DRAFT 01/16/97

"Food Reform And National Uniformity Act Of 1997"

A BILL

To amend the Federal Food, Drug, and Cosmetic Act and other statutes to provide for improvements in the regulation of food additives, color additives, food ingredients, nutrient content claims, and health claims; to provide for national uniformity of requirements for products regulated by the Food and Drug Administration; and for other purposes.

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

SEC. 1. SHORT TITLE; REFERENCE; TABLE OF CONTENTS.

(a) SHORT TITLE. -- This act may be cited as the "Food Reform And National Uniformity Act Of 1997".

(b) REFERENCE. -- Unless otherwise stated, whenever in this Act 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 (21 U.S.C. 301 et seq.).

(c) TABLE OF CONTENTS. -- The table of contents is as follows:

Sec. 1	Short title; reference; table of contents.
TITLE I.	FDA MISSION AND ANNUAL REPORT.
Sec. 101.	FDA mission and annual report.
TITLE II.	FOOD ADDITIVE, ANIMAL DRUG, AND COLOR ADDITIVE SAFETY; ACCREDITED PERSON REVIEW; FOOD CONTACT SUBSTANCES.
Sec. 201.	Improving the Delaney clause.
Sec. 202.	Accredited person review.
Sec. 203.	Accredited persons.
Sec. 204.	Food contact substances.
Sec. 205.	International harmonization.
TITLE III.	NATIONAL UNIFORMITY.

Sec. 301. National uniformity in the regulation of foods, drugs, and cosmetics.
TITLE IV. LABELING AMENDMENTS.
Sec. 401. Nutrient content claims.
Sec. 402. Health claims for food products.
Sec. 403. Petitions for claims.
Sec. 404. Prominence of disclosure.
TITLE V. ADMINISTRATIVE AMENDMENTS.
Sec. 501. Protection for trade secrets and proprietary information.
Sec. 502. Limitation on use of adverse publicity.
Sec. 503. Repeal of strict criminal liability.
Sec. 504. Informal agency statements.
TITLE VI. REMOVAL OF OUTDATED AND UNNECESSARY REQUIREMENTS.
Sec. 601. Margarine.
TITLE VII. EFFECTIVE DATE.
Sec. 701. Effective date.

TITLE I. FDA MISSION AND ANNUAL REPORT.

SEC. 101. FDA MISSION AND ANNUAL REPORT.

(a) MISSION. -- Section 903 (21 U.S.C. 393) is amended by redesignating subsections (b) and (c) as subsections (c) and (d), respectively, and by adding after subsection (a) the following:

"(b) MISSION. -- The Administration shall protect the public health and safety and promptly and efficiently review and approve clinical research and marketing of products in a manner that does not unduly impede innovation or product availability. The Administration shall participate with other countries to reduce the burden of regulation, harmonize regulatory requirements, and achieve appropriate reciprocal arrangements."

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

"(e) ANNUAL REPORT. -- The Secretary shall, simultaneously with the submission each year of the budget for the Administration, submit to the Committee on Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate an annual report which shall --

"(1) review the performance of the Administration in meeting its mission and the development of Administration policies to implement such mission;

"(2) review the performance of the Administration in meeting its own performance standards, including its own outcome measurements and statutory deadlines for the approval of products or for other purposes contained in this Act;

"(3) describe the staffing and resources of the Administration and list those persons and organizations accredited to review petitions under sections 409 and 721;

"(4) describe the goals, activities, and accomplishments of the Administration in bilateral and multinational meetings that addressed methods and approaches to reduce the burden of regulation, harmonize regulation, and to seek appropriate reciprocal arrangements; list each such meeting, and list pending issues specifying those that are not consistent with or are contrary to the provisions of this Act; and

"(5) compare the performance of the Administration in approving innovative products with that of the most successful agencies performing similar functions in other countries and compare the resources used by such agencies."

TITLE II. FOOD ADDITIVE, ANIMAL DRUG, AND COLOR ADDITIVE SAFETY; ACCREDITED PERSON REVIEW; FOOD CONTACT SUBSTANCES.

SEC. 201. IMPROVING THE DELANEY CLAUSE.

(a) Food Additives. -- Section 409(c)(3)(A) (21 U.S.C. 348(c)(3)(A)) is amended by striking everything after "substance" and inserting "that presents a reasonable certainty of no harm; or".

(b) Animal Drugs. -- Section 512(d)(1)(I) (21 U.S.C. 360b(d)(1)(I)) is amended by striking everything after "if" and inserting "such drug presents a reasonable certainty of no harm;".

(c) Color Additives. -- Section 721(b)(5)(B) (21 U.S.C. 379e(b)(5)(B)) is amended by striking everything after "with respect to the use of a color additive" and inserting "if such color additive presents a reasonable certainty of no harm.".

SEC. 202. ACCREDITED PERSON REVIEW.

(a) Food Additives. -- Section 409 (21 U.S.C. 348) is amended:

(1) by inserting at the end of subsection (b)(1) the following:

"If review by an accredited person is desired, a copy of the safety and functionality data in the petition shall also be submitted to a person accredited under section 712.";

(2) by deleting "and" at the end of subsection (b)(2)(D), deleting the period at the end of subsection (b)(2)(E) and adding "; and", and adding at the end of subsection (b)(2) the following:

"(F) the name and address of a person accredited under section 712 to whom a copy of the safety and functionality data in the petition has been provided."

(3) by amending subsection (b)(5) to read as follows:

"(5) Notice of the regulation proposed by the petitioner including the identity of the accredited person, if any, shall be published in general terms by the Secretary within 30 days after filing."

(4) by adding at the end of subsection (c) the following:

"(6)(A) An accredited person shall review the safety and functionality data in a petition submitted to it under subsection (b)(1) to determine whether the additive has been shown to be safe under the intended conditions of use. All filings provided to an accredited person shall be provided to the Secretary. During the period of review of a petition, the Secretary and the accredited person may communicate with each other and with the petitioner in person or in writing; a complete record of all such communications and the petitioner's responses shall be maintained by the Secretary. In evaluating a petition, neither the Secretary nor the accredited person may consider any data or information which are not filed with the Secretary within 2 months of the notice of filing of the petition unless such data and information were provided by the petitioner.

The review of a petition by an accredited person shall be conducted in accordance with the standards and requirements of this Act that apply to the review of petitions by the Secretary.

"(B) Within 150 days of the notice of filing of the petition, the accredited person shall provide to the Secretary a report and recommendations, together with a statement of the reasons or basis for the recommendations. The accredited person shall recommend that the petition be approved if a fair evaluation of the data and information before it establishes that the proposed use of the additive under the conditions of use to be specified in the regulation will be safe. The Secretary shall promptly provide a copy of the report and recommendations to the petitioner and shall promptly place a copy on public display in a location maintained by the Secretary for the examination of public documents, except that trade secret and confidential commercial information shall not be disclosed.

"(C) A report and recommendations from an accredited person shall be deemed to be the decision of the Secretary and the Secretary shall issue a regulation providing for the use of the additive under the conditions of use found by the accredited person to be safe, unless within 30 days of receipt of the report and recommendations the Secretary finds that the data relied on by the accredited person in making its report and

recommendations fail to establish that the use of the additive under the intended conditions of use will be safe. If the Secretary makes such a finding, the Secretary shall provide to the petitioner a detailed written explanation of the basis for the finding within such 30 day period."

(5) by adding at the end of subsection (g) the following:

"(6) Upon issuance of a regulation or finding by the Secretary under subsection (c)(6)(C), any person who will be adversely affected by the decision of the Secretary, and without regard to the provisions of subsection (f) of this section, may obtain judicial review in accordance with this subsection."

(b) Color Additives. -- Section 721 (21 U.S.C. 379e) is amended:

(1) by adding a new subsection (d)(1) as follows:

"(1) if a review of a petition by an accredited person is desired, a copy of the safety and functionality data in the petition shall also be submitted to a person accredited under section 712. If such review is sought, the name and address of the person accredited under 712 to whom a copy of the safety and functionality data in the petition has been provided shall be included in the petition. The review by the accredited person shall be conducted in accordance with subsection (e)."

(2) by renumbering subsections (d)(1), (2), (3), and (4) as subsections (d)(2), (3), (4), and (5), respectively;

(3) in renumbered subsection (d)(2), by inserting ", including the identity of the accredited person, if any," following "notice of the proposal made by the petition";

(4) by adding a new subsection (e) as follows:

"(e) Review by Accredited Persons.

"(1) An accredited person shall review the safety and functionality data in a petition submitted to it under subsection (d)(1) to determine whether the additive has been shown to be safe under the intended conditions of use. All filings provided to an accredited person shall be provided to the Secretary. During the period of review of a petition, the Secretary and the accredited person may communicate with each other and with the petitioner in person or in writing; a complete record of all such communications and the petitioner's responses shall be maintained by the Secretary. In evaluating a petition, neither the Secretary nor the accredited person may consider any data or information which are not filed with the Secretary within 2 months of the notice of filing of the petition unless such data and information were provided by the petitioner. The review of a petition by an accredited person shall be conducted in

accordance with the standards and requirements of this Act that apply to the review of petitions by the Secretary.

"(2) Within 150 days of the notice of filing of the petition, the accredited person shall provide to the Secretary a report and recommendations, together with a statement of the reasons or basis for the recommendations. The accredited person shall recommend that the petition be approved if a fair evaluation of the data and information before it establishes that the proposed use of the additive under the conditions of use to be specified in the regulation will be safe. The Secretary shall promptly provide a copy of the report and recommendations to the petitioner and shall promptly place a copy on public display in a location maintained by the Secretary for the examination of public documents, except that trade secret and confidential information shall not be disclosed.

"(3) A report and recommendations from an accredited person shall be deemed to be the decision of the Secretary and the Secretary shall issue a regulation providing for the use of the additive under the conditions of use found by the accredited person to be safe, unless, within 30 days of receipt of the report and recommendations, the Secretary finds that the data relied on by the accredited person in making its report and recommendation fail to establish that the use of the additive under the intended conditions of

use will be safe. If the Secretary makes such a finding, the Secretary shall provide to the petitioner a detailed written explanation of the basis for the finding within such 30 day period.

"(4) Upon issuance of a regulation or finding by the Secretary under paragraph (3), any person who will be adversely affected by the decision of the Secretary, and without regard to the provisions of section 701(e), (f), and (g), may obtain judicial review in accordance with section 409(g)."

(5) by renumbering current subsections (e) and (f) as subsections (f) and (g), respectively.

SEC. 203. ACCREDITED PERSONS.

(a) New section 712 (21 U.S.C. § 379d-1) is added to read as follows:

"SEC. 712. ACCREDITED PERSONS.

"(a) Accreditation. --

"(1) Programs. -- The Secretary shall provide for such accreditation through programs administered by government agencies or by other qualified organizations.

"(2) Implementation. -- The Secretary may designate one or more qualified non-government organizations to implement such programs. Such

organizations shall implement such programs from fees charged to applicants for accreditation.

"(3) Qualifications. -- An accredited person shall meet the following requirements:

"(A) Such person shall be an independent organization which is not owned or controlled by a manufacturer, supplier, or vendor of food or of color additives and which has no organizational, material, or financial affiliation with such a manufacturer, supplier, or vendor.

"(B) Such person shall be a legally constituted entity permitted to conduct the activities for which it seeks accreditation.

"(C) Such person shall not engage in the design, manufacture, promotion, or sale of food or of color additives.

"(D) Such person shall be operated in accordance with generally accepted professional and ethical business practices and shall agree in writing that at a minimum it will --

"(i) certify that reported information accurately reflects data reviewed;

"(ii) limit work to that for which competence and capacity are available;

"(iii) treat information received, records, reports, and recommendations as proprietary information; and

"(iv) promptly respond and attempt to resolve complaints regarding its activities for which it is accredited."

(b) Conforming Amendment. -- Section 301 (21 U.S.C. 331) is amended by redesignating the second subsection (u) as subsection (v) and by adding after that subsection the following:

"(w) In the case of a food additive or color additive --

"(1) the submission of a report or recommendation by a person accredited under section 712 that is false or misleading in any material respect;

"(2) the disclosure by a person accredited under section 712 of confidential commercial information or any trade secret without the express written consent of the person who submitted such information or secret to such person; or

"(3) the receipt by a person accredited under section 712 of a bribe in any form or the doing of any corrupt act by such person associated with a responsibility delegated to such person under this Act."

SEC. 204. FOOD CONTACT SUBSTANCES.

(a) Food Contact Substances. -- Section 409(a) (21 U.S.C. 348(a)) is amended--

(1) by striking at the end of paragraph (2) "." and inserting "; or"

(2) by adding, as a new paragraph after paragraph (2): "(3) in the case of a food additive that is a food contact substance, there is in effect, and the substance and its use are in conformity with, a regulation issued under this section prescribing the conditions under which such additive may be safely used, or a notification submitted under subsection (h) which is effective."

(3) by striking the matter following paragraph (3) (as added by paragraph (2)) and inserting the following flush sentence:

> "While such a regulation relating to a food additive, or such a notification relating to a food additive that is a food contact substance, is in effect, and has not been revoked pursuant to subsection (j), a food shall not, by reason of bearing or containing such a food additive in accordance with the regulation or notification, be considered adulterated under section 402(a)(1)."

(b) Notification for Food Contact Substances.

(1) Section 409 (21 U.S.C. 348), as amended by subsection (a) of this section, is further amended by redesignating subsection (h) as subsection (j), and adding new subsection (h) as follows:

"(h)(1) Subject to such regulations as may be promulgated under paragraph (3), a manufacturer or supplier of a food contact substance may, at least 120 days prior to the introduction or delivery for introduction into interstate commerce of the food contact substance, notify the Secretary of the identity and intended use of the food contact substance, and of such person's determination that the intended use of such food contact substance is safe under the standard of subsection (c)(3)(A). Such notification shall contain the information that forms the basis of such determination, and all information required to be submitted by regulations promulgated by the Secretary.

"(2) A notification submitted under paragraph (1) shall become effective 120 days after the date of receipt by the Secretary and the manufacturer or supplier making the notification, and all persons purchasing such food contact substance from such manufacturer or supplier, may introduce or deliver for introduction into interstate commerce such food contact substance, unless the Secretary makes a determination within the 120 day period that, based on the data and information before the Secretary, such use of the food contact substance has not been shown to be safe under the standard of subsection (c)(3)(A), and informs the manufacturer or supplier of such determination. The decision of the Secretary to object to a notification shall constitute final agency action subject to judicial review.

"(3) The process in this subsection shall be utilized for authorizing the marketing of a food contact substance except where the Secretary determines that submission and review of a petition under subsection (b) is necessary to provide adequate assurance of safety, or where the Secretary and any manufacturer or supplier agree that such manufacturer or supplier may submit a petition under subsection (b). The Secretary is authorized to promulgate regulations to identify the circumstances in which a petition shall be filed under subsection (b), and shall consider criteria such as the probable consumption of such food contact substance and potential toxicity of the food contact substance in determining the circumstances in which a petition shall be filed under subsection (b).

"(4) The Secretary shall keep confidential any information provided in a notification under paragraph (1) for 120 days following receipt by the Secretary of the notification. After the expiration of such 120 days, the information shall be available to any interested party except for matters in the notification that are trade secrets or confidential commercial information.

"(5) For purposes of this section, the term 'food contact substance' means any substance intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if such use is not intended to have any technical effect in such food."

(2) Redesignated subsection (j) is amended by adding at the end the following:

"The Secretary shall by regulation prescribe the procedure by which the Secretary may deem a notification under subsection (h) to no longer be effective."

SEC. 205. INTERNATIONAL HARMONIZATION.

New section 713 (21 U.S.C. 379d-2) is added to read as follows:

"International Harmonization

"SEC. 713. In promulgating a regulation under sections 406, 409, 512, or 721, the Secretary shall take into account any corresponding recommended standard established by the Codex Alimentarius Commission. If a Codex standard is in effect, the Secretary shall either adopt the Codex standard or publish for public comment a notice explaining the reasons for departing from the Codex standard. If the Secretary issues a final regulation departing from a Codex standard, the Secretary shall publish together with the final regulation a determination with supporting data that the Codex standard is not supported by adequate and reliable scientific evidence, or is inadequate to protect the public health."

TITLE III. NATIONAL UNIFORMITY.

SEC. 301. NATIONAL UNIFORMITY IN THE REGULATION OF FOODS, DRUGS, AND COSMETICS.

(a) Section 403A(a) (21 U.S.C. 343-1(a)) is amended by striking "or" at the end of paragraph (4), by changing the period to a comma at the end of paragraph (5), and by adding at the end thereof the following:

"(6) any requirement for the labeling of food of the type described in section 403(j) or 403(s) that is not identical to the requirements of such section, or

"(7) any requirement for a food of the type required by section 402(a)(1), 402(a)(2), 402(a)(7), 402(c), 402(f), 404, 406, 408, 409, 512, or 721(a), that is not identical to the requirements of such section. "

(b) Chapter VII is amended by adding at the end thereof the following:

" SUBCHAPTER D -- NATIONAL UNIFORMITY

"National Uniformity for Drugs and Cosmetics

"SEC. 741. (a) Except as provided in section 743, no State or political subdivision thereof may establish or continue in effect any requirement --

"(1) that relates to the regulation of a drug or cosmetic; and

"(2) that is different from or in addition to, or that is otherwise not identical with, a requirement of this Act, section 351 of the Public Health Service Act (42 U.S.C. 262), the Fair Packaging and Labeling Act (15 U.S.C. 1451 et seq.), and the administrative implementation of such acts.

"(b) For purposes of this section, a requirement relating to the regulation of a drug or cosmetic shall be deemed to include any

requirement relating to the subject matter in any provision of this Act, section 351 of the Public Health Service Act (42 U.S.C. 262), or the Fair Packaging and Labeling Act (15 U.S.C. 1451 et seq.), but shall not include any requirement relating to the practice of pharmacy or any requirement that a drug be dispensed only upon the prescription of a practitioner licensed by law to administer such drug.

"Warning Uniformity

"SEC. 742. (a) Except as provided in section 743, no State or political subdivision of a State may, directly or indirectly, establish or continue in effect under any authority any notification requirement for a food, drug, or cosmetic that provides for a warning concerning the safety of the food, drug, or cosmetic or any component or package thereof, unless such notification requirement has been prescribed under the authority of this Act and the State or political subdivision notification requirement is identical to the notification requirement prescribed under the authority of this Act.

"(b) For purposes of subsection (a) --

"(1) the term 'warning' with respect to a food, drug, or cosmetic means any statement, vignette, or other representation

which indicates, directly or by implication, that the food, drug, or cosmetic presents or may present a hazard to health or safety; and

"(2) the term 'notification requirement' includes any mandatory disclosure requirement relating to the dissemination of information about a food, drug, or cosmetic in any manner, such as labels, labeling, posters, public notices, advertising, or any other means of communication.

"Exemptions from Uniformity

"SEC. 743. (a) Upon application of a State, the Secretary may by regulation, after notice and opportunity for written and oral presentation of views, exempt from section 741 or section 742, under such conditions as the Secretary may impose, a State requirement which --

"(1) is justified by compelling and unique local conditions,

"(2) protects an important public interest that would otherwise be unprotected,

"(3) would not cause any food, drug, or cosmetic to be in violation of any applicable requirement or prohibition under Federal law, and

"(4) would not unduly burden interstate commerce.

"(b) Notwithstanding section 742, a State may establish a warning notification requirement that would otherwise violate section 742(a) if --

"(1) the warning is needed to address an imminent hazard to health that is likely to result in serious adverse health consequences or death, and

"(2) a petition for an exemption is submitted by the State under subsection (a) no later than 7 days after the warning notification requirement is established.

If the Secretary denies the petition for an exemption under subsection (a), the State warning notification requirement shall become null and void.

"Exclusion of Product Liability

SEC. 744. Nothing in this subchapter shall be construed to modify or otherwise affect any action or the liability of any person under the product liability law of any State."

TITLE IV. LABELING AMENDMENTS.

SEC. 401. NUTRIENT CONTENT CLAIMS.

(a) Section 403(r)(2) (21 U.S.C. 343(r)(2)) is amended as follows:

(1) By adding the following at the end of subparagraph (A)(i):

"provided, that an undefined term that is reasonably understood by consumers to be a synonym for a defined term may be used if it is truthful

and not misleading in the context of the entire label or labeling of a product, and the term is used in accordance with regulations of the Secretary for use of the defined term,"

(2) By repealing subparagraph (B) in its entirety.

(3) By renumbering subparagraphs (C), (D), (E), and (F) as (B), (C), (D), and (E), respectively.

(4) By adding new subparagraphs (F) and (G) at the end, to read as follows:

"(F) A claim of the type described in subparagraph (1)(A) for a nutrient for which the Secretary has not promulgated a regulation setting forth a daily intake value shall be presumed to be authorized and may be made if --

"(i) the claim and the food for which the claim is made meet the general requirements for nutrient content claims as prescribed in subparagraph (A) and in regulations promulgated by the Secretary (other than requirements relating to the Secretary's authorization of nutrient content claims only for nutrients for which a daily intake value has been established), and satisfy the requirements of sections 403(a) and 201(n);

"(ii) the manufacturer or distributor of the food for which a claim for such a nutrient is made has submitted to the Secretary at least 120 days before the introduction of such food into interstate commerce the data and information relied upon as a basis for concluding that an authoritative scientific body of the United States Government responsible for public health protection or research directly relating to human nutrition (such as the National Institutes of Health or the Centers for Disease Control and Prevention), the National Academy of Sciences, or subdivisions of the scientific body or the National Academy of Sciences, has published an authoritative determination currently in effect, which sets forth a daily intake value for the nutrient; and

"(iii) unless the nutrient is required by regulations issued by the Secretary to be listed in the information presented pursuant to subsection (q), a quantitative disclosure of the amount of the nutrient in each serving size or other unit of measure of the food is presented in proximity to the claim or at the end of information required to be presented by subsection (q).

"A statement of an authoritative scientific body of the United States Government or the National Academy of Sciences shall constitute an authoritative determination within the meaning of this

subparagraph if: (1) it is based upon a fair evaluation of the totality of the available scientific evidence, (2) it has not been disclaimed by the body, and (3) it is not a statement of an employee of the body made in an individual capacity.

"(G) The presumption of eligibility of a nutrient for a claim under subparagraph (F) shall terminate when --

"(i) a regulation establishing a daily intake value for the nutrient has been promulgated by the Secretary and has become effective;

"(ii) a regulation determining that a daily intake value for the nutrient cannot be established has been promulgated by the Secretary and has become effective; or

"(iii) a district court of the United States determines, in an enforcement proceeding under chapter III of this Act, that the requirements of subparagraph (F) have not been met."

SEC. 402. HEALTH CLAIMS FOR FOOD PRODUCTS.

(a) Section 403(r)(3)(A) (21 U.S.C. 343(r)(3)(A)) is amended by striking out subclause (ii) and substituting in lieu thereof the following:

"(ii) if the food for which the claim is made does not contain any nutrient in an amount which increases to persons in the general population the risk ot a disease or health-related condition to which the claim refers."

(b) Section 403(r)(3) (21 U.S.C. 343(r)(3)) is amended by adding at the end thereof the following new subparagraphs:

"(C) Notwithstanding the provisions of subparagraphs (A)(i) and (B), a claim of the type described in paragraph (1)(B) which is not authorized by the Secretary in a regulation promulgated in accordance with subparagraph (B) shall be authorized and may be made if --

"(i) an authoritative scientific body of the United States Government with official responsibility for public health protection or research directly relating to human nutrition (such as the National Institutes of Health or the Centers for Disease Control and Prevention), the National Academy of Sciences, or subdivisions of the scientific body or the National Academy of Sciences has published an authoritative determination currently in effect recognizing that the relationship between the nutrient and disease or health-related condition to which the claim refers is supported by pertinent scientific evidence;

"(ii) a manufacturer or supplier of a food, at least 120 days prior to the introduction or delivery for introduction into interstate commerce of the food, notifies the Secretary of the claim, including a concise description of the basis upon which such manufacturer or distributor relied for determining that the requirements of clause (i) have been satisfied; and

"(iii) the claim and the food for which the claim is made are in compliance with clause (A)(ii), and satisfy the requirements of sections 403(a) and 201(n).

"A statement of an authoritative scientific body of the United States Government or the National Academy of Sciences shall constitute an authoritative determination within the meaning of this subparagraph if: (1) it is based upon a fair evaluation of the totality of the available scientific evidence, (2) it has not been disclaimed by the body, and (3) it is not a statement of an employee of the body made in an individual capacity.

"(D) a claim meeting the requirements of subparagraph (C) may be made until such time as the Secretary has promulgated a regulation prohibiting or modifying the claim and the regulation has become effective, or a district court of the United States in an enforcement proceeding under subchapter III of this Act has determined that the requirements of subparagraph (C) have not been met."

SEC. 403. PETITIONS FOR CLAIMS.

Section 403(r)(4) (21 U.S.C. 343(r)(4)) is amended as follows:

(1) By striking the period at the end of the third sentence in subparagraph (A)(i) and adding the following: ", and the decision of the Secretary shall constitute final agency action subject to judicial review. If the Secretary does not act within such 100 days, the petition shall be deemed to be filed."

(2) By adding at the end of subparagraph (A)(i) the following:

"A decision of the Secretary to deny the petition shall constitute final agency action subject to judicial review. If the Secretary does not act within such 90 days, the petition shall be deemed to be granted. If the Secretary issues a proposed regulation, the rulemaking shall be completed within 540 days of the date the petition is received by the Secretary and the proposed regulation shall be considered a final regulation if the Secretary does not complete the rulemaking within such 540 days."

SEC. 404. PROMINENCE OF DISCLOSURE.

New section 414 (21 U.S.C. 350c) is added to read as follows:

"Prominence of Disclosure

"SEC. 414. No provision of section 403 or section 409 shall be construed to require on a food a separate disclosure that is more prominent than required for the declaration of ingredients required by section 403(i)(2) that the food or a component thereof --

"(a) has been intentionally subject to radiation,

"(b) is derived from new or modified plan varieties, or

"(c) is derived from animals treated with a new animal drug."

TITLE V. ADMINISTRATIVE AMENDMENTS

SEC. 501. PROTECTION FOR TRADE SECRETS AND PROPRIETARY INFORMATION.

The first sentence of section 301(j) (21 U.S.C. 331(j)) is amended by deleting everything following the phrase "authority of" and inserting the following: "this Act or provided to the

Secretary or officers or employees of the Department in response to a written request, which information is designated by the owner thereof as proprietary, unless the person can establish that the information is in the public domain."

SEC. 502. LIMITATION ON USE OF ADVERSE PUBLICITY.

Section 705(b) (21 U.S.C. 375(b)) is amended by inserting the following after the first sentence:

> "The Secretary shall provide a written report to Congress within 30 days after each dissemination of information under this subsection. The authority to disseminate information and to report to Congress may be delegated to the Commissioner of Food and Drugs, but such authority shall not be further delegated."

SEC. 503. REPEAL OF STRICT CRIMINAL LIABILITY.

Section 303(a)(1) (21 U.S.C. 333(a)(1)) is amended by inserting after "who" the following: "knowingly or willfully".

SEC. 504. INFORMAL AGENCY STATEMENTS.

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

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

"(2) The Secretary shall publish notice in the Federal Register of the availability to the public of each type of statement identified in paragraph (1). Additionally, the Secretary shall undertake to make available all such statements by electronic or other similar means."

TITLE VI. REMOVAL OF OUTDATED AND UNNECESSARY REQUIREMENTS

SEC. 601. MARGARINE.

(a) Section 301(m). -- Subsection (m) of section 301 (21 U.S.C. 331) is repealed.

(b) Section 407. -- Section 407 (21 U.S.C. 347) is repealed.

(c) Act of March 16, 1950. -- Sections 3(a) and 6 of the Act of March 16, 1950 (21 U.S.C. 347a, 347b) are repealed.

(d) Federal Trade Commission Act. -- Section 15 of the Federal Trade Commission Act (15 U.S.C. 55) is amended:

(1) in subsection (a), by deleting "(a)(1)" and inserting "(a)", and by striking paragraph (2); and

(2) by striking subsection (f).

TITLE VII. EFFECTIVE DATE.

SEC. 701. EFFECTIVE DATE.

(a) Except as provided in subsection (b), the amendments made by this Act shall take effect on the date of the enactment of this Act. The Secretary of Health and Human Services shall not enforce any regulation that is inconsistent with the amendments made by this Act after the date of the enactment of this Act.

(b) Notifications under section 409(h) (21 U.S.C. 348(h)), as amended by this Act, may be submitted beginning 1 year from the date of enactment of this Act.

(c) The provisions of section 403(r)(4)(A)(i) (21 U.S.C. 343(r)(4)(A)(i)) as amended by this Act shall apply to all petitions pending before the Secretary of Health and Human Services on the date of enactment of this Act, provided that no petition shall be deemed to be granted and no proposed regulation shall be deemed to be a final regulation before 30 days after the date of enactment of this Act.

--END--

SEC. 501. PROTECTION FOR TRADE SECRETS AND PROPRIETARY INFORMATION

The first sentence of section 301(j) (21 U.S.C. 331(j)) is amended by deleting everything following the phrase "authority of" and inserting at the end the following: "this Act or provided to the Secretary or officers or employees of the Department in response to a written request, which information is protected under 5 U.S.C. 552(b)(4)."

Summary:

Under existing law, the Federal Food, Drug, and Cosmetic Act (FDC Act) prohibits the disclosure of any information concerning "any method or process which as a trade secret is entitled to protection." acquired by FDA under the authority of a number of listed sections of the FDC Act that require the submission of information to the agency. Trade secrets are narrowly defined by FDA and the courts, as applying only to formulas, manufacturing processes or methods, and the like.

The Act would broaden the protection accorded to proprietary information, by applying it to all information acquired by FDA pursuant to the Act or pursuant to written request, which is protected under the Freedom Of Information Act as "trade secrets and commercial or financial information obtained from a person and privileged or confidential." Protected information would include information that concerns or relates to all control programs, whether mandatory or voluntary, as well as any data and reports generated under such programs.

SECTION-BY-SECTION ANALYSIS

Section 1 would amend Section 25 of the Poultry Products Inspection Act (21 U.S.C. 468) to authorize the Secretary of Agriculture to charge and collect fees to cover the cost to the Department of Agriculture of on-site inspection services incident to the inspection of poultry and poultry products, including the inspection of records, facilities, conveyances, and products. The fees authorized by this section will cover the costs of salaries and benefits for personnel conducting the on-site inspection services, except that all costs of overtime and holiday work performed in establishments requesting such work will be borne by those establishments. All other costs of administering the Act will be borne by the United States.

Section 2 would amend the Act of June 5, 1948 (21 U.S.C. 695) to authorize the Secretary of Agriculture to charge and collect fees to cover the cost to the Department of Agriculture of on-site inspection services incident to the inspection of livestock and meat products, including the inspection of records, facilities, conveyances, and products. The fees authorized by this section will cover the costs of salaries and benefits for personnel conducting the on-site inspection services, except that all costs of overtime and holiday work performed in establishments requesting such work will be borne by those establishments. All other costs of administering the Federal Meat Inspection Act will be borne by the United States.

Section 3 would amend Section 24(a) of the Egg Products Inspection Act (21 U.S.C. 1053(a)) to authorize the Secretary of Agriculture to charge and collect fees to cover the cost to the Department of Agriculture of on-site inspection services incident to the inspection of egg products, including the inspection of records, facilities, conveyances, and products. The fees authorized by this section will cover the costs of salaries and benefits for personnel conducting the on-site inspection services, except that all costs of overtime and holiday work performed in establishments requesting such work will be borne by those establishments. All other costs of administering the Act will be borne by the United States.

Section 4 would amend the Act of July 24, 1919 (7 U.S.C. 394) to delete a provision, which provides the Secretary with the authority to charge for overtime work conducted by the Department in federally inspected meat establishments. This authority is contained in Section 2 of this proposed bill.

Section 5 would set October 1, 1997, as the effective date for the provisions of the bill.

FOOD SAFETY

User Fee Proposal for Meat, Poultry, and Egg Products Inspection

Question: Why is the Department proposing user fees for meat, poultry, and egg products inspection when these proposals have not been approved on numerous occasions?

Answer: The President has staked out a very clear vision of where he wants to take America in the 21st century and that vision protects our priorities and gets us to a balanced budget. By seeking a combination of user fees and appropriated funding, the 1998 budget proposal for food safety helps achieve both of these goals.

The Administration believes that the collection of user fees is essential to the successful long-term implementation of meat, poultry, and egg products inspection reforms. The budget proposes collecting new user fees to cover the cost of providing on-site inspection services. This action ensures that there will be adequate inspection personnel to meet the demand for inspection services by meat, poultry, and egg processors. In addition, we have requested a level of appropriated funding to ensure that the Government meets its responsibilities for ensuring that America has one of the safest food supplies in the world. We must continue to meet the need for investing limited resources in developing inspection improvements that enhance food safety and productivity. Ensuring adequate inspection coverage and improving inspection processes will give consumers greater confidence in the safety of the American food supply.

It is fair to ask the industry to help pay for these services. It is the only way we get to a balanced budget and meet the increased demand for inspection as the industry grows. Philosophically, you will find throughout this budget a fundamental shift in the role of Government. We can no longer be expected to do everything. FSIS will be meeting with industry soon to obtain input on how best to implement the user fee legislation.

Under the proposal, we would collect approximately $390 million in new user fees for on-site inspection services. Industry currently reimburses the Federal Government for all the costs associated with providing overtime, holiday, and voluntary inspection, which is approximately 14 percent of the cost of the program. Under this proposal, the industry would pay for approximately 70 percent of the cost of the entire program. Currently, we utilize over 8,000 inspection personnel to provide inspection in 5,785 establishments ~~at approximately $25 per hour per employee and~~ This proposal would impact consumer prices by less than one cent per pound of slaughtered product. The Federal Government will cover the remaining $201 million with appropriated funds to pay for activities such as, laboratory functions, public health and educations activities, emergency response functions, and other administrative responsibilities.

Honorable Albert Gore, Jr.
President of the United States Senate
Washington, DC 20250

Dear Mr. President:

Transmitted herewith, for the consideration of the Congress, is a draft bill "To authorize the Secretary of Agriculture to collect fees to cover the cost of inspection services performed under the Federal Meat Inspection Act, the Poultry Products Inspection Act, and the Egg Products Inspection Act."

The Department of Agriculture (USDA) recommends that the draft bill be enacted.

Currently, meat, poultry, and egg products inspection services for all regularly scheduled and approved shifts are paid for out of Federal funds. Fees are charged to cover the cost of overtime and holiday work performed in establishments. We are proposing that additional fees be collected to cover the costs of salaries and benefits of personnel conducting non-overtime and non-holiday inspection services for livestock, meat products, poultry, poultry products, and egg products.

This legislative proposal is a part of the President's Fiscal Year 1998 Budget. The Federal Government would continue to fund the cost of administrative activities performed in support of inspection services.

For Fiscal Year 1998, it is estimated that the new fees authorized in the legislative proposal would generate $390 million for the Federal Government. Requiring the payment of user fees for direct inspection services, instead of using appropriated funds, would result in savings to the taxpayer.

The Omnibus Budget Reconciliation Act (OBRA) requires that all revenue and direct spending legislation meet a pay as you go requirement. That is, no such bill should result in an increase in the deficit; and if it does, it must trigger a sequester if it is not fully offset. Offsetting collections in this bill would recover costs of services provided, resulting in a net zero PAYGO effect. Thus, considered alone, this bill meets the pay as you go requirement of OBRA.

Enactment of this proposed legislation would have no significant effect on the quality of the human environment.

The Office of Management and Budget advises that enactment of this proposed legislation would be in accord with the President's program.

A similar letter is being sent to the Speaker of the House.

Sincerely,

DAN GLICKMAN
Secretary

Enclosures

Honorable Newt Gingrich
Speaker of the House of Representatives
Washington, DC 20515

Dear Mr. Speaker:

Transmitted herewith, for the consideration of the Congress, is a draft bill "To authorize the Secretary of Agriculture to collect fees to cover the cost of inspection services performed under the Federal Meat Inspection Act, the Poultry Products Inspection Act, and the Egg Products Inspection Act."

The Department of Agriculture (USDA) recommends that the draft bill be enacted.

Currently, meat, poultry, and egg products inspection services for all regularly scheduled and approved shifts are paid for out of Federal funds. Fees are charged to cover the cost of overtime and holiday work performed in establishments. We are proposing that additional fees be collected to cover the costs of salaries and benefits of personnel conducting non-overtime and non-holiday inspection services for livestock, meat products, poultry, poultry products, and egg products.

This legislative proposal is a part of the President's Fiscal Year 1998 Budget. The Federal Government would continue to fund the cost of administrative activities performed in support of inspection services.

For Fiscal Year 1998, it is estimated that the new fees authorized in the legislative proposal would generate $390 million for the Federal Government. Requiring the payment of user fees for direct inspection services, instead of using appropriated funds, would result in savings to the taxpayer.

The Omnibus Budget Reconciliation Act (OBRA) requires that all revenue and direct spending legislation meet a pay as you go requirement. That is, no such bill should result in an increase in the deficit; and if it does, it must trigger a sequester if it is not fully offset. Offsetting collections in this bill would recover costs of services provided, resulting in a net zero PAYGO effect. Thus, considered alone, this bill meets the pay as you go requirement of OBRA.

Enactment of this proposed legislation would have no significant effect on the quality of the human environment.

The Office of Management and Budget advises that enactment of this proposed legislation would be in accord with the President's program.

A similar letter is being sent to the President of the Senate.

Sincerely,

DAN GLICKMAN
Secretary

Enclosures

A BILL

To authorize the Secretary of Agriculture to collect fees to cover the cost of inspection services performed under the Federal Meat Inspection Act, the Poultry Products Inspection Act, and the Egg Products Inspection Act.

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

SECTION 1. Section 25 of the Poultry Products Inspection Act (21 U.S.C. 468) is amended to read as follows:

"SEC. 25. The Secretary shall, by regulation, charge and collect fees to cover the cost to the Department of Agriculture of on-site inspection services incident to the inspection of poultry and poultry products including inspections of records, facilities, conveyances, and products. The fees authorized by this section shall cover the costs of salaries and benefits for personnel conducting on-site inspection services, except that all costs of overtime and holiday work performed in establishments requesting such work shall be borne by those establishments. All other costs for administering the Act shall be borne by the United States. Fees collected in accordance with this section shall be deposited into a fund that shall be available without fiscal year limitation for the expenses of the Department of Agriculture related to providing services described in this section."

SEC. 2. The Act of June 5, 1948 (21 U.S.C. 695) is amended to read as follows:

"The Secretary of Agriculture shall, by regulation, charge and collect fees to cover the cost to the Department of Agriculture of on-site inspection services incident to the inspection of livestock, meat, and meat products under the requirements of the Federal

Meat Inspection Act (21 U.S.C. 601et seq.) including inspections of records, facilities, conveyances, and products. The fees authorized by this section shall cover the costs of salaries and benefits for personnel conducting on-site inspection services, except that all costs of overtime and holiday work performed in establishments requesting such work shall be borne by those establishments. All other costs for administering the Federal Meat Inspection Act shall be borne by the United States. Fees collected in accordance with this section shall be deposited into a fund that shall be available without fiscal year limitation for the expenses of the Department of Agriculture related to providing services described in this section."

SEC. 3. Section 24(a) of the Egg Products Inspection Act (21 U.S.C. 1053(a)) is amended to read as follows:

"SEC. 24(a) The Secretary shall, by regulation, charge and collect fees to cover the cost to the Department of Agriculture of on-site inspection services incident to the inspection of egg products including inspections of records, facilities, conveyances, and products. The fees authorized by this section shall cover the costs of salaries and benefits for personnel conducting on-site inspection services, except that all costs of overtime and holiday work performed in official plants requesting such work shall be borne by those official plants. All other costs for administering the Act shall be borne by the United States. Fees collected in accordance with this section shall be deposited into a fund that shall be available without fiscal year limitation for the expenses of the Department of Agriculture related to providing services described in this section."

SEC. 4. The Act of July 24, 1919 (7 U.S.C. 394) is amended by striking ", and to accept from such establishments wherein such overtime work is performed reimbursement for any sums paid out by him for such overtime work".

SEC. 5. The provisions of this act shall become effective on October 1, 1997.

facsimile TRANSMITTAL

to: Elizabeth Arye
fax #: 456-5581
re:
date:
pages: 9, including this cover sheet.

All Draft

From the desk of...

Thomas J. Billy
Administrator
Food Safety and Inspection Service
1400 Jefferson Drive, SW
Washington, DC 20250-3700

202-720-7025
Fax: 202-205-0158