents reasonable clinical practice based upon reli-
18 able clinical experience and confirmatory informa-
19 tion.

20 “(3) For purposes of paragraph (1), the determina-
21 tion of effectiveness shall not include—

22 “(A) relative effectiveness, unless the effective-
23 ness of the drug is explicitly compared in the label-
24 ing to the effectiveness of another drug;

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

3 “(C) the cost-effectiveness of the drug as com-
4 pared to the cost-effectiveness of another drug un-
5 less the labeling explicitly includes a representation
6 about cost-effectiveness.”.

7 **SEC. 6. SCIENTIFIC ADVISORY PANELS.**

8 Section 505 (21 U.S.C. 355) is amended by adding
9 at the end the following:

10 “(n)(1) For the purpose of providing expert scientific
11 advice and recommendations to the Secretary regarding
12 a clinical investigation of a drug or biological product or
13 the approval for marketing of a drug or biological product
14 under section 505 or 506, the Secretary shall establish
15 panels of experts or use panels of experts established be-
16 fore the date of the enactment of this subsection, or both.
17 Scientific advisory panels shall consider scientific issues
18 and shall not include considerations of cost, economic as-
19 pects, comparative effectiveness, or legal matters.

20 “(2) The Secretary may delegate the appointment
21 and oversight authority granted under section 904 to a
22 director of a center or successor entity within the Food
23 and Drug Administration.

24 “(3) The Secretary shall appoint to each panel estab-
25 lished under paragraph (1) persons who are qualified by

1 training and experience to evaluate the safety and effec-
2 tiveness of the drugs and biological products to be referred
3 to the panel and who, to the extent feasible, possess skill
4 in the use of, or experience in, the development, manufac-
5 ture, or utilization of, such drugs or biological products.
6 The Secretary shall make appointments to each panel so
7 that each panel shall consist of members with adequately
8 diversified expertise in such fields as clinical and adminis-
9 trative medicine, engineering, biological and physical
10 sciences, and other related professions. In addition, each
11 panel shall include as nonvoting members a representative
12 of consumer interests and a representative of interests of
13 the drug and biological product manufacturing industry.
14 Scientific, trade, and consumer organizations shall be af-
15 forded an opportunity to nominate individuals for appoint-
16 ment to the panels. No individual who is in the regular
17 full-time employ of the United States and engaged in the
18 administration of this Act may be a member of any panel.
19 The Secretary shall designate one of the members of each
20 panel to serve as chairman thereof.

21 “(4) Each member of a panel shall publically disclose
22 all conflicts of interest that member may have with the
23 work to be undertaken by the panel. No member of a panel
24 may vote on any matter where the member could gain fi-
25 nancially from the advice given to the Secretary. The Sec-

1 retary may grant a waiver of any conflict of interest upon
2 public disclosure of such conflict of interest if such waiver
3 contributes to the ability of a panel to contribute to the
4 public health, except that the Secretary may not grant a
5 waiver for a member of a panel when the member's own
6 scientific work is involved.

7 “(5) The Secretary shall provide education and train-
8 ing to each new panel member before such member partici-
9 pates in a panel's activities. Such education and training
10 shall include a familiarization with certain requirements
11 under this Act and any related regulation of the Secretary
12 and the administrative process and procedures related to
13 panel meetings.

14 “(6) Panel members (other than officers or employees
15 of the United States), while attending meetings or con-
16 ferences of a panel or otherwise engaged in its business,
17 shall be entitled to receive compensation at rates to be
18 fixed by the Secretary, but not at rates exceeding the daily
19 equivalent of the rate in effect for grade GS-18 of the
20 General Schedule, for each day so engaged, including trav-
21 eltime. While so serving away from their homes or regular
22 places of business, each member may be allowed travel ex-
23 penses (including per diem in lieu of subsistence) as au-
24 thorized by section 5703 of title 5, United States Code,

1 for persons in the Government service employed intermit-
2 tently.

3 “(7) The Secretary shall take whatever action is nec-
4 essary to ensure that regular meetings are held by sci-
5 entific advisory panels, at appropriate intervals and for a
6 sufficient length of time, so that any matter to be reviewed
7 by any such panel shall be presented to the panel not more
8 than 60 days after the matter is ready for review by the
9 panel. The meetings shall occur not less than 6 times each
10 year unless there are compelling reasons for fewer meet-
11 ings. Such meetings shall be held with the physical pres-
12 ence of panel members at least 3 times each calendar year.
13 Other meetings of the panel may be held using electronic
14 communication to convene the meeting.

15 “(8)(A) All persons, including employees of the Sec-
16 retary, shall have the same rights and responsibilities re-
17 garding—

18 “(i) the submission of data and information to,
19 and contact and discussion with, a scientific advisory
20 panel;

21 “(ii) the participation of the persons at meet-
22 ings of the panel; and

23 “(iii) access to data and information submitted
24 to a scientific advisory panel (except for data and in-

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

3 “(B) In a case in which a scientific advisory panel
4 reviews an application submitted under section 505 or 506
5 (including a petition, notification, or other similar re-
6 quest), all related data and information that are not avail-
7 able for public disclosure under section 552 of title 5,
8 United States Code, shall be exchanged between the appli-
9 cant and the Food and Drug Administration at the time
10 the data and information are submitted to such panel but
11 shall not otherwise be publicly disclosed.

12 “(C) Any meetings of a scientific advisory panel shall
13 provide adequate time for initial presentations and for re-
14 sponse to any differing views and shall encourage free and
15 open participation by all interested persons.

16 “(9) Within 30 days after the date a scientific advi-
17 sory panel makes its conclusions and recommendations on
18 any matter under review by the panel, the Food and Drug
19 Administration official responsible for the matter shall re-
20 view the conclusions and recommendations of the panel,
21 shall make a final decision on the matter, and shall notify
22 the affected persons of the decision in writing and, if the
23 decision differs from the conclusions and recommendations
24 of the panel, shall include the reasons for the difference.

1 “(10) A scientific advisory panel under this sub-
2 section shall not be subject to the annual chartering and
3 annual report requirements of the Federal Advisory Com-
4 mittee Act. Such a panel shall make an annual report of
5 its activities to the Secretary.”.

6 **SEC. 7. MARKETING APPROVAL.**

7 Section 505(b) (21 U.S.C. 355(b)), as amended by
8 section 4(a), is amended—

9 (1) in the first sentence of paragraph (1), by
10 inserting immediately after “the Secretary” the fol-
11 lowing: “or may file such application with a person
12 authorized to review applications for marketing ap-
13 proval under section 712”; and

14 (2) by adding after paragraph (4) the following:

15 “(5)(A) The scope of review responsibilities of accred-
16 ited persons authorized to conduct reviews of marketing
17 approval applications under section 712 shall include the
18 review of applications to determine whether there is a rea-
19 sonable assurance that a drug is safe and effective under
20 the conditions prescribed, recommended, or suggested in
21 the proposed labeling. The review shall be conducted under
22 the standards and requirements of this Act applicable to
23 reviews by the Secretary. Prior to 60 days before the end
24 of the period prescribed by subsection (c), the accredited
25 person shall submit a report of its review to the Secretary

1 and its recommendations. Recommendations to the Sec-
2 retary shall specify whether an application should be ap-
3 proved or denied and shall state the basis for the rec-
4 ommendation.

5 “(B) The recommendation of the accredited person
6 shall be deemed to be approved by the Secretary unless
7 the Secretary finds that there is a reasonable probability
8 that the drug is not safe or effective. Upon receipt of the
9 recommendation from an accredited person to approve or
10 deny an application, the Secretary shall evaluate the rec-
11 ommendation within 60 days of such receipt. In the event
12 that the Secretary makes such a finding, the Secretary
13 shall provide a detailed explanation of the basis of the dif-
14 ference.”.

15 **SEC. 8. ACCREDITATION OF THIRD PARTIES.**

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

18 **“SEC. 712. ACCREDITED PERSONS.**

19 “(a) IN GENERAL.—The Secretary shall, within 180
20 days of the date of the enactment of this section, by regu-
21 lation establish procedures for the accreditation of persons
22 for the purposes of—

23 “(1) reviewing applications under section
24 505(b) or 506, providing written reviews to the Sec-
25 retary for the Secretary’s consideration, and making

1 recommendations on whether or not such applica-
2 tions should be approved; and

3 “(2) conducting good manufacturing practice
4 inspections to determine the conformance of a facil-
5 ity with regulations promulgated under sections
6 501(a)(2), 505(d)(3), and 520(f).

7 “(b) ACCREDITATION.—

8 “(1) PROGRAMS.—The Secretary shall provide
9 for such accreditation through programs adminis-
10 tered by government agencies or by other qualified
11 organizations.

12 “(2) IMPLEMENTATION.—The Secretary may
13 designate one or more qualified non-government or-
14 ganizations to implement such programs. Such orga-
15 nizations shall implement such programs from fees
16 charged to applicants for accreditation.

17 “(3) QUALIFICATIONS.—An accredited person
18 shall meet the following requirements:

19 “(A) Such person shall be an independent
20 organization which is not owned or controlled
21 by manufacturer, supplier or vendor of drugs
22 and which has no organizational, material, or
23 financial affiliation with such a manufacturer,
24 supplier, or vendor.

1 “(B) Such person shall be a legally con-
2 stituted entity permitted to conduct the activi-
3 ties for which it seeks accreditation.

4 “(C) Such person shall not engage in the
5 development, manufacture, promotion, or sale
6 of drugs.

7 “(D) Such person shall be operated in ac-
8 cordance with generally accepted professional
9 and ethical business practices and shall agree in
10 writing that as a minimum it will—

11 “(i) certify that reported information
12 accurately reflects data reviewed;

13 “(ii) limit work to that for which com-
14 petence and capacity are available;

15 “(iii) treat information received,
16 records, reports, and recommendations as
17 proprietary information; and

18 “(iv) promptly respond and attempt to
19 resolve complaints regarding its activities
20 for which it is accredited.”.

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

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

1 “(A) the submission of a report or rec-
2 ommendation by a person accredited under section
3 712 that is false or misleading in any material re-
4 spect;

5 “(B) the disclosure by a person accredited
6 under section 712 of confidential commercial infor-
7 mation or any trade secret without the express writ-
8 ten consent of the person who submitted such infor-
9 mation or secret to such person; or

10 “(C) the receipt by a person accredited under
11 section 712 of a bribe in any form or the doing of
12 any corrupt act by such person associated with a re-
13 sponsibility delegated to such person under this
14 Act.”.

15 **SEC. 9. DISPUTE RESOLUTION.**

16 Chapter V, as amended by section 14(b)(1), is
17 amended by adding after section 506 the following:

18 “DISPUTE RESOLUTION

19 “SEC. 507. (a) At any time before the issuance of
20 the notice under section 505(c)(1)(B) or an exemption for
21 investigational use under section 505(i) for a drug subject
22 to section 505 or 506, the applicant may, in writing, notify
23 the Secretary that an impasse exists in the review of the
24 application for a drug under section 505(b) or the submis-
25 sion for such an exemption with respect to a specifically
26 identified issue.

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

3 “(1) to an existing (as of the date of the notifi-
4 cation) scientific advisory panel having expertise re-
5 lated to the issue;

6 “(2) to a special Government employee, as de-
7 fined in section 202(a) of title 18, United States
8 Code, or to a non-governmental person qualified to
9 mediate or arbitrate the substance of such impasse
10 who is acceptable to the Secretary and the applicant.

11 “(c) The applicant and representatives of the Sec-
12 retary may consult with the panel, special Government em-
13 ployee, or non-governmental person on the matter re-
14 ferred. The panel, special Governmental employee, or non-
15 governmental person shall submit to the Secretary and the
16 applicant a report containing recommendations (including
17 a statement of reasons for the recommendations) regard-
18 ing the matter not later than 60 days after the date of
19 the referral, or not later than 90 days after the date of
20 the referral if the panel, special Governmental employee,
21 or non-governmental person considers the additional 30
22 days to be necessary. Not later than 30 days after the
23 date of receiving the report, the Secretary shall, in writing,
24 confirm or modify the recommendations received, provid-
25 ing reasons and reference to data before the panel, special

1 Governmental employee, or non-governmental person for
2 any modification. If the Secretary fails to act on such a
3 recommendation within 30 days of its receipt, the rec-
4 ommendation of the panel, special Government employee,
5 or non-governmental person shall be deemed to be the rec-
6 ommendation of the Secretary.

7 “(d) The Federal Advisory Committee Act shall not
8 apply to any scientific advisory panel acting under this
9 section.”.

10 **SEC. 10. GOOD MANUFACTURING PRACTICE INSPECTIONS.**

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

12 (1) in subsection (a)(1), by inserting “, or an
13 accredited person to conduct good manufacturing
14 practice inspections under section 712” after “Sec-
15 retary”;

16 (2) in subsection (a)(3), by inserting “, or an
17 accredited organization or individual under section
18 712,” after “employee”;

19 (3) in subsection (b), by inserting “, or an ac-
20 credited person under section 712,” after “em-
21 ployee”;

22 (4) in subsection (b), by inserting “(1)” after
23 “(b)”, by redesignating clauses (1) and (2) as
24 clauses (A) and (B), respectively, and by adding at
25 the end the following:

1 “(2) The Secretary shall provide, at least 10 days
2 from the date of presentation of the report of conditions
3 or practices identified in paragraph (1), for the person re-
4 ceiving such report to respond. The Secretary shall take
5 no regulatory action against a person or article identified
6 in such a report until completing a review of such response
7 which is timely submitted to the Secretary, except the Sec-
8 retary may take immediate action when the Secretary
9 finds that there is a reasonable probability that a drug
10 intended for human use would cause serious, adverse
11 health consequences or death or that any regulated article
12 could present an unreasonable and substantial risk of in-
13 jury or illness to the public health. The Secretary shall
14 provide to the regulated person, within 30 days of receiv-
15 ing a response to the report identified in paragraph (1),
16 a written detailed assessment of the response.

17 “(3) At the time an accredited person completes an
18 inspection under the authority of this section and section
19 712, such person shall identify in writing to the person
20 subject to the inspection each condition or practice ob-
21 served during such inspection which suggests a deviation
22 from requirements of this Act. However, such accredited
23 person shall immediately submit to the Secretary the find-
24 ings of the inspection when the drug to which such find-
25 ings relate is intended for human use and presents a rea-

1 sonable probability that such drug would cause serious,
2 adverse health consequences or death or that such drug
3 could present an unreasonable and substantial risk of in-
4 jury or illness to the public unless the person subject to
5 the inspection—

6 “(A) immediately ceases distribution of the
7 drug;

8 “(B) immediately notifies health professionals
9 and drug user facilities to instruct such professionals
10 and facilities to cease use of the drug; and

11 “(C) immediately undertakes all corrections
12 identified by the accredited person.

13 When such compliance is complete, the accredited person
14 shall provide the inspected person a certification of compli-
15 ance which includes the dates of inspections, a statement
16 that the inspected facility is in compliance with the re-
17 quirements of section 520(f), the date the compliance was
18 achieved at the facility, and the signature of the accredited
19 person attesting to the finding that the inspected facility
20 is in good manufacturing practices compliance as defined
21 by such section. When an accredited person has certified
22 compliance with good manufacturing practices require-
23 ments and provided the Secretary with a copy of the cer-
24 tification within 10 days of its being made, the Secretary
25 may not perform a good manufacturing practices inspec-

1 tion of the person subject to an inspection for a period
2 of 2 years after the date of the certification unless justified
3 by good cause.”; and

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

6 (6) in subsection (e), by striking “or employee”
7 each place it occurs and inserting “, employee, or ac-
8 credited person”; and

9 (7) by adding at the end the following:

10 “(f) Persons duly designated by the Secretary to con-
11 duct inspections under this section shall not request any
12 information not permitted under subsections (a) and (e)
13 unless such person states with specificity and in writing
14 the identification of the information subject to the request,
15 the reason for the request, and that the written request
16 seeks to obtain information not required to be produced
17 under this section. Such request shall not include informa-
18 tion related to sales (other than distribution), personnel,
19 or pricing data.”.

20 **SEC. 11. GOOD MANUFACTURING PRACTICES.**

21 (a) AMENDMENT.—Section 501(a) (21 U.S.C.
22 351(a)) is amended—

23 (1) by striking “(a)(1)” and inserting
24 “(a)(1)(A)”;

1 (2) by redesignating subclauses (A) and (B) in
2 clauses (2) and (4) as subclauses (i) and (ii), respec-
3 tively; and

4 (3) by redesignating clauses (2) through (6) as
5 clauses (B) through (F), respectively;

6 (4) by adding at the end the following:

7 “(2) All chemistry, manufacturing, and controls
8 which comply with an approved new drug application
9 under section 505 or an approved drug application under
10 section 506 or with the opinion of an appropriate official
11 in the component of the Food and Drug Administration
12 responsible for the review of such chemistry, manufactur-
13 ing, or controls and which is reduced to writing and made
14 part of the administrative record shall be deemed to com-
15 ply with current good manufacturing practice. The Sec-
16 retary shall not take action to delay or prevent the manu-
17 facture or marketing of a drug under section 505 or 506
18 for failure to conform to current good manufacturing
19 practice unless there is reasonable probability of actual
20 harm to the public health or the Secretary determines in
21 writing, after an informal hearing, that the drug is—

22 “(A) not bioequivalent,

23 “(B) deviates from the specifications for the
24 drug established in the approved new drug applica-

1 tion from the specifications for the drug established
2 by the manufacturer,

3 “(C) lacks adequate assurance that it will meet
4 the represented sterility, or

5 “(D) has been rendered unsafe or ineffective.”.

6 (b) CONFORMING AMENDMENTS.—

7 (1) SECTION 303.—Section 303(g)(1)(B)(iii)
8 (21 U.S.C. 333(g)(1)(B)(iii)) is amended by striking
9 “501(a)(2)(A)” and inserting “501(a)(1)(B)(i)”.

10 (2) SECTION 304.—Section 304(d)(1) (21
11 U.S.C. 334(d)(1)) is amended by striking
12 “501(a)(3)” and inserting “501(a)(1)(C)”.

13 (3) SECTION 512.—Section 512(a)(1) (21
14 U.S.C. 360c(a)(1)) is amended by striking
15 “501(a)(5)” and inserting “501(a)(1)(E)”, section
16 512(a)(2) (21 U.S.C. 360c(a)(2)) is amended by
17 striking “501(a)(6)” and inserting “501(a)(1)(F)”,
18 and section 512(a)(3) (21 U.S.C. 360c(a)(3)) is
19 amended by striking “501(a)(5) or (6)” and insert-
20 ing “501(a)(1)(E) or 501(a)(1)(F)”.

21 (4) SECTION 721.—Section 721(a) (21 U.S.C
22 379e(a)) is amended by striking “501(a)(4)” and in-
23 serting “501(a)(1)(D)”.

24 (5) SECTION 802.—Sections 802(b)(1)(D) and
25 802(f)(1)(B) (21 U.S.C.382(b)(1)(D),382(f)(1)(B))

1 are each amended by striking “(a)(1), (a)(2)(A),
2 (a)(3)” and inserting “(a)(1)(A), (a)(1)(B)(i),
3 (a)(1)(C)” .

4 **SEC. 12. 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:

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

15 **SEC. 13. MANUFACTURING CHANGES.**

16 Chapter VII (21 U.S.C. 371 et seq.) is amended by
17 adding at the end thereof the following:

18 “SUBCHAPTER D—MANUFACTURING CHANGES

19 **“SEC. 740. MANUFACTURING CHANGES.**

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

24 “(b) DRUG AND BIOLOGICAL PRODUCT.—A change
25 in the manufacture of a new drug or a biological product

1 that is the subject of a monograph in an official compen-
2 dium, a biological product that can be adequately charac-
3 terized by chemical, physical, or biological means, or a new
4 animal drug, blood, or blood component shall require—

5 “(1) validation; and

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

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

22 “(c) BIOLOGICAL PRODUCT NOT SUBJECT TO A
23 MONOGRAPH.—A change in the manufacture of a biologi-
24 cal product that is not the subject of a monograph in an
25 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 506 whether
20 the product can be adequately characterized for purposes
21 of this subsection. With respect to biological products ap-
22 proved prior to the date of enactment of the Drug and
23 Biological Products Reform Act of 1996, the determina-
24 tion shall be made within 90 days after the date of enact-
25 ment of such Act. Any determination under this sub-

1 section is subject to change based upon new scientific in-
2 formation.”.

3 **SEC. 14. INSULIN AND ANTIBIOTICS.**

4 (a) CERTIFICATION OF DRUGS CONTAINING INSU-
5 LIN.—

6 (1) AMENDMENT.—Section 506 (21 U.S.C.
7 356) is repealed.

8 (2) CONFORMING AMENDMENTS.—

9 (A) Sections 301(i)(1) and 301(j)(1) (21
10 U.S.C. 321(i)(1), 321(j)(1)) are each amended
11 by striking “506, 507,”.

12 (B) Section 501(k) (21 U.S.C. 351(k)) is
13 repealed

14 (C) Section 502(k) (21 U.S.C. 352(k)) is
15 repealed.

16 (D) Sections 510(j)(1)(A) and
17 510(j)(1)(D) (21 U.S.C. 360(j)(1)(A),
18 360(j)(1)(D)) are each amended by striking
19 “506, 507,”.

20 (E) Section 8126(h)(2) of title 38, United
21 States Code, is amended by inserting “or” at
22 the end of subparagraph (B), by striking “; or”
23 at the end of subparagraph (C) and inserting a
24 period, and by striking subparagraph (D).

1 (F) Section 1927(k)(2) of the Social Secu-
2 rity Act (42 U.S.C. 1396r-8(k)(2)) is amended
3 by striking “; and” at the end of subparagraph
4 (B) and inserting a period and by striking sub-
5 paragraph (C).

6 (b) CERTIFICATION OF ANTIBIOTICS.—

7 (1) AMENDMENT.—Section 507 (21 U.S.C.
8 357), as in effect on the date of the enactment of
9 this Act, is repealed.

10 (2) CONFORMING AMENDMENTS.—

11 (A) Section 201(aa) (21 U.S.C. 321(aa)) is
12 amended by striking out “or 507”, section
13 201(dd) (21 U.S.C. 321(dd)) is amended by
14 striking “507,”, and sections 201(ff)(2)(B) and
15 201(ff)(3) (21 U.S.C. 321(ff)(2)(B), 321(ff)(3))
16 are each amended by striking “, certified as an
17 antibiotic under section 507,”.

18 (B) Section 301(e) (21 U.S.C. 331(e)) is
19 amended by striking “507(d) or (g),”.

20 (C) Sections 301(i)(1) and 301(j) (21
21 U.S.C. 321(i)(1), 321(j)) are each amended by
22 striking “507,”.

23 (D) Section 306(d)(4)(B)(ii) (21 U.S.C.
24 335a(d)(4)(B)(ii)) is amended by striking “or
25 507”.

1 (E) Section 502 (21 U.S.C. 352) is
2 amended by striking subsection (l).

3 (F) Section 510(j)(1)(D) (21 U.S.C.
4 360(j)(1)(D)) is amended by striking “507,”.

5 (G) Section 520(l) is amended by striking
6 paragraph (4) and by striking “or Antibiotic
7 Drugs” in the subsection heading.

8 (H) Section 525(a) (21 U.S.C. 360aa(a))
9 is amended by inserting “or” at the end of
10 paragraph (1), by striking paragraph (2), and
11 by redesignating paragraph (3) as paragraph
12 (2).

13 (I) Section 525(a) (21 U.S.C. 360aa(a)) is
14 amended by striking “, certification of such
15 drug for such disease or condition under section
16 507,”.

17 (J) Section 526(a)(1) (21 U.S.C. 360bb) is
18 amended by striking “the submission of an ap-
19 plication for certification of the drug under sec-
20 tion 507,”, by inserting “or” at the end of sub-
21 paragraph (A), by striking subparagraph (B),
22 and by redesignating subparagraph (C) as sub-
23 paragraph (B).

24 (K) Section 526(b) (21 U.S.C. 360bb(b))
25 is amended by striking “, a certificate was is-

1 sued for the drug under section 507,” each time
2 it appears and by striking “, approval of an ap-
3 plication for certification under section 507,”.

4 (L) Section 527(a) (21 U.S.C. 360cc(a)) is
5 amended by inserting “or” at the end of para-
6 graph (1), by striking paragraph (2), by redes-
7 ignating paragraph (3) as paragraph (2), and
8 by striking “, issue another certificate under
9 section 507,”.

10 (M) Section 527(b) (21 U.S.C. 360cc(b))
11 is amended by striking “, if a certification is is-
12 sued under section 507 for such a drug,” and
13 “, of the issuance of the certification under sec-
14 tion 507,”.

15 (N) Section 704(a)(1) (21 U.S.C. 374) is
16 amended by striking “, section 507 (d) or (g)”.

17 (O) Section 735(1) (21 U.S.C. 379g(1)(C))
18 is amended by inserting “or” at the end of sub-
19 paragraph (B), by striking subparagraph (C),
20 and by redesignating subparagraph (D) as sub-
21 paragraph (C).

22 (P) Sections 5(b)(1)(A) and 5(b)(1)(B) of
23 the Orphan Drug Act (21 U.S.C.
24 360ee(b)(1)(A), 360ee(b)(1)(B)) are each
25 amended by striking “or 507”.

1 report directly to the Director of the Center. A single sci-
2 entific advisory panel may provide conclusions and rec-
3 ommendations regarding any such matter.”.

4 **SEC. 16. INFORMATION SYSTEM.**

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

7 **“SEC. 907. INFORMATION SYSTEM.**

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

14 **SEC. 17. ENVIRONMENTAL IMPACT REVIEW.**

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

17 **“SUBCHAPTER E—ENVIRONMENTAL IMPACT REVIEW**

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

19 “No action by the Secretary pursuant to this Act
20 shall require, with respect to an action to be taken by the
21 Secretary, the preparation of an environmental impact
22 statement under the National Environmental Policy Act
23 of 1969 or an environmental assessment unless the Sec-
24 retary demonstrates that—

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

4 “(2) the consideration of such significant effect
5 on the human environment will directly affect the
6 Secretary’s decision on the action.”.

7 **SEC. 18. APPLICATION OF FEDERAL LAW TO THE PRACTICE**
8 **OF PHARMACY COMPOUNDING.**

9 Section 503 (21 U.S.C. 353) is amended by adding
10 at the end the following:

11 “(h)(1) Sections 501(a)(1)(B)(ii), 501(f), 501(h),
12 502(f)(1), 502(l), 502(o), 502(s), 502(t), 505, 506, and
13 510 and sections 510 through 520 shall not apply to a
14 drug that is compounded by a licensed pharmacist on the
15 order of a licensed physician.

16 “(2) No provision of this Act shall apply to a bulk
17 drug product or other drug, including an imported product
18 drug, that is intended for use by a licensed pharmacist
19 in compounding a drug or device on the order of a licensed
20 physician, except to the extent that the provision relates
21 directly to the quality, purity, or identity of such drug.”.

22 **SEC. 19. HARMONIZATION.**

23 Section 803 (21 U.S.C. 383) is amended by adding
24 at the end the following:

1 “(c)(1) The Secretary shall regularly and continu-
2 ously participate in meetings with other countries to dis-
3 cuss methods and approaches to reduce the burden of reg-
4 ulation, harmonize regulatory requirements, and seek ap-
5 propriate reciprocal arrangements. The Secretary shall,
6 within 180 days of the date of enactment of this sub-
7 section, make public a plan that establishes a framework
8 for achieving mutual recognition of good manufacturing
9 practices.

10 “(2) The Secretary shall report to the Committee on
11 Commerce of the House of Representatives and the Com-
12 mittee on Labor and Human Resources of the Senate at
13 least 60 days before executing any bilateral or multilateral
14 agreement under paragraph (1).”.

15 **SEC. 20. USE OF SCIENTIFIC AND MEDICAL INFORMATION.**

16 Section 502(f) (21 U.S.C. 352(f)) is amended by add-
17 ing at the end the following: “The dissemination of medi-
18 cal texts, articles from peer-reviewed scientific publica-
19 tions, information from Federal Government agencies, and
20 presentations at medical and scientific meetings shall not
21 form a basis to require adequate directions for use under
22 clause (1) or information for use (or the equivalent there-
23 of) under any exemption to clause (1) and shall not form
24 a basis to require the filing of a report required under
25 section 510(k) or the filing of an application under section

1 505 or 515 unless such person, in addition to disseminat-
2 ing the above-referenced information, encourages the un-
3 approved use of a legally marketed drug or device through
4 labeling, advertising, or other means of promotion. Mere
5 knowledge that a legally available drug or device is used
6 by licensed practitioners for the treatment or diagnosis of
7 diseases or conditions in individual patients shall not form
8 a basis to require adequate directions for use under clause
9 (1), or information for use (or the equivalent thereof)
10 under any exemption to clause (1), and shall not form a
11 basis to require either the filing of a notification required
12 under section 510(k) or an application under section 505
13 or 515. The Secretary shall not consider the dissemination
14 of medical texts, articles from peer review scientific publi-
15 cations, information from Federal Government agencies,
16 presentations at medical and scientific meetings, and dis-
17 plays at trade shows relating to a drug or device which
18 is not approved for marketing or investigational use within
19 the meaning of section 505(i) or 520(g) to be activities
20 prohibited under published regulations of the Secretary
21 unless the sponsor of an investigation for the drug or de-
22 vice, or an agent of such sponsor, in addition to the afore-
23 mentioned activities encourages the use of a drug or de-
24 vice.”.

1 **SEC. 21. INFORMAL AGENCY STATEMENTS.**

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

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

11 “(2) The Secretary shall publish notice in the Federal
12 Register of the availability to the public of each type of
13 statement identified in paragraph (1). Additionally, the
14 Secretary shall undertake to make available all such state-
15 ments by electronic or other similar means.”.

16 **SEC. 22. EDUCATION AND RESEARCH; PRACTICE OF MEDI-**
17 **CINE.**

18 Chapter IX, as amended by section 16, is amended
19 by adding at the end the following:

20 **“SEC. 908. EDUCATION AND RESEARCH.**

21 “(a) EDUCATION.—The Secretary shall conduct
22 training and education programs for the employees of the
23 Food and Drug Administration relating to the regulatory
24 responsibilities and policies established by this Act, includ-
25 ing programs for scientific training, administrative process
26 and procedure, and integrity issues.

1 “(b) RESEARCH.—The Secretary, acting through the
2 Food and Drug Administration, may conduct or contract
3 for scientific research only if it is directly related to the
4 implementation of this Act.

5 **“SEC. 909. PRACTICE OF MEDICINE.**

6 “Nothing in this Act shall be construed to limit or
7 interfere with the authority of a health care practitioner,
8 licensed by law to administer drugs and devices, to pre-
9 scribe or administer any legally marketed drug or device
10 to a patient for any condition or disease within a legiti-
11 mate health care practitioner-patient relationship.”.

12 **SEC. 23. DELEGATION OF AUTHORITY.**

13 Section 903 (21 U.S.C. 393), as amended by section
14 2(b), is amended by adding at the end the following:

15 “(f) DELEGATION OF AUTHORITY.—The reference in
16 sections 505(b)(4)(A), 505(b)(4)(C), 505(i)(2)(B), and
17 505(n)(1) to the authority of a specific official or position
18 in the Food and Drug Administration to perform a par-
19 ticular function is an authority which shall be only exer-
20 cised by such official or individual in such position and
21 the authority to exercise such authority may not be dele-
22 gated.”.

23 **SEC. 24. JUDICIAL REVIEW.**

24 Section 505(h) (21 U.S.C. 355(h)) is amended to
25 read as follows:

1 “(h)(1) Not later than 30 days after—

2 “(A) any written decision respecting any aspect
3 of an investigational new drug; or

4 “(B) any written decision respecting any aspect
5 of an application, petition, or notification for mar-
6 keting review or approval for a drug under this sec-
7 tion;

8 any person adversely affected by such decision, notice, or
9 warning may file a petition with the United States Court
10 of Appeals for the District of Columbia or for the circuit
11 wherein such person resides or such person has a principal
12 place of business for judicial review of such decision, no-
13 tice, or warning. A copy of the petition shall be transmit-
14 ted by the clerk of the court to the Secretary or other
15 officer designated by the Secretary for that purpose. The
16 Secretary shall file in the court the record of the proceed-
17 ings on which the Secretary based the Secretary’s decision,
18 notice, or warning as provided in section 2112 of title 28,
19 United States Code. For purposes of this subsection, the
20 term “record” means all notices and other matter pub-
21 lished in the Federal Register with respect to the decision,
22 notice, or warning reviewed, all information submitted to
23 the Secretary with respect to such decision, notice, or
24 warning, proceedings of any scientific advisory panel with
25 respect to such decision, notice, or warning, any hearing

1 held with respect to such decision, notice, or warning, and
2 any other information identified by the Secretary, in the
3 administrative proceeding held with respect to such deci-
4 sion, notice, or warning as being relevant to such regula-
5 tion or order.

6 “(2) If the petitioner applies to the court for leave
7 to adduce additional data, views, or arguments respecting
8 the decision, notice, or warning being reviewed and shows
9 to the satisfaction of the court that such additional data,
10 views, or arguments are material and that there were rea-
11 sonable grounds for the petitioner’s failure to adduce such
12 data, views, or arguments in the proceedings before the
13 Secretary, the court may order the Secretary to provide
14 additional opportunity for the oral presentation of data,
15 views, or arguments and for written submissions. The Sec-
16 retary may modify the Secretary’s findings, or make new
17 findings by reason of the additional data, views, or argu-
18 ments so taken and shall file with the court such modified
19 or new findings, and the Secretary’s recommendation, if
20 any, for the modification or setting aside of the decision,
21 notice, or warning being reviewed, with the return of such
22 additional data, views, or arguments.

23 “(3) Upon the filing of the petition under paragraph
24 (1) for judicial review of a decision, notice, or warning,
25 the court shall have jurisdiction to review the decision, no-

1 tice, or warning in accordance with chapter 7 of title 5,
2 United States Code, and to grant appropriate relief, in-
3 cluding interim relief, as provided in such chapter.

4 “(4) The judgment of the court affirming or setting
5 aside, in whole or in part, any decision, notice, or warning
6 shall be final, subject to review by the Supreme Court of
7 the United States upon certiorari or certification, as pro-
8 vided in section 1254 of title 28 of the United States Code.

9 “(5) The remedies provided for in this subsection
10 shall be in addition to and not in lieu of any other rem-
11 edies provided by law.

12 “(6) To facilitate judicial review under this sub-
13 section or under any other provision of law of a decision,
14 notice, or warning issued under this section, each such de-
15 cision, notice, or warning shall contain a statement of the
16 reasons for its issuance and the basis, in the record of
17 the proceedings held in connection with its issuance, for
18 its issuance.”.

19 **SEC. 25. PUBLICATION OF NOTICE OF DEVIATION.**

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

22 “(c) The Secretary may make public or communicate
23 to any person outside the Food and Drug Administration
24 any information regarding a notice which informs a regu-
25 lated person of a purported deviation from a requirement

1 of this Act only after the Secretary has completed the in-
2 vestigation of such deviation.”.

3 **SEC. 26. BIOLOGICAL PRODUCTS.**

4 (a) DEFINITIONS.—

5 (1) BIOLOGICAL PRODUCT AND TISSUE.—Sec-
6 tion 201 (21 U.S.C. 321) is amended by adding at
7 the end the following:

8 “(gg) The term ‘biological product’ means a virus,
9 therapeutic serum, toxin, antitoxin, vaccine, allergenic
10 product, derivative of blood and blood components, or
11 analogous product, or arsphenamine or its derivatives, in-
12 tended for use in the diagnosis, cure, mitigation, treat-
13 ment, or prevention of a disease or physiologic condition
14 in man, but does not include blood, blood components, or-
15 gans, eyes, milk, or human tissue. A biological product is
16 a drug within the meaning of paragraph (g) but is not
17 a new drug within the meaning of paragraph (p).

18 “(hh) The term ‘human tissue’ means a collection of
19 human cells which are intended for use in the diagnosis,
20 cure, mitigation, treatment, or prevention of a disease or
21 physiological condition in man or for the augmentation of
22 a natural bodily function. Human tissue may be combined
23 with biologically inactive substances and subjected to any
24 form of processing before use subject to operating stand-
25 ards established under section 506(a)(2)(A). Human tis-

1 sue achieves its primary intended purposes through struc-
2 tural support or cellular function and not systemic action.
3 Human tissue is not a drug or device and does not include
4 blood, blood components, organs, or milk.”.

5 (2) BLOOD, BLOOD COMPONENTS, ORGANS,
6 MILK, OR HUMAN TISSUE.—Section 201(g)(1) (21
7 U.S.C 321(g)(1)) is amended by adding at the end
8 the following: “Blood, a blood component, an organ,
9 milk, or human tissue is not a drug.”.

10 (3) DEVICE.—Section 201(h) (21 U.S.C.
11 321(h)) is amended by adding at the end the follow-
12 ing: “Computer software developed by, modified by,
13 and used in a human tissue establishment shall not
14 be subject to any premarket clearance requirement
15 under this Act but such software shall be validated
16 to demonstrate that it achieves its intended purpose
17 before use and it shall be subject to the good manu-
18 facturing requirements of this Act.”.

19 (b) REGULATION OF BIOLOGICAL PRODUCTS.—
20 Chapter V, as amended by section 14, is amended by add-
21 ing after section 505 the following:

22 “BIOLOGICAL PRODUCTS

23 “SEC. 506. (a) No person shall introduce or deliver
24 for introduction into interstate commerce a biological
25 product unless an approval of a product license application
26 filed pursuant to this section is effective with respect to

1 such product and the biological product meets the good
2 manufacturing practice requirement of section
3 501(a)(1)(B)(ii).

4 “(b) A product license application for a biological
5 product shall—

6 “(1) contain the information that is required
7 for a new drug under the second sentence of section
8 505(b)(1);

9 “(2) be subject to the procedures and standards
10 established for a new drug in sections 505(c)(1),
11 505(d), 505(e), 505(f), 505(g), and 505(h) but not
12 the standards of sections 505(d)(6) and 505(e)(4);

13 “(3) be subject to the provisions for an inves-
14 tigational new drug in section 505(i);

15 “(4) be subject to the requirements for a new
16 drug established in section 505(k); and

17 “(5) in the case of a derivative of blood and
18 blood components, apply to all facilities of the appli-
19 cant that are licensed under subsection (c).

20 Within 2 years of the date of enactment of this section
21 the Secretary shall harmonize the regulations governing
22 product license applications with the regulations governing
23 new drug applications filed pursuant to section 505(b)(1)
24 and the regulations governing good manufacturing prac-
25 tices promulgated under section 501(a)(1)(B)(ii). If the

1 Secretary fails to implement such harmonization within 2
2 years, the regulations governing product license applica-
3 tions shall be null and void and all biological products shall
4 be subject to the regulations governing new drug applica-
5 tions filed pursuant to section 505(b)(1). The amendments
6 made to section 505 by the Drug Price Competition and
7 Patent Term Restoration Act of 1984 shall not apply to
8 biological products.

9 “(c)(1) No person shall introduce or deliver for intro-
10 duction into interstate commerce blood or blood compo-
11 nents unless an approval of a product license application
12 filed pursuant to this section is effective with respect to
13 such product. Blood and blood components intended for
14 use in the diagnosis, cure, mitigation, treatment, or pre-
15 vention of a disease or physiologic condition in man shall
16 be subject to—

17 “(A) performance standards for safety, purity,
18 and where applicable, potency,

19 “(B) good manufacturing practices, and

20 “(C) labeling,

21 established by regulations promulgated by the Secretary,
22 and shall be obtained and processed only in facilities li-
23 censed by the Secretary.

24 “(2) Licensed establishments shall be subject to in-
25 spection under section 704. During such an inspection the

1 Secretary shall have access to or copies of patient and
2 donor names and other donor identifying information
3 when such access is critical to public health. Such an in-
4 spection may be conducted by nonprofit membership orga-
5 nizations that meet requirements established by the Sec-
6 retary for individuals and organizations accredited by the
7 Secretary under section 712.

8 “(3)(A) The Secretary shall by regulation establish
9 the requirements that a facility or a group of facilities
10 within one corporate entity shall meet to be eligible to be
11 licensed under a single facility license to obtain and proc-
12 ess a specific set of blood and blood components.

13 “(B) Within 90 days after the Secretary receives an
14 application for a license under this subsection from a facil-
15 ity, the Secretary shall review the application and may in-
16 spect the facility to determine compliance with the require-
17 ments established under this subsection. Such inspection
18 may be conducted by non-profit organizations that meet
19 requirements established by the Secretary or by persons
20 accredited by the Secretary under section 712. Within
21 such 90 days, the Secretary shall grant a license or shall
22 deny a license and specify in writing the reasons for the
23 denial and the requirements that must be met to obtain
24 a license.

1 “(C) The Secretary may at any time revoke or sus-
2 pend a license in accordance with this paragraph for fail-
3 ure to comply with the requirements established under this
4 subsection as follows:

5 “(i) The license may be immediately suspended
6 with an informal hearing to follow if the Secretary
7 demonstrates that the deficiencies identified con-
8 stitute an immediate danger of serious adverse
9 health consequences or death.

10 “(ii) Before revoking a license, the Secretary
11 shall provide the facility in writing a list of specific
12 deficiencies that must be corrected in order to retain
13 the license and shall provide 30 days for a written
14 response and for correction of the deficiencies. If the
15 facility fails to provide an adequate response or to
16 make a correction, the Secretary shall provide the
17 opportunity for an informal hearing. Such hearing
18 shall be held within 30 days of the receipt of the
19 written response.

20 “(iii) The revocation or suspension of any li-
21 cense shall not prevent the continued use of any
22 blood or blood component which has left the control
23 of the licensee unless the Secretary determines, as
24 part of the revocation or suspension order, that such
25 use represents an actual harm to the public health.

1 “(4) Blood and blood components are not biological
2 products, drugs, devices, or human tissue. Computer soft-
3 ware developed by, modified by, and used in a blood or
4 blood component establishment shall not be subject to any
5 premarket clearance requirement under this Act but such
6 software shall be validated to demonstrate that it achieves
7 its intended purpose before use and it shall be subject to
8 the good manufacturing requirements of this Act.

9 “(5) Blood components and derivatives of blood and
10 blood components intended for use as a blood test or in
11 the diagnosis of disease are devices and are not drugs, bio-
12 logical products, or human tissue.

13 “(d)(1) Human tissue shall be subject to regulation
14 under this subsection only if the Secretary demonstrates,
15 in writing published in the Federal Register and after a
16 hearing before the Commissioner, that voluntary regula-
17 tion under generally accepted scientific standards is inad-
18 equate to protect the public health with respect to any par-
19 ticular type of human tissue or human tissue generally.

20 “(2)(A) Based upon such a demonstration, the Sec-
21 retary may establish by regulation operating standards for
22 the safety of human tissue and may require human tissue
23 to be processed only in an establishment registered in ac-
24 cordance with the procedures established for drugs under
25 section 510.

1 “(B) The operating standards authorized under this
2 paragraph shall be limited to the following general require-
3 ments for the recovery, processing, storage, and shipment
4 of human tissue:

5 “(i) Requirements for universal infection con-
6 trol designs to prevent transmission of disease.

7 “(ii) Good processing practices that assure the
8 safety, maintenance of structure, and preservation of
9 original cellular function of tissue.

10 “(iii) Labeling requirements for the identifica-
11 tion of the type of tissue, the addition of any foreign
12 substance, and information needed to permit tracing.

13 “(C) Registered establishments shall be subject to in-
14 spection under section 704. During such an inspection the
15 Secretary shall have access to or copies of patient and
16 donor names and other donor identifying information
17 when such access is critical to public health as defined in
18 regulations to be promulgated by the Secretary for par-
19 ticular types of tissue. Such inspection may be conducted
20 by nonprofit membership organizations that meet require-
21 ments established by the Secretary for individuals and or-
22 ganizations accredited by the Secretary under section 712.

23 “(3) The requirements established under paragraph
24 (2) shall not apply to human tissue not stored for a signifi-
25 cant period or not significantly processed.

1 “(e) The Secretary may take action to enforce the
2 requirements of good manufacturing practice for blood,
3 blood components, and good operating standards for
4 human tissue in the same manner as is done for drugs.”.

5 (c) TRANSITION.—The requirements of the interim
6 regulation promulgated by the Secretary of Health and
7 Human Services on December 1993, shall remain in effect
8 for a period of 18 months after the date of the enactment
9 of this section so that the Secretary may have an oppor-
10 tunity to establish general controls for tissue pursuant to
11 section 506(d)(1)(A) of the Federal Food, Drug, and Cos-
12 metic Act. The Secretary shall not regulate eyes until such
13 time that the Secretary makes a finding under section
14 506(d)(1)(A) of such Act that voluntary regulation under
15 generally accepted standards is inadequate to protect the
16 public health.

17 (d) CONFORMING AMENDMENTS.—

18 (1) SECTION 301(d).—Section 301(d) (21
19 U.S.C. 331(d)) is amended by striking “or 505” and
20 inserting “, 505, or 506”.

21 (2) SECTION 301(e).—Section 301(e) (21
22 U.S.C. 331(e)) is amended by inserting after “(k),”
23 the following: “506(b),”.

1 (3) SECTION 301.—Section 301 (21 U.S.C.
2 331), as amended by section 8(b), is amended by
3 adding after paragraph (w) the following:

4 “(x) The failure of blood, blood component, or human
5 tissue to comply with any applicable requirement estab-
6 lished under section 506.”.

7 (4) SECTION 501.—Section 501 (21 U.S.C. 351)
8 is amended by adding at the end the following:

9 “(j) If it is a biological product, blood, blood compo-
10 nent, or human tissue and it does not comply with any
11 applicable requirement established under section 506.”.

12 (5) SECTION 351.—Section 351 of the Public
13 Health Service Act (42 U.S.C. 262) is amended by
14 striking the section heading and “SEC. 351.” and
15 subsections (a) through (d)(1) and (e) through (g)
16 of such section 351 are repealed.

17 (6) SECTION 351.—Subsection (d)(2) of such
18 section 351 is redesignated as subsection (g) of sec-
19 tion 511.

20 (7) MULTIPLE SECTIONS.—Sections 525(a),
21 526(a)(1), 526(a)(1)(C), 526(b)(1), 526(b)(2),
22 527(a), 527(b), 735(1)(D), 735(3), 735(6)(D),
23 802(a)(1)(B), 802(b)(1)(A)(ii)(II), 802(b)(1)(C),
24 802(c)(1)(C), 802(d)(3), 802(d)(4), and 902(c) (21
25 U.S.C. 360aa(a), 360bb(a)(1), (a)(1)(C), (b)(1),

1 (b)(2), 360cc(a), (b), 379g(1)(D), (3), (6)(D),
2 382(a)(1)(B), (b)(1)(A)(ii)(II), (b)(1)(C), (c)(1)(C),
3 (d)(3), (d)(4), 392(c)) are each amended by striking
4 “section 351 of the Public Health Service Act”
5 wherever it appears and inserting “section 506”.

6 (8) SECTION 201.—Section 201(ff)(3)(A) (21
7 U.S.C 321(ff)(3)(A)) is amended by striking “under
8 section 351 of the Public Health Service Act (42
9 U.S.C.262)” and inserting “section 506”.

10 (9) SECTION 503.—Section 503(g)(4)(A) (21
11 U.S.C 353(g)(4)(A)) is amended by striking “in sec-
12 tion 351(a) of the Public Health Service Act (42
13 U.S.C. 262(a))” and inserting “in section 506”.

14 (10) SECTION 503.—Section 503(g)(4)(B) (21
15 U.S.C. 353(g)(4)(B)) is amended to read as follows:

16 “(B) As used in this subsection, the term ‘mar-
17 ket clearance’ includes—

18 “(i) approval of an application under sec-
19 tion 505, 507, 511, 515, or 520(g) and

20 “(ii) a finding of substantial equivalence
21 under this subchapter.”.

22 (11) PUBLIC HEALTH SERVICE ACT.—The fol-
23 lowing sections of the Public Health Service Act are
24 amended as follows:

1 (A) Section 227(c)(5) (42 U.S.C.
2 236(c)(5)) is amended by striking “under sec-
3 tion 351 of this Act” and inserting “under sec-
4 tion 506 of such Act”.

5 (B) Sections 352(a) and 352(b) (42 U.S.C.
6 263(a), 263(b)) are each amended by striking
7 “in section 351” and inserting “in section 506
8 of the Federal Food, Drug, and Cosmetic Act”.

9 (C) Section 2122(b)(2) (42 U.S.C. 360aa-
10 22(b)(2)) is amended by striking “section 351
11 of the Public Health Service Act” and inserting
12 “section 506 of the Federal Food, Drug, and
13 Cosmetic Act”.

14 (D) Section 2123(d)(2)(A) (42 U.S.C.
15 360aa-23(d)(2)(A)) is amended by striking
16 “under section 351” and inserting “under sec-
17 tion 506 of the Federal Food, Drug, and Cos-
18 metic Act”.

19 (12) SECTION 1927.—Section 1927(k)(2)(B) of
20 the Social Security Act (42 U.S.C. 1396r-
21 8(k)(2)(B)) is amended by striking “under section
22 351 of the Public Health Service Act” and inserting
23 “under section 506 of the Federal Food, Drug, and
24 Cosmetic Act”.

1 (13) ORPHAN DRUG ACT.—Sections 5(b)(1)(A)
2 and 5(b)(1)(B) of the Orphan Drug Act (21 U.S.C.
3 360ee(b)(1)(A), 360ee(b)(1)(B)) are each amended
4 by striking “section 351 of the Public Health Serv-
5 ice Act” and inserting “section 506 of the Federal
6 Food, Drug, and Cosmetic Act”.

7 (14) PATENTS.—Section 156 of title 35, United
8 States Code, is amended—

9 (A) in subsection (f)(2)(A), by striking
10 “and the Public Health Service Act”;

11 (B) in subsection (f)(4)—

12 (i) by striking subparagraph (A) and
13 redesignating subparagraphs (B) and (C)
14 as subparagraphs (A) and (B), respec-
15 tively; and

16 (ii) by inserting “506,” after “505,”
17 each place it appears in subparagraph (A)
18 (as so redesignated); and

19 (C) in subsection (g)(1)(B)(ii), by striking
20 “under section 351, subsection (b) of section
21 505” and inserting “under subsection (b) of
22 section 505, 506”.

23 (15) INTERNAL REVENUE CODE OF 1986.—Sec-
24 tion 28(b)(2)(A)(ii)(II) of the Internal Revenue Code
25 of 1986 is amended by striking “under section 351

1 of the Public Health Service Act” and inserting
2 “under section 506 of such Act”.

3 (d) LICENSES.—All licenses effective under section
4 351 of the Public Health Service Act as of the date of
5 enactment of the Drug and Biological Products Reform
6 Act of 1996 shall be deemed to have been granted under
7 the applicable provisions of this Act as of such date and
8 shall be subject to the provisions of this Act as of such
9 date.

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