

Public Law 102-571
102d Congress

An Act

To amend the Federal Food, Drug, and Cosmetic Act to authorize human drug application, prescription drug establishment, and prescription drug product fees and for other purposes.

Oct. 29, 1992
[H.R. 6181]

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

TITLE I—USER FEES

Prescription
Drug User
Fee Act of
1992.
21 USC 301
note.

SEC. 101. SHORT TITLE AND REFERENCE.

(a) **SHORT TITLE.**—This title may be cited as the “Prescription Drug User Fee Act of 1992”.

(b) **REFERENCE.**—Whenever in this title an amendment or repeal is expressed in terms of an amendment to, or repeal of, a section or other provision, the reference shall be considered to be made to a section or other provision of the Federal Food, Drug, and Cosmetic Act.

SEC. 102. FINDINGS.

21 USC 379g
note.

The Congress finds that—

(1) prompt approval of safe and effective new drugs is critical to the improvement of the public health so that patients may enjoy the benefits provided by these therapies to treat and prevent illness and disease;

(2) the public health will be served by making additional funds available for the purpose of augmenting the resources of the Food and Drug Administration that are devoted to the process for review of human drug applications; and

(3) the fees authorized by this title will be dedicated toward expediting the review of human drug applications as set forth in the goals identified in the letters of September 14, 1992, and September 21, 1992, from the Commissioner of Food and Drugs to the Chairman of the Energy and Commerce Committee of the House of Representatives and the Chairman of the Labor and Human Resources Committee of the Senate, as set forth at 138 Cong. Rec. H9099–H9100 (daily ed. September 22, 1992).

SEC. 103. FEES RELATING TO DRUGS.

Chapter VII, as amended by section 106, is amended by adding at the end of subchapter C the following:

“PART 2—FEES RELATING TO DRUGS

“SEC. 735. DEFINITIONS.

21 USC 379g.

“For purposes of this subchapter:

“(1) The term ‘human drug application’ means an application for—

“(A) approval of a new drug submitted under section 505(b)(1),

“(B) approval of a new drug submitted under section 505(b)(2) after September 30, 1992, which requests approval of—

“(i) a molecular entity which is an active ingredient (including any salt or ester of an active ingredient), or

“(ii) an indication for a use, that had not been approved under an application submitted under section 505(b),

“(C) initial certification or initial approval of an antibiotic drug under section 507, or

“(D) licensure of a biological product under section 351 of the Public Health Service Act.

Such term does not include a supplement to such an application, does not include an application with respect to whole blood or a blood component for transfusion, does not include an application with respect to a bovine blood product for topical application licensed before September 1, 1992, an allergenic extract product, or an in vitro diagnostic biologic product licensed under section 351 of the Public Health Service Act, and does not include an application with respect to a large volume parenteral drug product approved before September 1, 1992.

“(2) The term ‘supplement’ means a request to the Secretary to approve a change in a human drug application which has been approved.

“(3) The term ‘prescription drug product’ means a specific strength or potency of a drug in final dosage form—

“(A) for which a human drug application has been approved, and

“(B) which may be dispensed only under prescription pursuant to section 503(b).

Such term does not include whole blood or a blood component for transfusion, does not include a bovine blood product for topical application licensed before September 1, 1992, an allergenic extract product, or an in vitro diagnostic biologic product licensed under section 351 of the Public Health Service Act, and does not include a large volume parenteral drug product approved before September 1, 1992.

“(4) The term ‘final dosage form’ means, with respect to a prescription drug product, a finished dosage form which is approved for administration to a patient without further manufacturing.

“(5) The term ‘prescription drug establishment’ means a foreign or domestic place of business which is—

“(A) at one general physical location consisting of one or more buildings all of which are within 5 miles of each other, at which one or more prescription drug products are manufactured in final dosage form, and

“(B) under the management of a person that is listed as the applicant in a human drug application for a prescription drug product with respect to at least one such product.

For purposes of this paragraph, the term ‘manufactured’ does not include packaging.

“(6) The term ‘process for the review of human drug applications’ means the following activities of the Secretary with respect to the review of human drug applications and supplements:

“(A) The activities necessary for the review of human drug applications and supplements.

“(B) The issuance of action letters which approve human drug applications or which set forth in detail the specific deficiencies in such applications and, where appropriate, the actions necessary to place such applications in condition for approval.

“(C) The inspection of prescription drug establishments and other facilities undertaken as part of the Secretary’s review of pending human drug applications and supplements.

“(D) Activities necessary for the review of applications for licensure of establishments subject to section 351 of the Public Health Service Act and for the release of lots of biologics under such section.

“(E) Monitoring of research conducted in connection with the review of human drug applications.

“(7) The term ‘costs of resources allocated for the process for the review of human drug applications’ means the expenses incurred in connection with the process for the review of human drug applications for—

“(A) officers and employees of the Food and Drug Administration, employees under contract with the Food and Drug Administration who work in facilities owned or leased for the Food and Drug Administration, advisory committees, and costs related to such officers, employees, and committees,

“(B) management of information, and the acquisition, maintenance, and repair of computer resources,

“(C) leasing, maintenance, renovation, and repair of facilities and acquisition, maintenance, and repair of fixtures, furniture, scientific equipment, and other necessary materials and supplies, and

“(D) collecting fees under section 736 and accounting for resources allocated for the review of human drug applications and supplements.

“(8) The term ‘adjustment factor’ applicable to a fiscal year is the lower of—

“(A) the Consumer Price Index for all urban consumers (all items; United States city average) for August of the preceding fiscal year divided by such Index for August 1992, or

“(B) the total of discretionary budget authority provided for programs in the domestic category for the immediately preceding fiscal year (as reported in the Office of Management and Budget sequestration preview report, if available, required under section 254(d) of the Balanced Budget and Emergency Deficit Control Act of 1985) divided by such budget authority for fiscal year 1992 (as reported in the Office of Management and Budget final sequestration report submitted after the end of the 102d Congress, 2d Session).

The terms 'budget authority' and 'category' in subparagraph (B) are as defined in the Balanced Budget and Emergency Deficit Control Act of 1985, as in effect as of September 1, 1992.

21 USC 379h.

"SEC. 736. AUTHORITY TO ASSESS AND USE DRUG FEES.

"(a) TYPES OF FEES.—Beginning in fiscal year 1993, the Secretary shall assess and collect fees in accordance with this section as follows:

"(1) HUMAN DRUG APPLICATION AND SUPPLEMENT FEE.—

"(A) IN GENERAL.—Each person that submits, on or after September 1, 1992, a human drug application or a supplement shall be subject to a fee as follows:

"(i) A fee established in subsection (b) for a human drug application for which clinical data (other than bioavailability or bioequivalence studies) with respect to safety or effectiveness are required for approval.

"(ii) A fee established in subsection (b) for a human drug application for which clinical data with respect to safety or effectiveness are not required or a supplement for which clinical data (other than bioavailability or bioequivalence studies) with respect to safety or effectiveness are required.

"(B) PAYMENT SCHEDULE.—

"(i) FIRST PAYMENT.—50 percent of the fee required by subparagraph (A) shall be due upon submission of the application or supplement.

"(ii) FINAL PAYMENT.—The remaining 50 percent of the fee required by subparagraph (A) shall be due upon—

"(I) the expiration of 30 days from the date the Secretary sends to the applicant a letter designated by the Secretary as an action letter described in section 735(6)(B), or

"(II) the withdrawal of the application or supplement after it is filed unless the Secretary waives the fee or a portion of the fee because no substantial work was performed on such application or supplement after it was filed.

The designation under subclause (I) or the waiver under subclause (II) shall be solely in the discretion of the Secretary and shall not be reviewable.

"(C) EXCEPTION FOR PREVIOUSLY FILED APPLICATION OR SUPPLEMENT.—If a human drug application or supplement was submitted by a person that paid the fee for such application or supplement, was accepted for filing, and was not approved or was withdrawn (without a waiver), the submission of a human drug application or a supplement for the same product by the same person (or the person's licensee, assignee, or successor) shall not be subject to a fee under subparagraph (A).

"(D) REFUND OF FEE IF APPLICATION NOT ACCEPTED FOR FILING.—The Secretary shall refund 50 percent of the fee paid under subparagraph (B)(i) for any application or supplement which is not accepted for filing.

"(2) PRESCRIPTION DRUG ESTABLISHMENT FEE.—Each person that—

"(A) owns a prescription drug establishment, at which is manufactured at least 1 prescription drug product which is not the, or not the same as a, product approved under an application filed under section 505(b)(2) or 505(j), and

"(B) after September 1, 1992, had pending before the Secretary a human drug application or supplement, shall be subject to the annual fee established in subsection (b) for each such establishment, payable on or before January 31 of each year.

"(3) PRESCRIPTION DRUG PRODUCT FEE.—

"(A) IN GENERAL.—Except as provided in subparagraph (B), each person—

"(i) who is named as the applicant in a human drug application for a prescription drug product which is listed under section 510, and

"(ii) who, after September 1, 1992, had pending before the Secretary a human drug application or supplement, shall pay for each such prescription drug product the annual fee established in subsection (b). Such fee shall be payable at the time of the first such listing of such product in each calendar year. Such fee shall be paid only once each year for each listed prescription drug product irrespective of the number of times such product is listed under section 510.

"(B) EXCEPTION.—The listing of a prescription drug product under section 510 shall not require the person who listed such product to pay the fee prescribed by subparagraph (A) if such product is the same product as a product approved under an application filed under section 505(b)(2) or 505(j).

"(b) FEE AMOUNTS.—

"(1) SCHEDULE.—Except as provided in paragraph (2) and subsections (c), (d), (f), and (g), the fees required under subsection (a) shall be paid in accordance with the following schedule:

	Fiscal Year 1993	Fiscal Year 1994	Fiscal Year 1995	Fiscal Year 1996	Fiscal Year 1997
Drug application fee:					
Subsection					
(a)(1)(A)(i) fee	\$100,000	\$150,000	\$208,000	\$217,000	\$233,000
Subsection					
(a)(1)(A)(ii) fee	\$50,000	\$75,000	\$104,000	\$108,000	\$116,000
Fee revenue	\$12,000,000	\$18,000,000	\$25,000,000	\$26,000,000	\$28,000,000
Annual establishment fee:					
Fee per establishment	\$60,000	\$88,000	\$126,000	\$131,000	\$138,000
Fee revenue	\$12,000,000	\$18,000,000	\$25,000,000	\$26,000,000	\$28,000,000
Annual product fee:					
Fee per product	\$6,000	\$9,000	\$12,500	\$13,000	\$14,000
Fee revenue	\$12,000,000	\$18,000,000	\$25,000,000	\$26,000,000	\$28,000,000
Total fee revenues	\$36,000,000	\$54,000,000	\$75,000,000	\$78,000,000	\$84,000,000

"(2) SMALL BUSINESS EXCEPTION.—Any business which has fewer than 500 employees, including employees of affiliates, and which does not have a prescription drug product introduced

or delivered for introduction into interstate commerce shall pay one-half the amount of the fee for human drug applications it submits and shall pay the entire amount of the fee for supplements it submits. Such a business shall not be required to pay any portion of any fee required under subsection (a)(1)(A) until 1 year after the date of the submission of the application involved. For purposes of this paragraph, one business is an affiliate of another business when, directly or indirectly, one business controls, or has the power to control, the other business or a third party controls, or has the power to control, both businesses.

"(c) INCREASES AND ADJUSTMENTS.—

"(1) REVENUE INCREASE.—The total fee revenues established by the schedule in subsection (b)(1) shall be increased by the Secretary by notice, published in the Federal Register, for a fiscal year to reflect the greater of—

"(A) the total percentage increase that occurred during the preceding fiscal year in the Consumer Price Index for all urban consumers (all items; U.S. city average), or

"(B) the total percentage increase for such fiscal year in basic pay under the General Schedule in accordance with section 5332 of title 5, United States Code, as adjusted by any locality-based comparability payment pursuant to section 5304 of such title for Federal employees stationed in the District of Columbia.

"(2) ANNUAL FEE ADJUSTMENT.—Subject to the amount appropriated for a fiscal year under subsection (g), the Secretary shall, within 60 days after the end of each fiscal year beginning after October 1, 1992, adjust the fees established by the schedule in subsection (b)(1) for the following fiscal year to achieve the total fee revenues, as may be increased under paragraph (1). Such fees shall be adjusted under this paragraph to maintain the proportions established in such schedule.

"(3) LIMIT.—The total amount of fees charged, as adjusted under paragraph (2), for a fiscal year may not exceed the total costs for such fiscal year for the resources allocated for the process for the review of human drug applications.

"(d) FEE WAIVER OR REDUCTION.—The Secretary shall grant a waiver from or a reduction of 1 or more fees under subsection (a) where the Secretary finds that—

"(1) such waiver or reduction is necessary to protect the public health,

"(2) the assessment of the fee would present a significant barrier to innovation because of limited resources available to such person or other circumstances,

"(3) the fees to be paid by such person will exceed the anticipated present and future costs incurred by the Secretary in conducting the process for the review of human drug applications for such person, or

"(4) assessment of the fee for an application or a supplement filed under section 505(b)(1) pertaining to a drug containing an active ingredient would be inequitable because an application for a product containing the same active ingredient filed by another person under section 505(b)(2) could not be assessed fees under subsection (a)(1).

In making the finding in paragraph (3), the Secretary may use standard costs.

Federal
Register,
publication.

"(e) **EFFECT OF FAILURE TO PAY FEES.**—A human drug application or supplement submitted by a person subject to fees under subsection (a) shall be considered incomplete and shall not be accepted for filing by the Secretary until all fees owed by such person have been paid.

"(f) **ASSESSMENT OF FEES.**—

"(1) **LIMITATION.**—Fees may not be assessed under subsection (a) for a fiscal year beginning after fiscal year 1993 unless appropriations for salaries and expenses of the Food and Drug Administration for such fiscal year (excluding the amount of fees appropriated for such fiscal year) are equal to or greater than the amount of appropriations for the salaries and expenses of the Food and Drug Administration for the fiscal year 1992 multiplied by the adjustment factor applicable to the fiscal year involved.

"(2) **AUTHORITY.**—If the Secretary does not assess fees under subsection (a) during any portion of a fiscal year because of paragraph (1) and if at a later date in such fiscal year the Secretary may assess such fees, the Secretary may assess and collect such fees, without any modification in the rate, for human drug applications and supplements, prescription drug establishments, and prescription drug products at any time in such fiscal year notwithstanding the provisions of subsection (a) relating to the date fees are to be paid.

"(g) **CREDITING AND AVAILABILITY OF FEES.**—

"(1) **IN GENERAL.**—Fees collected for a fiscal year pursuant to subsection (a) shall be credited to the appropriation account for salaries and expenses of the Food and Drug Administration and shall be available in accordance with appropriation Acts until expended without fiscal year limitation.

"(2) **COLLECTIONS AND APPROPRIATION ACTS.**—The fees authorized by this section—

"(A) shall be collected in each fiscal year in an amount equal to the amount specified in appropriation Acts for such fiscal year, and

"(B) shall only be collected and available to defray increases in the costs of the resources allocated for the process for the review of human drug applications (including increases in such costs for an additional number of full-time equivalent positions in the Department of Health and Human Services to be engaged in such process) over such costs for fiscal year 1992 multiplied by the adjustment factor.

"(3) **AUTHORIZATION OF APPROPRIATIONS.**—There are authorized to be appropriated for fees under this section—

"(A) \$36,000,000 for fiscal year 1993,

"(B) \$54,000,000 for fiscal year 1994,

"(C) \$75,000,000 for fiscal year 1995,

"(D) \$78,000,000 for fiscal year 1996, and

"(E) \$84,000,000 for fiscal year 1997,

as adjusted to reflect increases in the total fee revenues made under subsection (c)(1).

"(h) **COLLECTION OF UNPAID FEES.**—In any case where the Secretary does not receive payment of a fee assessed under subsection (a) within 30 days after it is due, such fee shall be treated as a claim of the United States Government subject to subchapter II of chapter 37 of title 31, United States Code.

“(i) CONSTRUCTION.—This section may not be construed to require that the number of full-time equivalent positions in the Department of Health and Human Services, for officers, employers, and advisory committees not engaged in the process of the review of human drug applications, be reduced to offset the number of officers, employees, and advisory committees so engaged.”.

21 USC 379g
note.

SEC. 104. ANNUAL REPORTS.

(a) FIRST REPORT.—Within 60 days after the end of each fiscal year during which fees are collected under part 2 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act, the Secretary of Health and Human Services shall submit a report stating the Food and Drug Administration's progress in achieving the goals identified in section 102(3) of this Act during such fiscal year and that agency's future plans for meeting such goals.

(b) SECOND REPORT.—Within 120 days after the end of each fiscal year during which such fees are collected, the Secretary of Health and Human Services shall submit a report on the implementation of the authority for such fees during such fiscal year and on the use the Food and Drug Administration made of the fees collected during such fiscal year for which the report is made.

(c) COMMITTEES.—The reports described in subsections (a) and (b) shall be submitted to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate.

21 USC 379g
note.

SEC. 105. SUNSET.

The amendments made by section 103 shall not be in effect after October 1, 1997 and section 104 shall not be in effect after 120 days after such date.

SEC. 106. CONFORMING AMENDMENTS TO CHAPTER VII

Chapter VII is amended—

(1) by striking out in the chapter heading “ADMINISTRATIVE PROVISIONS” and inserting in lieu thereof “AUTHORITY”,

(2) by inserting before the section heading for section 701 the following:

“SUBCHAPTER A—GENERAL ADMINISTRATIVE PROVISIONS”,

21 USC 379a,
376.

(3) by redesignating section 702A (21 U.S.C. 372a) as section 706 and by inserting it after section 705 (21 U.S.C. 375) and by redesignating section 712 (21 U.S.C. 379d) as section 711,

21 USC 376,
379e.

(4) by moving section 706 (21 U.S.C. 376), as in effect on the date of the enactment of this Act, to the end of chapter VII, by redesignating the section as section 721, and by inserting before the section heading for the section the following:

“SUBCHAPTER B—COLORS”,

(5) by inserting after section 721 (as so redesignated) the following:

"SUBCHAPTER C—FEES

**"PART 1—FREEDOM OF INFORMATION FEES",
and**

(6) by inserting section 711 (21 U.S.C. 379c), as in effect on the date of the enactment of this Act, after the heading for part 1 of subchapter C and redesignating it as section 731. 21 USC 379c,
379f.

SEC. 107. GENERAL CONFORMING AMENDMENTS.

To conform the Federal Food, Drug, and Cosmetic Act, to the amendments made to that Act by section 106(4), the following conforming amendments are made:

(1) Section 201(u) (21 U.S.C. 321(u)) is amended by striking out "706" and inserting in lieu thereof "721".

(2) Section 301(i)(1) (21 U.S.C. 331(i)(1)) is amended by striking out "706" and inserting in lieu thereof "721".

(3) Section 301(j) (21 U.S.C. 331(j)) is amended by striking out "706" and inserting in lieu thereof "721".

(4) Section 402(c) (21 U.S.C. 342(c)) is amended by striking out "706" and inserting in lieu thereof "721".

(5) Section 403(i) (21 U.S.C. 343(i)) is amended by striking out "706" and inserting in lieu thereof "721".

(6) Section 403(m) (21 U.S.C. 343(m)) is amended by striking out "706" and inserting in lieu thereof "721".

(7) Section 408(g) (21 U.S.C. 346a(g)) is amended by striking out "706" and inserting in lieu thereof "721".

(8) Section 501(a)(4) (21 U.S.C. 351(a)(4)) is amended by striking out "706" each place it occurs and inserting in lieu thereof "721".

(9) Section 502(m) (21 U.S.C. 352(m)) is amended by striking out "706" and inserting in lieu thereof "721".

(10) Section 520(g)(2)(A) (21 U.S.C. 360j(g)(2)(A)) is amended by striking out "706" and by inserting in lieu thereof "721".

(11) Section 601(e) (21 U.S.C. 361(e)) is amended by striking out "706" and inserting in lieu thereof "721".

(12) Section 602(e) (21 U.S.C. 362(e)) is amended by striking out "706" and inserting in lieu thereof "721".

(13) Section 4(g)(2)(D) of the Poultry Products Inspection Act (21 U.S.C. 453(g)(2)(D)) is amended by striking out "706" and inserting in lieu thereof "721".

(14) Section 1(m)(2)(D) of the Federal Meat Inspection Act (21 U.S.C. 601(m)(2)(D)) is amended by striking out "706" and inserting in lieu thereof "721".

(15) Section 4(a)(2)(D) of the Egg Products Inspection Act (21 U.S.C. 1033(a)(2)(D)) is amended by striking out "706" and inserting in lieu thereof "721".

(16) Section 10(b) of the Nutrition Labeling and Education Act of 1990 (21 U.S.C. 343 note) is amended—

(A) in paragraph (2)—

(i) by striking "(1) 24" and inserting "(A) 24"; and
(ii) by striking "(2) action" and inserting "(B) action";

(B) by indenting, and aligning the margins of, paragraph (2) so as to align with paragraph (1); and

21 USC 343-1
note.

(C) by indenting, and aligning the margins of, subparagraphs (A) and (B) of paragraph (2) (as so designated by subparagraph (A)) so as to align with the subparagraphs of paragraph (1).

(17) Section 10(c)(2)(A) of the Nutrition Labeling and Education Act of 1990 (21 U.S.C. 343 note) (as amended by section 1 of the Act entitled "An Act to make Technical Amendments to the Nutrition Information and Labeling Act, and for other purposes", approved August 17, 1991 (Public Law 102-108; 105 Stat. 549) is amended by striking "706" and inserting "721".

21 USC 379g
note.

SEC. 108. ANIMAL DRUG USER FEE STUDY.

(a) **STUDY.**—The Secretary, in consultation with manufacturers of animal drug products and other interested persons, shall undertake a study to evaluate whether, and under what conditions, to impose user fees to supplement appropriated funds in order to improve the process of reviewing applications (including abbreviated and supplemental applications) for new animal drugs under section 512 of the Federal Food, Drug, and Cosmetic Act. The study shall include—

(1) an assessment of the overall review process for animal drugs at the Center for Veterinary Medicine, including the number of applications received, and the average times for interim and final decisions on each type of application,

(2) the current allocation of funds to the animal drug review process,

(3) recommendations for goals for decision making times on applications submitted to the Center for Veterinary Medicine and for additional resources required to meet the goals, and

(4) recommendations for supplementing the resources for the animal drug review process through user fees.

(b) **COMPLETION.**—The results of the study required by subsection (a) shall be presented no later than January 4, 1994, to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate.

Dietary
Supplement
Act of 1992.

21 USC 301
note.

TITLE II—DIETARY SUPPLEMENTS

SEC. 201. SHORT TITLE.

This title may be cited as the "Dietary Supplement Act of 1992".

SEC. 202. PROHIBITION.

(a) **IN GENERAL.**—

(1) **PROHIBITION ON IMPLEMENTATION.**—Notwithstanding any other provision of law and except as provided in subsection (b) and in the amendment made by paragraph (2)(A), the Secretary of Health and Human Services may not implement the Nutrition Labeling and Education Act of 1990 (Public Law 101-535; 104 Stat. 2353), or any amendment made by such Act, earlier than December 15, 1993, with respect to dietary supplements of vitamins, minerals, herbs, or other similar nutritional substances.

(2) **FEDERAL REGULATORY ACTION.**—

21 USC 343
note.

(A) PROPOSED REGULATIONS.—The first sentence of section 2(b)(1), and the first sentence of section 3(b)(1)(A), of the Nutrition Labeling and Education Act of 1990 (21 U.S.C. 343 note) are each amended by inserting before the period the following: “, except that the Secretary shall issue, not later than June 15, 1993, proposed regulations that are applicable to dietary supplements of vitamins, minerals, herbs, or other similar nutritional substances to implement such section”.

(B) FINAL REGULATIONS.—

(i) ISSUANCE OF FINAL REGULATIONS.—The second sentence of section 2(b)(1), and section 3(b)(1)(B), of the Nutrition Labeling and Education Act of 1990 (21 U.S.C. 343 note) are each amended by inserting before the period the following: “, except that the Secretary shall issue, not later than December 31, 1993, such a final regulation applicable to dietary supplements of vitamins, minerals, herbs, or other similar nutritional substances.”

(ii) REGULATIONS CONSIDERED TO BE FINAL.—The first sentence of section 2(b)(2), and the first sentence of section 3(b)(2), of the Nutrition Labeling and Education Act of 1990 (21 U.S.C. 343 note) are each amended by inserting before the period the following: “, except that the proposed regulations applicable to dietary supplements of vitamins, minerals, herbs, or other similar nutritional substances shall not be considered to be final regulations until December 31, 1993”.

(C) CONSTRUCTION.—The amendments made by subparagraph (B) shall not be construed to modify the effective date of final regulations under sections 2(b) and 3(b) of the Nutrition Labeling and Education Act of 1990 (21 U.S.C. 343 note) with respect to foods that are not such dietary supplements.

21 USC 343
note.

(3) STATE ACTION.—Section 10(a)(1)(C) of the Nutrition Labeling and Education Act of 1990 (21 U.S.C. 343 note) is amended by inserting before the comma the following: “, except that such amendments shall take effect with respect to such dietary supplements on December 31, 1993”.

(4) PREEMPTION.—Section 10(b) of the Nutrition Labeling and Education Act of 1990 (21 U.S.C. 343 note) is amended by adding at the end the following:

21 USC 343-1
note.

“(3) REQUIREMENTS PERTAINING TO CERTAIN CLAIMS.—Notwithstanding subparagraphs (D) and (E) of paragraph (1) and except with respect to claims approved in accordance with section 202(b) of the Dietary Supplement Act of 1992, the requirements described in paragraphs (4) and (5) of section 403A(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343-1(a) (4) and (5)) that pertain to dietary supplements of vitamins, minerals, herbs, or other similar nutritional substances shall not take effect until the date final regulations take effect to implement subsection (q) or (r), as appropriate, of section 403 of such Act with respect to such dietary supplements.”

(b) HEALTH CLAIMS.—Notwithstanding section 403(r)(5)(D) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343(r)(5)(D)) and subsection (a), the Secretary of Health and Human Services

21 USC 343
note.

may, earlier than December 15, 1993, approve claims made with respect to dietary supplements of vitamins, minerals, herbs, or other similar nutritional substances that are claims described in clauses (vi) and (x) of section 3(b)(1)(A) of the Nutrition Labeling and Education Act of 1990 (21 U.S.C. 343 note).

21 USC 343
note.

SEC. 203. UNITED STATES RECOMMENDED DAILY ALLOWANCES.

Notwithstanding any other provision of Federal law, no regulations that require the use of, or are based upon, recommended daily allowances of vitamins or minerals may be promulgated before November 8, 1993 (other than regulations establishing the United States recommended daily allowances specified at section 101.9(c)(7)(iv) of title 21, Code of Federal Regulations, as in effect on October 6, 1992, or regulations under section 403(r)(1)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343(r)(1)(A)) that are based on such recommended daily allowances).

SEC. 204. ENFORCEMENT REPORT.

(a) **CONTENTS.**—The Secretary of Health and Human Services shall prepare a report containing a statement of the enforcement priorities and practices of the Food and Drug Administration under section 409 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 348) with respect to dietary supplements of vitamins, minerals, herbs, or other similar nutritional substances.

(b) **REPORT.**—Not later than 30 days after the date of enactment of this Act, the Secretary of Health and Human Services shall submit the report described in subsection (a) to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate.

21 USC 393
note.

SEC. 205. MANAGEMENT ACTIVITIES STUDY.

(a) **STUDY.**—The Comptroller General shall conduct a study of the management of activities of the Food and Drug Administration that are related to dietary supplements of vitamins, minerals, herbs, or other similar nutritional substances.

(b) **CONTENTS.**—In conducting the study, the Comptroller General shall examine, with respect to such activities—

(1) the means by which the Food and Drug Administration makes a determination that a substance poses a risk to public health and safety that justifies the expenditure of resources by the agency;

(2) the means by which the Food and Drug Administration makes a determination that a substance is adulterated, misbranded, or improperly manufactured;

(3) the means by which the Food and Drug Administration makes a determination relating to the quantitative management of the agency response to specific issues, in order to adjust the efforts of the agency to be commensurate with the severity of the problem addressed by the agency;

(4) the approach by which the Food and Drug Administration determines the adequacy of proof related to the risk posed by, or the safety of, a substance, and the adequacy of such approach; and

(5) the relationship between—

(A)(i) the number of hours devoted by Food and Drug Administration personnel, and the expertise of such personnel, in conducting such activities;

(ii) the cost of conducting such activities; and

(iii) the cost to manufacturers of such supplements to achieve compliance with such activities; and

(B)(i) the level of risk suspected to be posed by such supplements; and

(ii) the level of risk determined to be posed by such supplements.

(c) **APPROACH.**—In conducting the study, the Comptroller General shall analyze the current practices of the Food and Drug Administration and the practices of the agency within the 5 years prior to the date of enactment of this Act.

(d) **ANALYSIS.**—In conducting the study, the Comptroller General shall—

(1) determine the relative proportion of resources devoted to Food and Drug Administration regulatory and enforcement activities that are related to—

(A) dietary supplements of vitamins, minerals, herbs, or other similar nutritional substances;

(B) food additives that are not such dietary supplements;

(C) foods that are not such dietary supplements;

(D) drugs that are not such dietary supplements, and devices; or

(E) cosmetics; and

(2) determine, with respect to such supplements, with respect to food additives, and with respect to foods, the proportion of the resources devoted to such regulatory and enforcement activities that are used to—

(A) determine whether a substance is misbranded;

(B) determine whether an improper manufacturing practice occurred during the manufacturing of a substance;

(C) determine whether a substance is unsafe; and

(D) determine whether a substance is adulterated or otherwise in violation of the Federal Food, Drug, and Cosmetic Act (other than by making a determination described in subparagraph (A), (B), or (C)).

(e) **REPORTS.**—

(1) **INTERIM REPORT.**—

(A) **IN GENERAL.**—Not later than 6 months after the date of enactment of this Act, the Comptroller General shall prepare and submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate an interim report containing the findings resulting from the study and the recommendations described in subparagraph (B).

(B) **RECOMMENDATIONS.**—Such report shall include the recommendations of the Comptroller General for administrative reform, including recommendations regarding opportunities for encouraging economy and efficiency through the appropriate targeting of problems, managing resources appropriately, and making adequate determinations of risk or safety, in carrying out activities related to such supplements.

(2) **FINAL REPORT.**—

(A) **IN GENERAL.**—Not later than 12 months after the date of enactment of this Act, the Comptroller General shall prepare and submit to the Committee on Energy

and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate a final report containing the findings resulting from the study and the recommendations described in subparagraph (B).

(B) RECOMMENDATIONS.—Such report shall contain the recommendations described in paragraph (1)(B).

SEC. 206. SAFETY AND REGULATORY OUTCOMES STUDY.

(a) SAFETY STUDY.—The Director of the Office of Technology Assessment, in cooperation with the Congressional Research Service and subject to the approval of the Technology Assessment Board, shall conduct a study of the relationship between—

(1) regulatory systems affecting the development and sale of dietary supplements of vitamins, minerals, herbs, or other similar nutritional substances; and

(2) health outcomes.

(b) CONTENTS.—

(1) IN GENERAL.—In carrying out the study, the Director of the Office of Technology Assessment shall examine the efforts of industrialized nations (including the United States) to regulate the manufacture and sale of such dietary supplements and the effect of the regulatory efforts on human health.

(2) INFORMATION.—The study shall include information regarding—

(A) whether and how other countries regulate products that are regulated as such dietary supplements in the United States;

(B) the classification systems used in regulating such products, such as systems that classify such supplements by safety, function, source, usage, dose, or other characteristics;

(C) the effect of the classification on the regulation of the supplements;

(D) how safety concerns, including safety concerns at the time of manufacture and sale of the product are addressed by the regulatory process;

(E) how deception concerns (including misbranding) are addressed by the regulatory process; and

(F) the labeling requirements, if any, for the sale of the products.

(3) ANALYSIS.—The study shall also examine—

(A) whether there are disparate rates of morbidity and mortality associated with the consumption of such dietary supplements among nations;

(B) whether particular regulatory systems may be associated with lower morbidity and mortality rates; and

(C) whether a causal relationship may be demonstrated between the regulatory system used and the health outcomes of the populations affected.

(c) **REPORT.**—The Director of the Office of Technology Assessment shall, not later than 6 months after the date on which the study is approved by the Technology Assessment Board, submit a report containing the findings of the study to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate.

Approved October 29, 1992.

LEGISLATIVE HISTORY—H.R. 6181:

CONGRESSIONAL RECORD, Vol. 138 (1992):

Oct. 5, considered and passed House.

Oct. 7, considered and passed Senate.