

**SEC. 415. CONTRACTS FOR EXPERT REVIEW.**

Chapter IX (21 U.S.C. 391 et seq.), as amended by section 214, is further amended by adding at the end the following:

**“SEC. 907. CONTRACTS FOR EXPERT REVIEW.**

“(a) IN GENERAL.—

“(1) AUTHORITY.—The Secretary may enter into a contract with any organization or any individual (who is not an employee of the Department) with relevant expertise, to review and evaluate, for the purpose of making recommendations to the Secretary on, part or all of any application or submission (including a petition, notification, and any other similar form of request) made under this Act for the approval or classification of an article or made under section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)) with respect to a biological product. Any such contract shall be subject to the requirements of section 708 relating to the confidentiality of information.

“(2) INCREASED EFFICIENCY AND EXPERTISE THROUGH CONTRACTS.—The Secretary may use the authority granted in paragraph (1) whenever the Secretary determines that use of a contract described in paragraph (1) will improve the timeliness of the review of an application or submission described in paragraph (1), unless using such authority would reduce the quality, or unduly increase the cost, of such review. The Secretary may use such authority whenever the Secretary determines that use of such a contract will improve the quality of the review of an application or submission described in paragraph (1), unless using such authority would unduly increase the cost of such review. Such improvement in timeliness or quality may include providing the Secretary increased scientific or technical expertise that is necessary to review or evaluate new therapies and technologies.

“(b) REVIEW OF EXPERT REVIEW.—

“(1) IN GENERAL.—Subject to paragraph (2), the official of the Food and Drug Administration responsible for any matter for which expert review is used pursuant to subsection (a) shall review the recommendations of the organization or individual who conducted the expert review and shall make a final decision regarding the matter in a timely manner.

“(2) LIMITATION.—A final decision by the Secretary on any such application or submission shall be made within the applicable prescribed time period for review of the matter as set forth in this Act or in the Public Health Service Act (42 U.S.C. 201 et seq.).”

**SEC. 416. PRODUCT CLASSIFICATION.**

Subchapter E of chapter V, as amended by section 404, is further amended by adding at the end the following:

**“SEC. 563. CLASSIFICATION OF PRODUCTS.**

“(a) REQUEST.—A person who submits an application or submission (including a petition, notification, and any other similar form of request) under this Act for a product, may submit a request to the Secretary respecting the classification of the product as a drug, biological product, device, or a combination product subject to section 503(g) or respecting the component of the Food and Drug Administration that will regulate the product. In submitting the request, the person shall recommend a classification for the product, or a component to regulate the product, as appropriate.

“(b) STATEMENT.—Not later than 60 days after the receipt of the request described in subsection (a), the Secretary shall determine the classification of the product under subsection (a), or the component of the Food and Drug Administration that will regulate the product, and shall provide to the person a written statement that identifies such classification or such component, and the reasons for such determination. The Sec-

retary may not modify such statement except with the written consent of the person, or for public health reasons based on scientific evidence.

“(c) INACTION OF SECRETARY.—If the Secretary does not provide the statement within the 60-day period described in subsection (b), the recommendation made by the person under subsection (a) shall be considered to be a final determination by the Secretary of such classification of the product, or the component of the Food and Drug Administration that will regulate the product, as applicable, and may not be modified by the Secretary except with the written consent of the person, or for public health reasons based on scientific evidence.”

**SEC. 417. REGISTRATION OF FOREIGN ESTABLISHMENTS.**

Section 510(i) (21 U.S.C. 360(i)) is amended to read as follows:

“(i)(1) Any establishment within any foreign country engaged in the manufacture, preparation, propagation, compounding, or processing of a drug or a device that is imported or offered for import into the United States shall register with the Secretary the name and place of business of the establishment and the name of the United States agent for the establishment.

“(2) The establishment shall also provide the information required by subsection (j).

“(3) The Secretary is authorized to enter into cooperative arrangements with officials of foreign countries to ensure that adequate and effective means are available for purposes of determining, from time to time, whether drugs or devices manufactured, prepared, propagated, compounded, or processed by an establishment described in paragraph (1), if imported or offered for import into the United States, shall be refused admission on any of the grounds set forth in section 801(a).”

**SEC. 418. CLARIFICATION OF SEIZURE AUTHORITY.**

Section 304(d)(1) (21 U.S.C. 334(d)(1)) is amended—

(1) in the fifth sentence, by striking “paragraphs (1) and (2) of section 801(e)” and inserting “subparagraphs (A) and (B) of section 801(e)(1)”; and

(2) by inserting after the fifth sentence the following: “Any person seeking to export an imported article pursuant to any of the provisions of this subsection shall establish that the article was intended for export at the time the article entered commerce.”

**SEC. 419. INTERSTATE COMMERCE.**

Section 709 (21 U.S.C. 379a) is amended by striking “a device” and inserting “a device, food, drug, or cosmetic”.

**SEC. 420. SAFETY REPORT DISCLAIMERS.**

Chapter VII (21 U.S.C. 371 et seq.), as amended by section 412, is further amended by adding at the end the following:

“SUBCHAPTER G—SAFETY REPORTS

**“SEC. 756. SAFETY REPORT DISCLAIMERS.**

“With respect to any entity that submits or is required to submit a safety report or other information in connection with the safety of a product (including a product that is a food, drug, device, dietary supplement, or cosmetic) under this Act (and any release by the Secretary of that report or information), such report or information shall not be construed to reflect necessarily a conclusion by the entity or the Secretary that the report or information constitutes an admission that the product involved malfunctioned, caused or contributed to an adverse experience, or otherwise caused or contributed to a death, serious injury, or serious illness. Such an entity need not admit, and may deny, that the report or information submitted by the entity constitutes an admission that the product involved malfunctioned, caused or

contributed to an adverse experience, or caused or contributed to a death, serious injury, or serious illness.”

**SEC. 421. LABELING AND ADVERTISING REGARDING COMPLIANCE WITH STATUTORY REQUIREMENTS.**

Section 301 (21 U.S.C. 331) is amended by striking paragraph (l).

**SEC. 422. RULE OF CONSTRUCTION.**

Nothing in this Act or the amendments made by this Act shall be construed to affect the question of whether the Secretary of Health and Human Services has any authority to regulate any tobacco product, tobacco ingredient, or tobacco additive. Such authority, if any, shall be exercised under the Federal Food, Drug, and Cosmetic Act as in effect on the day before the date of the enactment of this Act.

**TITLE V—EFFECTIVE DATE****SEC. 501. EFFECTIVE DATE.**

Except as otherwise provided in this Act, this Act and the amendments made by this Act, other than the provisions of and the amendments made by sections 111, 121, 125, and 307, shall take effect 90 days after the date of enactment of this Act.

And the House agree to the same.

That the House recede from its amendment to the title of the bill.

TOM BLILEY,  
MICHAEL BILIRAKIS,  
JOE BARTON,  
JAMES GREENWOOD,  
RICHARD BURR,  
ED WHITFIELD,  
JOHN D. DINGELL,  
SHERRON BROWN,  
HENRY A. WAXMAN,  
RON KLING,

*Managers of the Part of the House.*

JIM JEFFORDS,  
DAN COATS,  
JUDD GREGG,  
BILL FRIST,  
MIKE DEWINE,  
EDWARD M. KENNEDY,  
CHRISTOPHER DODD,  
TOM HARKIN,  
BARBARA A. MIKULSKI,

*Managers on the Part of the Senate.*

The SPEAKER pro tempore, Mr. PETRI, recognized Mr. BLILEY and Mr. DINGELL, each for 20 minutes.

After debate,

The question being put, viva voce,

Will the House suspend the rules and agree to said conference report?

The SPEAKER pro tempore, Mr. PETRI, announced that two-thirds of the Members present had voted in the affirmative.

So, two-thirds of the Members present having voted in favor thereof, the rules were suspended and said conference report was agreed to.

A motion to reconsider the vote whereby the rules were suspended and said conference report was agreed to was, by unanimous consent, laid on the table.

*Ordered*, That the Clerk notify the Senate thereof.

**¶130.30 ELECTIONS IN SAHARA**

Mr. ROYCE moved to suspend the rules and agree to the following resolution (H. Res. 245); as amended:

Whereas United Nations Secretary General Kofi Annan appointed former United States Secretary of State James Baker III as his