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104TH CONGRESS
2D SESSION

H. R. 3200

To amend the Federal Food, Drug, and Cosmetic Act to increase access to nutritional information about foods, to increase the availability of safe food products, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

MARCH 29, 1996

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

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A BILL

To amend the Federal Food, Drug, and Cosmetic Act to increase access to nutritional information about foods, to increase the availability of safe food products, and for other purposes.

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

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

(a) SHORT TITLE.—This Act may be cited as the ''Food Amendments and the Animal Drug Availability Act of 1996''.

(b) REFERENCE.—Whenever in this Act (other than in section 111) 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.

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

TITLE I—FOOD AMENDMENTS

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 Food and Drug 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 Food and Drug 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 Food and Drug 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 Food and Drug Administration in meeting its mission and the development of Food and Drug Administration policies to implement such mission;

''(2) review the performance of the Food and Drug 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 Food and Drug Administration and list those persons and organizations accredited to review petitions under sections 403(r), 409, and 721 and applications under section 512;

''(4) describe the goals, activities, and accomplishments of the Food and Drug 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 Food and Drug Administration in approving innovative prod-

ucts with that of the most successful agencies performing similar functions in other countries and compare the resources used by such agencies.''.

SEC. 102. ACCESS TO DISEASE PREVENTION INFORMATION.

Section 403(r)(3) (21 U.S.C. 343(r)(3)) is amended—

(1) in clause (B)(i), by adding at the end ''Significant scientific agreement does not require consensus or unanimity.''; and

(2) by adding at the end the following:

''(C) Information in materials prepared or distributed by a Federal health agency or by the National Academy of Sciences or its component organizations shall be deemed to comply with clauses (A)(i) and (B).''.

SEC. 103. ACCESS TO NUTRIENT DESCRIPTOR INFORMATION.

Section 403(r)(2)(A)(i) (21 U.S.C. 343(r)(2)(A)(i)) is amended by adding at the end the following: ''or terms which are synonyms of such defined terms and are not false or misleading''.

SEC. 104. SPECIAL LABELING TO PROTECT PUBLIC HEALTH.

Section 403 (21 U.S.C. 343) is amended by adding at the end the following:

''(t) No provision of this section or section 409 shall be construed to require on a food a separate disclosure of—

''(1) a method of production, or

''(2) an ingredient other than in the statement of ingredients,

unless such disclosure is necessary to protect the public health.''.

SEC. 105. ACCREDITED PERSON REVIEW.

(a) HEALTH CLAIMS.—Section 403(r)(4)(A) (21 U.S.C. 343(r)(4)(A)) is amended by inserting at the end of the first sentence in subclauses (i), (ii), and (iii) the following: ''or may file such a petition with a person authorized to review it under section 712''.

(b) ACCREDITED PERSON REVIEW.—Section 403(r)(4) (21 U.S.C. 434(r)(4)) is amended by adding at the end the following:

''(D)(i) In reviewing a petition submitted under clause (A) to an accredited person such a person shall determine if the petition meets the requirements for petitions to the Secretary. The review of such a petition shall be conducted under the standards and requirements of this Act that are applicable to the review of petitions to the Secretary. After a period of 120 days after such a petition is submitted, the accredited person shall submit a re-

port of its review of such petition to the Secretary and include its recommendations. Such recommendations to the Secretary shall specify—

''(I) in the case of a petition under subclause (i), whether the claim with respect to which the petition was made should be approved or denied;

''(II) in the case of a petition under subclause (ii), whether such claim may use the terms specified in the petition, and

''(III) in the case of a petition under subclause (iii), whether such claim may be made in a brand name, and

shall state the basis for the recommendation.

''(ii) The recommendation of an accredited person to approve or deny a petition submitted to such person shall be deemed to be the decision of the Secretary unless the Secretary finds that such recommendation is contrary to the findings required in this Act. If the Secretary makes such a finding, the Secretary shall provide a detailed explanation of the basis of the finding.''.

(c) FOOD ADDITIVES.—Section 409 (21 U.S.C. 348) is amended—

(1) by inserting at the end of subsection (b)(1) the following: ''Any person may submit such a petition to a person accredited under section 712.'';

(2) by inserting at the end of subsection (c)(2) the following: ''This paragraph shall apply to a petition submitted to an accredited person under subsection (b)(1).''; and

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

''(6)(A) An accredited person shall review a petition submitted to it under subsection (b)(1) to determine whether there is reasonable assurance that the food additive with respect to which the petition was submitted may be safely used under the proposed conditions of use. The review of such a petition shall be conducted under the standards and requirements of this Act that are applicable to the review of petitions to the Secretary. After expiration of the period prescribed by paragraph (2), the accredited person shall submit a report of its review of such petition to the Secretary and include its recommendations. Such recommendations to the Secretary shall specify whether a petition should be approved or denied and shall state the basis for the recommendation.

''(B) The recommendation of an accredited person to approve or deny a petition submitted to such person shall be deemed to be the decision of the Secretary unless the Secretary finds that there is a reasonable probability it is not safe. If the Secretary makes such a finding, the

Secretary shall provide a detailed explanation of the basis of the finding.''.

(d) COLOR ADDITIVES.—Section 721 (21 U.S.C 379e) is amended by adding at the end the following:

''(g) PETITION TO ACCREDITED PERSON.—(1) Any person may submit a petition to a person accredited under section 712 for the issuance of a regulation under subsection (b) or (c) or for the issuance of an exemption under subsection (f).

''(2) In reviewing a petition submitted under paragraph (1) to an accredited person, such a person shall determine if the petition meets the requirements for the issuance of a regulation under subsection (b) or (c) or for the issuance of an exemption under subsection (f). The review of such a petition shall be conducted under the standards and requirements of this Act that are applicable to the review of petitions to the Secretary for the issuance of such a regulation or exemption. After a period of 120 days after such a petition is submitted, the accredited person shall submit a report of its review of such petition to the Secretary and include its recommendations. Such recommendations to the Secretary shall specify if such a regulation or exemption should be issued and shall state the basis for its recommendation.

''(3) The recommendation of an accredited person to approve or deny a petition submitted to such person shall be deemed to be the decision of the Secretary unless the Secretary finds that there is a reasonable probability it is not safe. If the Secretary makes such a finding, the Secretary shall provide a detailed explanation of the basis of the finding.''.

SEC. 106. ACCREDITED PERSONS.

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

''SEC. 712. ACCREDITED PERSONS.

''(a) IN GENERAL.—The Secretary shall, within 180 days of the date of the enactment of this section, by regulation establish procedures for the accreditation of third parties for the purposes of—

''(1) reviewing petitions under sections 403(r), 409, and 721(g), an application under section 512, providing written reviews to the Secretary for the Secretary's consideration, and making recommendations on whether or not such petitions or application should be approved; and

''(2) conducting good manufacturing practice inspections to determine the conformance of a facility with regulations promulgated under section 402.

''(b) 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 manufacturer, supplier or vendor of food or animal drugs 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 animal drugs.

''(D) Such person shall be operated in accordance with generally accepted professional

and ethical business practices and shall agree in writing that as 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. 321) is amended by redesignating the second paragraph (u) as paragraph (v) and by adding after that paragraph the following:

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

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

''(B) the disclosure by a person accredited under section 712 of confidential commercial information or any trade secret without the express writ-

ten consent of the person who submitted such information or secret to such person; or

''(C) 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. 107. IMPROVING THE DELANEY CLAUSE.

(a) FOOD ADDITIVES.—

(1) AMENDMENT.—Section 409(c)(3)(A) (21 U.S.C. 348(c)(3)(A)) is amended by striking all after ''substance'' and inserting ''that presents a negligible or de minimus risk''.

(2) REGULATIONS.— The Secretary shall, within 180 days of the date of the enactment of this Act, issue a proposed regulation to establish criteria to determine a negligible or insignificant risk for purposes of section 409(c)(3)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 348(c)(3)(A)). Such proposed regulation shall become final unless the Secretary issues a final regulation before 18 months after such date of enactment.

(b) ANIMAL DRUGS.—

(1) AMENDMENT.—Section 512(d)(1)(I) (21 U.S.C 360b(d)(1)(I)) is amended by striking every-

thing after ''if'' and inserting ''if such drug presents a negligible or insignificant risk to humans or animals.''.

(2) REGULATIONS.— The Secretary shall, within 180 days of the date of the enactment of this Act, issue a proposed regulation to establish criteria to determine a negligible or insignificant risk for purposes of section 512(d)(1)(I) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(d)(1)(I)). Such proposed regulation shall become final unless the Secretary issues a final regulation before 18 months after such date of enactment.

(c) COLOR ADDITIVE.—

(1) AMENDMENT.—Section 721(b)(5)(B) (21 U.S.C 379e(b)(5)(B)) is amended by striking all after ''with respect to the use of a color additive'' and inserting ''if such color additive presents a negligible or insignificant risk to humans or animals.''.

(2) REGULATIONS.— The Secretary shall, within 180 days of the date of the enactment of this Act, issue a proposed regulation to establish criteria to determine a negligible or insignificant risk for purposes of section 721(b)(5)(B) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379e(b)(5)(B)). Such proposed regulation shall become final unless

the Secretary issues a final regulation before 18 months after such date of enactment.

SEC. 108. NATIONAL UNIFORMITY.

Chapter VII is amended by adding at the end the following:

''SUBCHAPTER D—NATIONAL UNIFORMITY

''SEC. 741. (a)(1) Except as provided in paragraph (2) or subsections (b) and (c), no State or political subdivision of a State may, directly or indirectly, establish or continue in effect under any authority any requirement (including a prohibition) for a—

''(A) food for human use,

''(B) a drug (including a biological product), or

''(C) a cosmetic,

which is of the type authorized or required under the adulteration, misbranding, or new drug provisions of this Act or any regulation to implement such provisions if such State or political subdivision requirement is not identical to a requirement imposed under this Act.

''(2) Paragraph (1) does not apply to a State or political subdivision requirement relating to the practice of pharmacy or the dispensing of a drug for human use only upon prescription of a practitioner licensed by law to administer such drug.

''(b)(1) Except as provided in subsection (c), 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—

''(A) for disclosure of the constituents, source, or method of production or processing of the food, drug, or cosmetic, or

''(B) 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.

''(2) For purposes of paragraph (1)—

''(A) 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 human health or safety; and

''(B) the term 'notification requirement' includes any 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.

''(c) Upon application of a State, the Secretary may by regulation, after notice and opportunity for written and oral presentation of views, exempt from subsection (a) or (b), 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 by 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.''.

SEC. 109. HARMONIZATION.

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

''(c)(1) The Secretary shall regularly and continuously participate in meetings with other countries to discuss methods and approaches to reduce the burden of regulation, harmonize regulatory requirements, and seek ap-

propriate reciprocal arrangements. The Secretary shall, within 180 days of the date of enactment of this subsection, make public a plan that establishes a framework for achieving mutual recognition of good manufacturing practices.

''(2) The Secretary shall report to the Committee on Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate at least 60 days before executing any bilateral or multilateral agreement under paragraph (1).''.

SEC. 110. 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 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.''.

SEC. 111. COLORED MARGARINE.

(a) SECTION 301(m).—Paragraph (m) of section 301 (21 U.S.C. 321) 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 striking ''(a)(1)'' and inserting ''(a)'' and by striking paragraph (2); and

(2) by striking subsection (f).

TITLE II—ANIMAL DRUGS

SEC. 201. EVIDENCE OF EFFECTIVENESS FOR ANIMAL DRUGS.

(a) ORIGINAL APPLICATIONS.—Section 512(d) (21 U.S.C. 360b(d)) is amended by striking paragraph (3) and by adding at the end the following:

''(4)(A) As used in this subsection and subsections (c)(2)(F)(iii) and (e)(1)(C), the term 'substantial evidence' means evidence from 1 or more scientifically sound studies, including as appropriate in vitro studies, studies in laboratory animals (including a target species), bioequivalence studies, and any studies voluntarily under-

taken by or for the applicant, that taken together provide reasonable assurance that the drug will have the claimed or intended effect of the drug.

''(B) For purposes of subparagraph (A), a study shall be considered to be scientifically sound if the study is designed and conducted in a manner that is consistent with generally recognized scientific procedures and principles.''.

(b) SUPPLEMENTAL APPLICATIONS.—Section 512(c)(2)(F)(iii) (21 U.S.C. 360b(c)(2)(F)(iii)) is amended—

(1) by striking ''reports of new clinical or field investigations (other than bioequivalence or residue studies) and'' and inserting ''substantial evidence (as defined in subsection (d)(4)) of the effectiveness of the drug involved, any studies of animal safety, or''; and

(2) by striking ''essential to'' and inserting '', required for''.

(c) MINOR SPECIES AND USES.—Section 512(d)(1) (21 U.S.C. 360b(d)(1)) is amended by adding at the end the following new sentence: ''Subparagraph (E) shall not apply to a claim for use of the drug described in subparagraph (E) in a minor species, or for a minor use of the drug, as the terms 'minor species' and 'minor use' are defined in regulations issued by the Secretary, if there is

an application filed under subsection (b) for the drug, and the application is approved, prior to the submission of the claim.''.

(d) COMBINATION DRUGS.—Section 512(d) (21 U.S.C. 360b(d)) is amended by inserting before paragraph (4) (as added by subsection (a)) the following new paragraph:

''(3) In a case in which a new animal drug contains more than 1 active ingredient, or the labeling of the drug prescribes, recommends, or suggests use of the drug in combination with another animal drug, and the active ingredients or drugs in the combination have been separately approved for particular uses and species prior to the approval of the application for the same uses and species in combination (or, in the absence of such approvals, after evaluating the safety and efficacy of the combination itself), the Secretary may only consider with respect to the combination whether any of the active ingredients or any of the drugs in the combination, respectively, at the longest withdrawal time of any of the active ingredients or drugs in the combination, respectively, is above its safe concentration, i.e. exceeds its established tolerance (as measured by its marker residue), or interferes with the methods of analysis for another of the active ingredients or drugs in the combination, respectively.''.

(e) WITHDRAWAL OF APPROVAL.—Section 512(e)(1)(C) (21 U.S.C. 360b(e)(1)(C)) is amended by inserting after ''substantial evidence'' the following: ''(as defined in subsection (d)(4))''.

(f) IMPLEMENTATION.—

(1) IN GENERAL.—Not later than 6 months after the date of enactment of this Act, the Secretary shall issue proposed regulations implementing the amendments made by this section. Not later than 18 months after the date of enactment of this Act, the Secretary shall issue final regulations implementing the amendments.

(2) CONTENTS.—In issuing regulations implementing the amendments made by this section, and in taking an action to review an application for approval of a new animal drug under section 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b), or a request for an investigational exemption for a new animal drug under subsection (j) of such section, that is pending or has been submitted prior to the effective date of the regulations, the Secretary shall—

(A) further define the term ''substantial evidence'', as defined in subsection (d)(4) of such section, in a manner that encourages the

submission of applications for production drugs that conserve food resources, of applications for veterinary prescription drugs whose use is designed to rely on the experience and training of practitioners in establishing effective doses for such drugs, and of supplemental applications, including applications seeking approval for uses of animal drugs in minor species, for minor uses of such drugs, and for permitted unlabeled uses of such drugs;

(B) take into account the proposals contained in the citizen petition (FDA Docket No. 91P–0434/CP) jointly submitted by the American Veterinary Medical Association and the Animal Health Institute, dated October 21, 1991;

(C)(i) provide for the opportunity for a conference prior to the submission of an application for approval of a new animal drug under such section, and prior to the submission of a request for an investigational exemption under subsection (j) of such section, to make a decision establishing a submission or an investigational requirement (which decision shall bind the Secretary and the applicant or requester

unless the Secretary by order determines that a documented scientific requirement essential to the determination of safety or effectiveness of the animal drug involved has appeared after the conference); and

(ii) not later than 10 days after each such conference, by written order, provide a scientific justification specific to the animal drug and intended uses under consideration for requiring studies of types other than the types of studies specified in subsection (d)(4) of such section, as being essential to provide substantial evidence of effectiveness for the intended uses of the drug.

SEC. 202. TIMEFRAME FOR APPROVAL FOR ANIMAL DRUGS.

The first sentence of section 512(c)(1) (21 U.S.C. 360b(c)(1)) is amended by striking ''one hundred and eighty'' and inserting ''90''.

SEC. 203. DISPUTE RESOLUTION.

Section 512(c)(1) (21 U.S.C. 360b(c)(1)) is amended—

(1) in the first sentence—

(A) by redesignating subparagraphs (A) and (B) as clauses (i) and (ii), respectively; and

(B) by inserting ''(A)'' after ''(1)'';

(2) in the second sentence, by striking ''If'' and inserting the following:

''(C) If''; and

(3) by inserting after subparagraph (A) (as designated by paragraph (1)(B)) the following new subparagraph:

''(B)(i) At any time prior to the issuance of the notice under subparagraph (A)(ii), the applicant may, in writing, notify the Secretary that an impasse exists in the review of the application with respect to a specifically identified issue that is preventing the issuance of an order under subparagraph (A)(i).

''(ii) On receipt of the notification from the applicant, the Secretary shall refer the disputed issue—

''(I) to an existing (as of the date of the notification) scientific advisory panel having expertise related to the issue;

''(II) to a special Government employee, as defined in section 202(a) of title 18, United States Code, or to a nongovernmental person qualified to mediate or arbitrate the substance of such impasse who is acceptable to the Secretary and the applicant.

''(iii) The applicant and representatives of the Secretary may consult with the committee, special Government employee, or nongovernmental person on the matter

referred. The committee, special Governmental employee, or nongovernmental person shall submit to the Secretary and the applicant a report containing recommendations (including a statement of reasons for the recommendations) regarding the matter not later than 60 days after the date of the referral, or not later than 90 days after the date of the referral if the committee, special Governmental employee, or nongovernmental person considers the additional 30 days to be necessary. Not later than 30 days after the date of receiving the report, the Secretary shall, in writing, confirm or modify the recommendations received, providing reasons and reference to data before the committee, special Governmental employee, or nongovernmental person for any modification.

''(iv) The Federal Advisory Committee Act shall not apply to any scientific advisory panel acting under this subparagraph.''.

SEC. 204. LIMITATION ON RESIDUES.

Section 512(d)(1)(F) (21 U.S.C. 360b(d)(1)(F)) is amended to read as follows:

''(F) on the basis of information submitted to the Secretary as part of the application or any other information before the Secretary with respect to such drug, any use prescribed, recommended, or suggested in labeling proposed for such drug will re-

sult in a residue of such drug in excess of a tolerance found by the Secretary to be safe for such drug;''.

SEC. 205. VETERINARY FEED DIRECTIVES.

(a) Section 503(f)(1)(A) (21 U.S.C. 353(f)(1)(A)) is amended by inserting after ''other than man'' the following: '', other than a veterinary feed directive drug intended for use in animal feed or an animal feed bearing or containing a veterinary feed directive drug,''.

(b) Chapter V is amended by inserting after section 503 the following new section:

''VETERINARY FEED DIRECTIVE DRUGS

''SEC. 504. (a)(1) A drug intended for use in or on animal feed which is limited by an approved application filed pursuant to section 512(b) to use under the professional supervision of a licensed veterinarian is a veterinary feed directive drug. Any animal feed bearing or containing a veterinary feed directive drug shall be fed to animals only by or upon the lawful veterinary feed directive issued by a licensed veterinarian in the course of the veterinarian's professional practice. When labeled, distributed, held, and used in accordance with this section, a veterinary feed directive drug and any animal feed bearing or containing a veterinary feed directive drug shall be exempt from section 502(f).

''(2) A veterinary feed directive is lawful if it—

''(A) contains such information as the Secretary may by general regulation or by order require; and

''(B) is in compliance with the conditions and indications for use of the drug set forth in the notice published pursuant to section 512(i).

''(3)(A) Any persons involved in the distribution or use of animal feed bearing or containing a veterinary feed directive drug and the licensed veterinarian issuing the veterinary feed directive shall maintain a copy of the veterinary feed directive applicable to each such feed, except in the case of a person distributing such feed to another person for further distribution, such person distributing the feed shall maintain a written acknowledgement from the person to whom the feed is shipped stating that that person shall not ship or move such feed to an animal production facility without a veterinary feed directive or ship such feed to another person for further distribution unless that person has provided the same written acknowledgement to its immediate supplier.

''(B) Every person required under subparagraph (A) to maintain records, and every person in charge or custody thereof, shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to and copy and verify such records.

''(C) Any person who distributes animal feed bearing or containing a veterinary feed directive drug shall upon first engaging in such distribution notify the Secretary of that person's name and place of business. The failure to provide such notification shall be deemed to be an act which results in the drug being misbranded.

''(b) A veterinary feed directive drug and any feed bearing or containing a veterinary feed directive drug shall be deemed to be misbranded if their labeling fails to bear such cautionary statement and such other information as the Secretary may by general regulation or by order prescribe, or their advertising fails to conform to the conditions and indications for use published pursuant to section 512(i) or fails to contain the general cautionary statement prescribed by the Secretary.

''(c) Neither a drug subject to this section, nor animal feed bearing or containing such a drug, shall be deemed to be a prescription article under any Federal or State law.''.

(c) Section 512 (21 U.S.C. 360b) is amended—

(1) in subsection (i), by inserting after ''including special labeling requirements'' the following: ''and any requirement that an animal feed bearing or containing the new animal drug be limited to use

under the professional supervision of a licensed veterinarian'';

(2) in subsection (a)(2)(C), by inserting after ''its labeling,'' the following: ''its distribution, its holding,''; and

(3) in subsection (m)(4)(B)(i)—

(A) by inserting after ''paragraph (5)(A)'' the following: ''or under section 504(a)(3)(A)''; and

(B) by inserting after ''subparagraph (B) of such paragraph'' the following: ''or section 504(a)(3)(B)''.

(d) Section 301(e) (21 U.S.C. 331(e)) is amended—

(1) by inserting after ''by section 412'' the following: '', 504,''; and

(2) by inserting after ''under section 412,'' the following: ''504,''.

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