108TH CONGRESS
2D SESSION

S. 741

AN ACT

To amend the Federal Food, Drug, and Cosmetic Act with regard to new animal drugs, and for other purposes.

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

TITLE I—MINOR USE AND MINOR SPECIES HEALTH

SECTION 101. SHORT TITLE.

This title may be cited as the ''Minor Use and Minor Species Animal Health Act of 2004''.

SEC. 102. MINOR USE AND MINOR SPECIES ANIMAL HEALTH.

(a) FINDINGS.—Congress makes the following findings:

(1) There is a severe shortage of approved new animal drugs for use in minor species.

(2) There is a severe shortage of approved new animal drugs for treating animal diseases and conditions that occur infrequently or in limited geographic areas.

(3) Because of the small market shares, low-profit margins involved, and capital investment required, it is generally not economically feasible for new animal drug applicants to pursue approvals for these species, diseases, and conditions.

(4) Because the populations for which such new animal drugs are intended may be small and conditions of animal management may vary widely, it is often difficult to design and conduct studies to establish drug safety and effectiveness under traditional new animal drug approval processes.

(5) It is in the public interest and in the interest of animal welfare to provide for special procedures to allow the lawful use and marketing of certain new animal drugs for minor species and minor uses that take into account these special cir-

cumstances and that ensure that such drugs do not endanger animal or public health.

(6) Exclusive marketing rights for clinical testing expenses have helped encourage the development of ''orphan'' drugs for human use, and comparable incentives should encourage the development of new animal drugs for minor species and minor uses.

(b) AMENDMENTS TO THE FEDERAL FOOD, DRUG, AND COSMETIC ACT.—

(1) DEFINITIONS.—Section 201 of the Federal, Food, Drug, and Cosmetic Act (21 U.S.C. 321) is amended by adding at the end the following:

''(nn) The term 'major species' means cattle, horses, swine, chickens, turkeys, dogs, and cats, except that the Secretary may add species to this definition by regulation.

''(oo) The term 'minor species' means animals other than humans that are not major species.

''(pp) The term 'minor use' means the intended use of a drug in a major species for an indication that occurs infrequently and in only a small number of animals or in limited geographical areas and in only a small number of animals annually.''.

(2) THREE-YEAR EXCLUSIVITY FOR MINOR USE AND MINOR SPECIES APPROVALS.—Section 512(c)(2)(F) (ii), (iii), and (v) of the Federal Food,

Drug, and Cosmetic Act is amended by striking ''(other than bioequivalence or residue studies)'' and inserting ''(other than bioequivalence studies or residue depletion studies, except residue depletion studies for minor uses or minor species)'' every place it appears.

(3) SCOPE OF REVIEW FOR MINOR USE AND MINOR SPECIES APPLICATIONS.—Section 512(d) of the Federal Food, Drug, and Cosmetic Act is amended by adding at the end the following new paragraph:

''(5) In reviewing an application that proposes a change to add an intended use for a minor use or a minor species to an approved new animal drug application, the Secretary shall reevaluate only the relevant information in the approved application to determine whether the application for the minor use or minor species can be approved. A decision to approve the application for the minor use or minor species is not, implicitly or explicitly, a reaffirmation of the approval of the original application.''.

(4) MINOR USE AND MINOR SPECIES NEW ANIMAL DRUGS.—Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by adding at the end the following:

"Subchapter F—New Animal Drugs for Minor Use and Minor Species

"SEC. 571. CONDITIONAL APPROVAL OF NEW ANIMAL DRUGS FOR MINOR USE AND MINOR SPECIES.

"(a)(1) Except as provided in paragraph (3) of this section, any person may file with the Secretary an application for conditional approval of a new animal drug intended for a minor use or a minor species. Such an application may not be a supplement to an application approved under section 512. Such application must comply in all respects with the provisions of section 512 of this Act except sections 512(a)(4), 512(b)(2), 512(c)(1), 512(c)(2), 512(c)(3), 512(d)(1), 512(e), 512(h), and 512(n) unless otherwise stated in this section, and any additional provisions of this section. New animal drugs are subject to application of the same safety standards that would be applied to such drugs under section 512(d) (including, for antimicrobial new animal drugs, with respect to antimicrobial resistance).

"(2) The applicant shall submit to the Secretary as part of an application for the conditional approval of a new animal drug—

"(A) all information necessary to meet the requirements of section 512(b)(1) except section 512(b)(1)(A);

''(B) full reports of investigations which have been made to show whether or not such drug is safe under section 512(d) (including, for an antimicrobial new animal drug, with respect to antimicrobial resistance) and there is a reasonable expectation of effectiveness for use;

''(C) data for establishing a conditional dose;

''(D) projections of expected need and the justification for that expectation based on the best information available;

''(E) information regarding the quantity of drug expected to be distributed on an annual basis to meet the expected need; and

''(F) a commitment that the applicant will conduct additional investigations to meet the requirements for the full demonstration of effectiveness under section 512(d)(1)(E) within 5 years.

''(3) A person may not file an application under paragraph (1) if—

''(A) the application seeks conditional approval of a new animal drug that is contained in, or is a product of, a transgenic animal.

''(B) the person has previously filed an application for conditional approval under paragraph (1) for the same drug in the same dosage form for the

same intended use whether or not subsequently conditionally approved by the Secretary under subsection (b), or

''(C) the person obtained the application, or data or other information contained therein, directly or indirectly from the person who filed for conditional approval under paragraph (1) for the same drug in the same dosage form for the same intended use whether or not subsequently conditionally approved by the Secretary under subsection (b).

''(b) Within 180 days after the filing of an application pursuant to subsection (a), or such additional period as may be agreed upon by the Secretary and the applicant, the Secretary shall either—

''(1) issue an order, effective for one year, conditionally approving the application if the Secretary finds that none of the grounds for denying conditional approval, specified in subsection (c) of this section applies and publish a Federal Register notice of the conditional approval, or

''(2) give the applicant notice of an opportunity for an informal hearing on the question whether such application can be conditionally approved.

''(c) If the Secretary finds, after giving the applicant notice and an opportunity for an informal hearing, that—

''(1) any of the provisions of section 512(d)(1)(A) through (D) or (F) through (I) are applicable;

''(2) the information submitted to the Secretary as part of the application and any other information before the Secretary with respect to such drug, is insufficient to show that there is a reasonable expectation that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof; or

''(3) another person has received approval under section 512 for the same drug in the same dosage form for the same intended use, and that person is able to assure the availability of sufficient quantities of the drug to meet the needs for which the drug is intended;

the Secretary shall issue an order refusing to conditionally approve the application. If, after such notice and opportunity for an informal hearing, the Secretary finds that paragraphs (1) through (3) do not apply, the Secretary shall issue an order conditionally approving the application effective for one year and publish a Federal Register notice of the conditional approval. Any order issued under this subsection refusing to conditionally approve an application shall state the findings upon which it is based.

''(d) A conditional approval under this section is effective for a 1-year period and is thereafter renewable by the Secretary annually for up to 4 additional 1-year terms. A conditional approval shall be in effect for no more than 5 years from the date of approval under subsection (b)(1) or (c) of this section unless extended as provided for in subsection (h) of this section. The following shall also apply:

''(1) No later than 90 days from the end of the 1-year period for which the original or renewed conditional approval is effective, the applicant may submit a request to renew a conditional approval for an additional 1-year term.

''(2) A conditional approval shall be deemed renewed at the end of the 1-year period, or at the end of a 90-day extension that the Secretary may, at the Secretary's discretion, grant by letter in order to complete review of the renewal request, unless the Secretary determines before the expiration of the 1-year period or the 90-day extension that—

''(A) the applicant failed to submit a timely renewal request;

''(B) the request fails to contain sufficient information to show that—

''(i) the applicant is making sufficient progress toward meeting approval requirements under section 512(d)(1)(E), and is likely to be able to fulfill those requirements and obtain an approval under section 512 before the expiration of the 5-year maximum term of the conditional approval;

''(ii) the quantity of the drug that has been distributed is consistent with the conditionally approved intended use and conditions of use, unless there is adequate explanation that ensures that the drug is only used for its intended purpose; or

''(iii) the same drug in the same dosage form for the same intended use has not received approval under section 512, or if such a drug has been approved, that the holder of the approved application is unable to assure the availability of sufficient quantities of the drug to meet the needs for which the drug is intended; or

''(C) any of the provisions of section 512(e)(1) (A) through (B) or (D) through (F) are applicable.

''(3) If the Secretary determines before the end of the 1-year period or the 90-day extension, if granted, that a conditional approval should not be renewed, the Secretary shall issue an order refusing to renew the conditional approval, and such conditional approval shall be deemed withdrawn and no longer in effect. The Secretary shall thereafter provide an opportunity for an informal hearing to the applicant on the issue whether the conditional approval shall be reinstated.

''(e)(1) The Secretary shall issue an order withdrawing conditional approval of an application filed pursuant to subsection (a) if the Secretary finds that another person has received approval under section 512 for the same drug in the same dosage form for the same intended use and that person is able to assure the availability of sufficient quantities of the drug to meet the needs for which the drug is intended.

''(2) The Secretary shall, after due notice and opportunity for an informal hearing to the applicant, issue an order withdrawing conditional approval of an application filed pursuant to subsection (a) if the Secretary finds that—

''(A) any of the provisions of section 512(e)(1)(A) through (B) or (D) through (F) are applicable; or

''(B) on the basis of new information before the Secretary with respect to such drug, evaluated together with the evidence available to the Secretary when the application was conditionally approved, that there is not a reasonable expectation that such drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling thereof.

''(3) The Secretary may also, after due notice and opportunity for an informal hearing to the applicant, issue an order withdrawing conditional approval of an application filed pursuant to subsection (a) if the Secretary finds that any of the provisions of section 512(e)(2) are applicable.

''(f)(1) The label and labeling of a new animal drug with a conditional approval under this section shall—

''(A) bear the statement, 'conditionally approved by FDA pending a full demonstration of effectiveness under application number'; and

''(B) contain such other information as prescribed by the Secretary.

''(2) An intended use that is the subject of a conditional approval under this section shall not be included in the same product label with any intended use approved under section 512.

''(g) A conditionally approved new animal drug application may not be amended or supplemented to add indications for use.

''(h) 180 days prior to the termination date established under subsection (d) of this section, an applicant shall have submitted all the information necessary to support a complete new animal drug application in accordance with section 512(b)(1) or the conditional approval issued under this section is no longer in effect. Following review of this information, the Secretary shall either—

''(1) issue an order approving the application under section 512(c) if the Secretary finds that none of the grounds for denying approval specified in section 512(d)(1) applies, or

''(2) give the applicant an opportunity for a hearing before the Secretary under section 512(d) on the question whether such application can be approved.

Upon issuance of an order approving the application, product labeling and administrative records of approval shall be modified accordingly. If the Secretary has not

issued an order under section 512(c) approving such application prior to the termination date established under subsection (d) of this section, the conditional approval issued under this section is no longer in effect unless the Secretary grants an extension of an additional 180-day period so that the Secretary can complete review of the application. The decision to grant an extension is committed to the discretion of the Secretary and not subject to judicial review.

''(i) The decision of the Secretary under subsection (c), (d), or (e) of this section refusing or withdrawing conditional approval of an application shall constitute final agency action subject to judicial review.

''(j) In this section and section 572, the term 'transgenic animal' means an animal whose genome contains a nucleotide sequence that has been intentionally modified in vitro, and the progeny of such an animal; Provided that the term 'transgenic animal' does not include an animal of which the nucleotide sequence of the genome has been modified solely by selective breeding.

''SEC. 572. INDEX OF LEGALLY MARKETED UNAPPROVED NEW ANIMAL DRUGS FOR MINOR SPECIES.

''(a)(1) The Secretary shall establish an index limited to—

''(A) new animal drugs intended for use in a minor species for which there is a reasonable certainty that the animal or edible products from the animal will not be consumed by humans or food-producing animals; and

''(B) new animal drugs intended for use only in a hatchery, tank, pond, or other similar contained man-made structure in an early, non-food life stage of a food-producing minor species, where safety for humans is demonstrated in accordance with the standard of section 512(d) (including, for an antimicrobial new animal drug, with respect to antimicrobial resistance).

''(2) The index shall not include a new animal drug that is contained in or a product of a transgenic animal.

''(b) Any person intending to file a request under this section shall be entitled to one or more conferences to discuss the requirements for indexing a new animal drug.

''(c)(1) Any person may submit a request to the Secretary for a determination whether a new animal drug may be eligible for inclusion in the index. Such a request shall include—

''(A) information regarding the need for the new animal drug, the species for which the new animal drug is intended, the proposed intended use and

conditions of use, and anticipated annual distribution;

''(B) information to support the conclusion that the proposed use meets the conditions of subparagraph (A) or (B) of subsection (a)(1) of this section;

''(C) information regarding the components and composition of the new animal drug;

''(D) a description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such new animal drug;

''(E) an environmental assessment that meets the requirements of the National Environmental Policy Act of 1969, as amended, and as defined in 21 CFR Part 25, as it appears on the date of enactment of this provision and amended thereafter or information to support a categorical exclusion from the requirement to prepare an environmental assessment;

''(F) information sufficient to support the conclusion that the proposed use of the new animal drug is safe under section 512(d) with respect to individuals exposed to the new animal drug through its manufacture or use; and

''(G) such other information as the Secretary may deem necessary to make this eligibility determination.

''(2) Within 90 days after the submission of a request for a determination of eligibility for indexing based on subsection (a)(1)(A) of this section, or 180 days for a request submitted based on subsection (a)(1)(B) of this section, the Secretary shall grant or deny the request, and notify the person who requested such determination of the Secretary's decision. The Secretary shall grant the request if the Secretary finds that—

''(A) the same drug in the same dosage form for the same intended use is not approved or conditionally approved;

''(B) the proposed use of the drug meets the conditions of subparagraph (A) or (B) of subsection (a)(1), as appropriate;

''(C) the person requesting the determination has established appropriate specifications for the manufacture and control of the new animal drug and has demonstrated an understanding of the requirements of current good manufacturing practices;

''(D) the new animal drug will not significantly affect the human environment; and

''(E) the new animal drug is safe with respect to individuals exposed to the new animal drug through its manufacture or use.

If the Secretary denies the request, the Secretary shall thereafter provide due notice and an opportunity for an informal conference. A decision of the Secretary to deny an eligibility request following an informal conference shall constitute final agency action subject to judicial review.

''(d)(1) With respect to a new animal drug for which the Secretary has made a determination of eligibility under subsection (c), the person who made such a request may ask that the Secretary add the new animal drug to the index established under subsection (a). The request for addition to the index shall include—

''(A) a copy of the Secretary's determination of eligibility issued under subsection (c);

''(B) a written report that meets the requirements in subsection (d)(2) of this section;

''(C) a proposed index entry;

''(D) facsimile labeling;

''(E) anticipated annual distribution of the new animal drug;

''(F) a written commitment to manufacture the new animal drug and animal feeds bearing or con-

taining such new animal drug according to current good manufacturing practices;

''(G) a written commitment to label, distribute, and promote the new animal drug only in accordance with the index entry;

''(H) upon specific request of the Secretary, information submitted to the expert panel described in paragraph (3); and

''(I) any additional requirements that the Secretary may prescribe by general regulation or specific order.

''(2) The report required in paragraph (1) shall—

''(A) be authored by a qualified expert panel;

''(B) include an evaluation of all available target animal safety and effectiveness information, including anecdotal information;

''(C) state the expert panel's opinion regarding whether the benefits of using the new animal drug for the proposed use in a minor species outweigh its risks to the target animal, taking into account the harm being caused by the absence of an approved or conditionally approved new animal drug for the minor species in question;

''(D) include information from which labeling can be written; and

''(E) include a recommendation regarding whether the new animal drug should be limited to use under the professional supervision of a licensed veterinarian.

''(3) A qualified expert panel, as used in this section, is a panel that—

''(A) is composed of experts qualified by scientific training and experience to evaluate the target animal safety and effectiveness of the new animal drug under consideration;

''(B) operates external to FDA; and

''(C) is not subject to the Federal Advisory Committee Act, 5 U.S.C. App. 2.

The Secretary shall define the criteria for selection of a qualified expert panel and the procedures for the operation of the panel by regulation.

''(4) Within 180 days after the receipt of a request for listing a new animal drug in the index, the Secretary shall grant or deny the request. The Secretary shall grant the request if the request for indexing continues to meet the eligibility criteria in subsection (a) and the Secretary finds, on the basis of the report of the qualified expert panel and other information available to the Secretary, that the benefits of using the new animal drug for the proposed use in a minor species outweigh its risks to the

target animal, taking into account the harm caused by the absence of an approved or conditionally-approved new animal drug for the minor species in question. If the Secretary denies the request, the Secretary shall thereafter provide due notice and the opportunity for an informal conference. The decision of the Secretary following an informal conference shall constitute final agency action subject to judicial review.

''(e)(1) The index established under subsection (a) shall include the following information for each listed drug—

''(A) the name and address of the person who holds the index listing;

''(B) the name of the drug and the intended use and conditions of use for which it is being indexed;

''(C) product labeling; and

''(D) conditions and any limitations that the Secretary deems necessary regarding use of the drug.

''(2) The Secretary shall publish the index, and revise it periodically.

''(3) The Secretary may establish by regulation a process for reporting changes in the conditions of manufacturing or labeling of indexed products.

''(f)(1) If the Secretary finds, after due notice to the person who requested the index listing and an opportunity for an informal conference, that—

''(A) the expert panel failed to meet the requirements as set forth by the Secretary by regulation;

''(B) on the basis of new information before the Secretary, evaluated together with the evidence available to the Secretary when the new animal drug was listed in the index, the benefits of using the new animal drug for the indexed use do not outweigh its risks to the target animal;

''(C) the conditions of subsection (c)(2) of this section are no longer satisfied;

''(D) the manufacture of the new animal drug is not in accordance with current good manufacturing practices;

''(E) the labeling, distribution, or promotion of the new animal drug is not in accordance with the index entry;

''(F) the conditions and limitations of use associated with the index listing have not been followed; or

''(G) the request for indexing contains any untrue statement of material fact,

the Secretary shall remove the new animal drug from the index. The decision of the Secretary following an informal conference shall constitute final agency action subject to judicial review.

''(2) If the Secretary finds that there is a reasonable probability that the use of the drug would present a risk to the health of humans or other animals, the Secretary may—

''(A) suspend the listing of such drug immediately;

''(B) give the person listed in the index prompt notice of the Secretary's action; and

''(C) afford that person the opportunity for an informal conference.

The decision of the Secretary following an informal conference shall constitute final agency action subject to judicial review.

''(g) For purposes of indexing new animal drugs under this section, to the extent consistent with the public health, the Secretary shall promulgate regulations for exempting from the operation of section 512 minor species new animal drugs and animal feeds bearing or containing new animal drugs intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety and effectiveness of minor species

animal drugs. Such regulations may, at the discretion of the Secretary, among other conditions relating to the protection of the public health, provide for conditioning such exemption upon the establishment and maintenance of such records, and the making of such reports to the Secretary, by the manufacturer or the sponsor of the investigation of such article, of data (including but not limited to analytical reports by investigators) obtained as a result of such investigational use of such article, as the Secretary finds will enable the Secretary to evaluate the safety and effectiveness of such article in the event of the filing of a request for an index listing pursuant to this section.

''(h) The labeling of a new animal drug that is the subject of an index listing shall state, prominently and conspicuously—

''(1) 'NOT APPROVED BY FDA.—Legally marketed as an FDA indexed product. Extra-label use is prohibited.';

''(2) except in the case of new animal drugs indexed for use in an early life stage of a food-producing animal, 'This product is not to be used in animals intended for use as food for humans or other animals.'; and

''(3) such other information as may be prescribed by the Secretary in the index listing.

''(i)(1) In the case of any new animal drug for which an index listing pursuant to subsection (a) is in effect, the person who has an index listing shall establish and maintain such records, and make such reports to the Secretary, of data relating to experience, and other data or information, received or otherwise obtained by such person with respect to such drug, or with respect to animal feeds bearing or containing such drug, as the Secretary may by general regulation, or by order with respect to such listing, prescribe on the basis of a finding that such records and reports are necessary in order to enable the Secretary to determine, or facilitate a determination, whether there is or may be ground for invoking subsection (f). Such regulation or order shall provide, where the Secretary deems it to be appropriate, for the examination, upon request, by the persons to whom such regulation or order is applicable, of similar information received or otherwise obtained by the Secretary.

''(2) Every person required under this subsection 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.

''(j)(1) Safety and effectiveness data and information which has been submitted in support of a request for a new animal drug to be indexed under this section and which has not been previously disclosed to the public shall be made available to the public, upon request, unless extraordinary circumstances are shown—

''(A) if no work is being or will be undertaken to have the drug indexed in accordance with the request,

''(B) if the Secretary has determined that such drug cannot be indexed and all legal appeals have been exhausted,

''(C) if the indexing of such drug is terminated and all legal appeals have been exhausted, or

''(D) if the Secretary has determined that such drug is not a new animal drug.

''(2) Any request for data and information pursuant to paragraph (1) shall include a verified statement by the person making the request that any data or information received under such paragraph shall not be disclosed by such person to any other person—

''(A) for the purpose of, or as part of a plan, scheme, or device for, obtaining the right to make, use, or market, or making, using, or marketing, out-

side the United States, the drug identified in the request for indexing; and

''(B) without obtaining from any person to whom the data and information are disclosed an identical verified statement, a copy of which is to be provided by such person to the Secretary, which meets the requirements of this paragraph.

''SEC. 573. DESIGNATED NEW ANIMAL DRUGS FOR MINOR USE OR MINOR SPECIES.

''(a) DESIGNATION.—

''(1) The manufacturer or the sponsor of a new animal drug for a minor use or use in a minor species may request that the Secretary declare that drug a 'designated new animal drug'. A request for designation of a new animal drug shall be made before the submission of an application under section 512(b) or section 571 for the new animal drug.

''(2) The Secretary may declare a new animal drug a 'designated new animal drug' if—

''(A) it is intended for a minor use or use in a minor species; and

''(B) the same drug in the same dosage form for the same intended use is not approved under section 512 or 571 or designated under this section at the time the request is made.

"(3) Regarding the termination of a designation—

"(A) the sponsor of a new animal drug shall notify the Secretary of any decision to discontinue active pursuit of approval under section 512 or 571 of an application for a designated new animal drug. The Secretary shall terminate the designation upon such notification;

"(B) the Secretary may also terminate designation if the Secretary independently determines that the sponsor is not actively pursuing approval under section 512 or 571 with due diligence;

"(C) the sponsor of an approved designated new animal drug shall notify the Secretary of any discontinuance of the manufacture of such new animal drug at least one year before discontinuance. The Secretary shall terminate the designation upon such notification; and

"(D) the designation shall terminate upon the expiration of any applicable exclusivity period under subsection (c).

''(4) Notice respecting the designation or termination of designation of a new animal drug shall be made available to the public.

''(b) GRANTS AND CONTRACTS FOR DEVELOPMENT OF DESIGNATED NEW ANIMAL DRUGS.—

''(1) The Secretary may make grants to and enter into contracts with public and private entities and individuals to assist in defraying the costs of qualified safety and effectiveness testing expenses and manufacturing expenses incurred in connection with the development of designated new animal drugs.

''(2) For purposes of paragraph (1) of this section—

''(A) The term 'qualified safety and effectiveness testing' means testing—

''(i) which occurs after the date such new animal drug is designated under this section and before the date on which an application with respect to such drug is submitted under section 512; and

''(ii) which is carried out under an investigational exemption under section 512(j).

''(B) The term 'manufacturing expenses' means expenses incurred in developing processes and procedures associated with manufacture of the designated new animal drug which occur after the new animal drug is designated under this section and before the date on which an application with respect to such new animal drug is submitted under section 512 or 571.

''(c) EXCLUSIVITY FOR DESIGNATED NEW ANIMAL DRUGS.—

''(1) Except as provided in subsection (c)(2), if the Secretary approves or conditionally approves an application for a designated new animal drug, the Secretary may not approve or conditionally approve another application submitted for such new animal drug with the same intended use as the designated new animal drug for another applicant before the expiration of seven years from the date of approval or conditional approval of the application.

''(2) If an application filed pursuant to section 512 or section 571 is approved for a designated new animal drug, the Secretary may, during the 7-year exclusivity period beginning on the date of the application approval or conditional approval, approve or conditionally approve another application under sec-

tion 512 or section 571 for such drug for such minor use or minor species for another applicant if—

"(A) the Secretary finds, after providing the holder of such an approved application notice and opportunity for the submission of views, that in the granted exclusivity period the holder of the approved application cannot assure the availability of sufficient quantities of the drug to meet the needs for which the drug was designated; or

"(B) such holder provides written consent to the Secretary for the approval or conditional approval of other applications before the expiration of such exclusivity period.".

(5) CONFORMING AMENDMENTS.—

(A) Section 201(u) of the Federal Food, Drug, and Cosmetic Act is amended by striking "512" and inserting "512, 571".

(B) Section 201(v) of the Federal Food, Drug, and Cosmetic Act is amended by inserting the following after paragraph (2): "Provided that any drug intended for minor use or use in a minor species that is not the subject of a final regulation published by the Secretary

through notice and comment rulemaking finding that the criteria of paragraphs (1) and (2) have not been met (or that the exception to the criterion in paragraph (1) has been met) is a new animal drug.''.

(C) Section 301(e) of the Federal Food, Drug, and Cosmetic Act is amended by striking ''512(a)(4)(C), 512(j), (l) or (m)'' and inserting ''512(a)(4)(C), 512 (j), (l) or (m), 572(i).''

(D) Section 301(j) of the Federal Food, Drug, and Cosmetic Act is amended by striking ''520'' and inserting ''520, 571, 572, 573.''

(E) Section 502 of the Federal Food, Drug, and Cosmetic Act is amended by adding at the end the following new subsection:

''(w) If it is a new animal drug—

''(1) that is conditionally approved under section 571 and its labeling does not conform with the approved application or section 571(f), or that is not conditionally approved under section 571 and its label bears the statement set forth in section 571(f)(1)(A); or

''(2) that is indexed under section 572 and its labeling does not conform with the index listing under section 572(e) or 572(h), or that has not been

indexed under section 572 and its label bears the statement set forth in section 572(h).''.

(F) Section 503(f) of the Federal Food, Drug, and Cosmetic Act is amended—

(i) in paragraph (1)(A)(ii) by striking ''512'' and inserting ''512, a conditionally-approved application under section 571, or an index listing under section 572''; and

(ii) in paragraph (3) by striking ''section 512'' and inserting ''section 512, 571, or 572''.

(G) Section 504(a)(1) of the Federal Food, Drug, and Cosmetic Act is amended by striking ''512(b)'' and inserting ''512(b), a conditionally-approved application filed pursuant to section 571, or an index listing pursuant to section 572''.

(H) Sections 504(a)(2)(B) and 504(b) of the Federal Food, Drug, and Cosmetic Act are amended by striking ''512(i)'' each place it appears and inserting ''512(i), or the index listing pursuant to section 572(e)''.

(I) Section 512(a) of the Federal Food, Drug, and Cosmetic Act is amended by striking

paragraphs (1) and (2) and inserting the following:

''(1) A new animal drug shall, with respect to any particular use or intended use of such drug, be deemed unsafe for purposes of section 501(a)(5) and section 402(a)(2)(C)(ii) unless—

''(A) there is in effect an approval of an application filed pursuant to subsection (b) with respect to such use or intended use of such drug, and such drug, its labeling, and such use conform to such approved application;

''(B) there is in effect a conditional approval of an application filed pursuant to section 571 with respect to such use or intended use of such drug, and such drug, its labeling, and such use conform to such conditionally approved application; or

''(C) there is in effect an index listing pursuant to section 572 with respect to such use or intended use of such drug in a minor species, and such drug, its labeling, and such use conform to such index listing.

A new animal drug shall also be deemed unsafe for such purposes in the event of removal from the establishment of a manufacturer, packer, or distributor of such drug for use in the manufacture of animal feed in any State unless

at the time of such removal such manufacturer, packer, or distributor has an unrevoked written statement from the consignee of such drug, or notice from the Secretary, to the effect that, with respect to the use of such drug in animal feed, such consignee (i) holds a license issued under subsection (m) and has in its possession current approved labeling for such drug in animal feed; or (ii) will, if the consignee is not a user of the drug, ship such drug only to a holder of a license issued under subsection (m).

''(2) An animal feed bearing or containing a new animal drug shall, with respect to any particular use or intended use of such animal feed be deemed unsafe for purposes of section 501(a)(6) unless—

''(A) there is in effect—

''(i) an approval of an application filed pursuant to subsection (b) with respect to such drug, as used in such animal feed, and such animal feed and its labeling, distribution, holding, and use conform to such approved application;

''(ii) a conditional approval of an application filed pursuant to section 571 with respect to such drug, as used in such animal feed, and such animal feed and its labeling, distribution,

holding, and use conform to such conditionally approved application; or

''(iii) an index listing pursuant to section 572 with respect to such drug, as used in such animal feed, and such animal feed and its labeling, distribution, holding, and use conform to such index listing; and

''(B) such animal feed is manufactured at a site for which there is in effect a license issued pursuant to subsection (m)(1) to manufacture such animal feed.''.

(J) Section 512(b)(3) of the Federal Food, Drug, and Cosmetic Act is amended by striking ''under paragraph (1) or a request for an investigational exemption under subsection (j)'' and inserting ''under paragraph (1), section 571, or a request for an investigational exemption under subsection (j)''.

(K) Section 512(d)(4) of the Federal Food, Drug, and Cosmetic Act is amended by striking ''have previously been separately approved'' and inserting ''have previously been separately approved pursuant to an application submitted under section 512(b)(1)''.

(L) Section 512(f) of the Federal Food, Drug, and Cosmetic Act is amended by striking ''subsection (d), (e), or (m)'' and inserting ''subsection (d), (e), or (m), or section 571 (c), (d), or (e)''.

(M) Section 512(g) of the Federal Food, Drug, and Cosmetic Act is amended by striking ''this section'' and inserting ''this section, or section 571''.

(N) Section 512(i) of the Federal Food, Drug, and Cosmetic Act is amended by striking ''subsection (b)'' and inserting ''subsection (b) or section 571'' and by inserting ''or upon failure to renew a conditional approval under section 571'' after ''or upon its suspension''.

(O) Section 512(l)(1) of the Federal Food, Drug, and Cosmetic Act is amended by striking ''subsection (b)'' and inserting ''subsection (b) or section 571''.

(P) Section 512(m)(1)(C) of the Federal Food, Drug, and Cosmetic Act is amended by striking ''applicable regulations published pursuant to subsection (i)'' and inserting ''applicable regulations published pursuant to subsection (i) or for indexed new animal drugs in accord-

ance with the index listing published pursuant to section 572(e)(2) and the labeling requirements set forth in section 572(h)''.

(Q) Section 512(m)(3) of the Federal Food, Drug, and Cosmetic Act is amended by inserting ''or an index listing pursuant to section 572(e)'' after ''subsection (i)'' each place it appears.

(R) Section 512(p)(1) of the Federal Food, Drug, and Cosmetic Act is amended by striking ''subsection (b)(1)'' and inserting ''subsection (b)(1) or section 571(a)''.

(S) Section 512(p)(2) of the Federal Food, Drug, and Cosmetic Act is amended by striking ''subsection (b)(1)'' and inserting ''subsection (b)(1) or section 571(a)''.

(T) Section 108(b)(3) of Public Law 90–399 is amended by striking ''section 201(w) as added by this Act'' and inserting ''section 201(v)''.

(6) REGULATIONS.—On the date of enactment of this Act, the Secretary of Health and Human Services shall implement sections 571 and 573 of the Federal Food, Drug, and Cosmetic Act and subsequently publish implementing regulations. Not

later than 12 months after the date of enactment of this Act, the Secretary shall issue proposed regulations to implement section 573 of the Federal Food, Drug, and Cosmetic Act (as added by this Act), and not later than 24 months after the date of enactment of this Act, the Secretary shall issue final regulations implementing section 573 of the Federal Food, Drug, and Cosmetic Act. Not later than 18 months after the date of enactment of this Act, the Secretary shall issue proposed regulations to implement section 572 of the Federal Food, Drug, and Cosmetic Act (as added by this Act), and not later than 36 months after the date of enactment of this Act, the Secretary shall issue final regulations implementing section 572 of the Federal Food, Drug, and Cosmetic Act. Not later than 30 months after the date of enactment of this Act, the Secretary shall issue proposed regulations to implement section 571 of the Federal Food, Drug, and Cosmetic Act (as added by this Act), and not later than 42 months after the date of enactment of this Act, the Secretary shall issue final regulations implementing section 571 of the Federal Food, Drug, and Cosmetic Act. These timeframes shall be extended by 12 months for each fiscal year, in which the funds au-

thorized to be appropriated under subsection (i) are not in fact appropriated.

(7) OFFICE.—The Secretary of Health and Human Services shall establish within the Center for Veterinary Medicine (of the Food and Drug Administration), an Office of Minor Use and Minor Species Animal Drug Development that reports directly to the Director of the Center for Veterinary Medicine. This office shall be responsible for overseeing the development and legal marketing of new animal drugs for minor uses and minor species. There is authorized to be appropriated to carry out this subsection $1,200,000 for fiscal year 2004 and such sums as may be necessary for each fiscal year thereafter.

(8) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out section 573(b) of the Federal Food, Drug, and Cosmetic Act (as added by this section) $1,000,000 for the fiscal year following publication of final implementing regulations, $2,000,000 for the subsequent fiscal year, and such sums as may be necessary for each fiscal year thereafter.

TITLE II—FOOD ALLERGEN LABELING AND CONSUMER PROTECTION

SEC. 201. SHORT TITLE.

This title may be cited as the ''Food Allergen Labeling and Consumer Protection Act of 2004''.

SEC. 202. FINDINGS.

Congress finds that—

(1) it is estimated that—

(A) approximately 2 percent of adults and about 5 percent of infants and young children in the United States suffer from food allergies; and

(B) each year, roughly 30,000 individuals require emergency room treatment and 150 individuals die because of allergic reactions to food;

(2)(A) eight major foods or food groups—milk, eggs, fish, Crustacean shellfish, tree nuts, peanuts, wheat, and soybeans—account for 90 percent of food allergies;

(B) at present, there is no cure for food allergies; and

(C) a food allergic consumer must avoid the food to which the consumer is allergic;

(3)(A) in a review of the foods of randomly selected manufacturers of baked goods, ice cream, and candy in Minnesota and Wisconsin in 1999, the Food and Drug Administration found that 25 percent of sampled foods failed to list peanuts or eggs as ingredients on the food labels; and

(B) nationally, the number of recalls because of unlabeled allergens rose to 121 in 2000 from about 35 a decade earlier;

(4) a recent study shows that many parents of children with a food allergy were unable to correctly identify in each of several food labels the ingredients derived from major food allergens;

(5)(A) ingredients in foods must be listed by their ''common or usual name'';

(B) in some cases, the common or usual name of an ingredient may be unfamiliar to consumers, and many consumers may not realize the ingredient is derived from, or contains, a major food allergen; and

(C) in other cases, the ingredients may be declared as a class, including spices, flavorings, and certain colorings, or are exempt from the ingredient labeling requirements, such as incidental additives; and

(6)(A) celiac disease is an immune-mediated disease that causes damage to the gastrointestinal tract, central nervous system, and other organs;

(B) the current recommended treatment is avoidance of glutens in foods that are associated with celiac disease; and

(C) a multicenter, multiyear study estimated that the prevalence of celiac disease in the United States is 0.5 to 1 percent of the general population.

SEC. 203. FOOD LABELING; REQUIREMENT OF INFORMATION REGARDING ALLERGENIC SUBSTANCES.

(a) IN GENERAL.—Section 403 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343) is amended by adding at the end the following:

''(w)(1) If it is not a raw agricultural commodity and it is, or it contains an ingredient that bears or contains, a major food allergen, unless either—

''(A) the word 'Contains', followed by the name of the food source from which the major food allergen is derived, is printed immediately after or is adjacent to the list of ingredients (in a type size no smaller than the type size used in the list of ingredients) required under subsections (g) and (i); or

''(B) the common or usual name of the major food allergen in the list of ingredients required

under subsections (g) and (i) is followed in parentheses by the name of the food source from which the major food allergen is derived, except that the name of the food source is not required when—

"(i) the common or usual name of the ingredient uses the name of the food source from which the major food allergen is derived; or

"(ii) the name of the food source from which the major food allergen is derived appears elsewhere in the ingredient list, unless the name of the food source that appears elsewhere in the ingredient list appears as part of the name of a food ingredient that is not a major food allergen under section 201(qq)(2)(A) or (B).

"(2) As used in this subsection, the term 'name of the food source from which the major food allergen is derived' means the name described in section 201(qq)(1); provided that in the case of a tree nut, fish, or Crustacean shellfish, the term 'name of the food source from which the major food allergen is derived' means the name of the specific type of nut or species of fish or Crustacean shellfish.

"(3) The information required under this subsection may appear in labeling in lieu of appearing on the label

only if the Secretary finds that such other labeling is sufficient to protect the public health. A finding by the Secretary under this paragraph (including any change in an earlier finding under this paragraph) is effective upon publication in the Federal Register as a notice.

''(4) Notwithstanding subsection (g), (i), or (k), or any other law, a flavoring, coloring, or incidental additive that is, or that bears or contains, a major food allergen shall be subject to the labeling requirements of this subsection.

''(5) The Secretary may by regulation modify the requirements of subparagraph (A) or (B) of paragraph (1), or eliminate either the requirement of subparagraph (A) or the requirements of subparagraph (B) of paragraph (1), if the Secretary determines that the modification or elimination of the requirement of subparagraph (A) or the requirements of subparagraph (B) is necessary to protect the public health.

''(6)(A) Any person may petition the Secretary to exempt a food ingredient described in section 201(qq)(2) from the allergen labeling requirements of this subsection.

''(B) The Secretary shall approve or deny such petition within 180 days of receipt of the petition or the petition shall be deemed denied, unless an extension of time

is mutually agreed upon by the Secretary and the petitioner.

''(C) The burden shall be on the petitioner to provide scientific evidence (including the analytical method used to produce the evidence) that demonstrates that such food ingredient, as derived by the method specified in the petition, does not cause an allergic response that poses a risk to human health.

''(D) A determination regarding a petition under this paragraph shall constitute final agency action.

''(E) The Secretary shall promptly post to a public site all petitions received under this paragraph within 14 days of receipt and the Secretary shall promptly post the Secretary's response to each.

''(7)(A) A person need not file a petition under paragraph (6) to exempt a food ingredient described in section 201(qq)(2) from the allergen labeling requirements of this subsection, if the person files with the Secretary a notification containing—

''(i) scientific evidence (including the analytical method used) that demonstrates that the food ingredient (as derived by the method specified in the notification, where applicable) does not contain allergenic protein; or

''(ii) a determination by the Secretary that the ingredient does not cause an allergic response that poses a risk to human health under a premarket approval or notification program under section 409.

''(B) The food ingredient may be introduced or delivered for introduction into interstate commerce as a food ingredient that is not a major food allergen 90 days after the date of receipt of the notification by the Secretary, unless the Secretary determines within the 90-day period that the notification does not meet the requirements of this paragraph, or there is insufficient scientific evidence to determine that the food ingredient does not contain allergenic protein or does not cause an allergenic response that poses a risk to human health.

''(C) The Secretary shall promptly post to a public site all notifications received under this subparagraph within 14 days of receipt and promptly post any objections thereto by the Secretary.

''(x) Notwithstanding subsection (g), (i), or (k), or any other law, a spice, flavoring, coloring, or incidental additive that is, or that bears or contains, a food allergen (other than a major food allergen), as determined by the Secretary by regulation, shall be disclosed in a manner specified by the Secretary by regulation.''.

(b) EFFECT ON OTHER AUTHORITY.—The amendments made by this section that require a label or labeling for major food allergens do not alter the authority of the Secretary of Health and Human Services under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) to require a label or labeling for other food allergens.

(c) CONFORMING AMENDMENTS.—

(1) Section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321) (as amended by section 102(b)) is amended by adding at the end the following:

''(qq) The term 'major food allergen' means any of the following:

''(1) Milk, egg, fish (e.g., bass, flounder, or cod), Crustacean shellfish (e.g., crab, lobster, or shrimp), tree nuts (e.g., almonds, pecans, or walnuts), wheat, peanuts, and soybeans.

''(2) A food ingredient that contains protein derived from a food specified in paragraph (1), except the following:

''(A) Any highly refined oil derived from a food specified in paragraph (1) and any ingredient derived from such highly refined oil.

''(B) A food ingredient that is exempt under paragraph (6) or (7) of section 403(w).''.

(2) Section 403A(a)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343–1(a)(2)) is amended by striking ''or 403(i)(2)'' and inserting ''403(i)(2), 403(w), or 403(x)''.

(d) EFFECTIVE DATE.—The amendments made by this section shall apply to any food that is labeled on or after January 1, 2006.

SEC. 204. REPORT ON FOOD ALLERGENS.

Not later than 18 months after the date of enactment of this Act, the Secretary of Health and Human Services (in this section referred to as the ''Secretary'') shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report that—

(1)(A) analyzes—

(i) the ways in which foods, during manufacturing and processing, are unintentionally contaminated with major food allergens, including contamination caused by the use by manufacturers of the same production line to produce both products for which major food allergens are intentional ingredients and products for which major food allergens are not intentional ingredients; and

(ii) the ways in which foods produced on dedicated production lines are unintentionally contaminated with major food allergens; and

(B) estimates how common the practices described in subparagraph (A) are in the food industry, with breakdowns by food type as appropriate;

(2) advises whether good manufacturing practices or other methods can be used to reduce or eliminate cross-contact of foods with the major food allergens;

(3) describes—

(A) the various types of advisory labeling (such as labeling that uses the words ''may contain'') used by food producers;

(B) the conditions of manufacture of food that are associated with the various types of advisory labeling; and

(C) the extent to which advisory labels are being used on food products;

(4) describes how consumers with food allergies or the caretakers of consumers would prefer that information about the risk of cross-contact be communicated on food labels as determined by using appropriate survey mechanisms;

(5) states the number of inspections of food manufacturing and processing facilities conducted in the previous 2 years and describes—

(A) the number of facilities and food labels that were found to be in compliance or out of compliance with respect to cross-contact of foods with residues of major food allergens and the proper labeling of major food allergens;

(B) the nature of the violations found; and

(C) the number of voluntary recalls, and their classifications, of foods containing undeclared major food allergens; and

(6) assesses the extent to which the Secretary and the food industry have effectively addressed cross-contact issues.

SEC. 205. INSPECTIONS RELATING TO FOOD ALLERGENS.

The Secretary of Health and Human Services shall conduct inspections consistent with the authority under section 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 374) of facilities in which foods are manufactured, processed, packed, or held—

(1) to ensure that the entities operating the facilities comply with practices to reduce or eliminate cross-contact of a food with residues of major food

allergens that are not intentional ingredients of the food; and

(2) to ensure that major food allergens are properly labeled on foods.

SEC. 206. GLUTEN LABELING.

Not later than 2 years after the date of enactment of this Act, the Secretary of Health and Human Services, in consultation with appropriate experts and stakeholders, shall issue a proposed rule to define, and permit use of, the term ''gluten-free'' on the labeling of foods. Not later than 4 years after the date of enactment of this Act, the Secretary shall issue a final rule to define, and permit use of, the term ''gluten-free'' on the labeling of foods.

SEC. 207. IMPROVEMENT AND PUBLICATION OF DATA ON FOOD-RELATED ALLERGIC RESPONSES.

(a) IN GENERAL.—The Secretary of Health and Human Services, acting through the Director of the Centers for Disease Control and Prevention and in consultation with the Commissioner of Food and Drugs, shall improve (including by educating physicians and other health care providers) the collection of, and publish as it becomes available, national data on—

(1) the prevalence of food allergies;

(2) the incidence of clinically significant or serious adverse events related to food allergies; and

(3) the use of different modes of treatment for and prevention of allergic responses to foods.

(b) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary.

SEC. 208. FOOD ALLERGIES RESEARCH.

(a) IN GENERAL.—The Secretary of Health and Human Services, acting through the Director of the National Institutes of Health, shall convene an ad hoc panel of nationally recognized experts in allergy and immunology to review current basic and clinical research efforts related to food allergies.

(b) RECOMMENDATIONS.—Not later than 1 year after the date of enactment of this Act, the panel shall make recommendations to the Secretary for enhancing and coordinating research activities concerning food allergies, which the Secretary shall make public.

SEC. 209. FOOD ALLERGENS IN THE FOOD CODE.

The Secretary of Health and Human Services shall, in the Conference for Food Protection, as part of its efforts to encourage cooperative activities between the States under section 311 of the Public Health Service Act (42 U.S.C. 243), pursue revision of the Food Code to provide guidelines for preparing allergen-free foods in food establishments, including in restaurants, grocery store

delicatessens and bakeries, and elementary and secondary school cafeterias. The Secretary shall consider guidelines and recommendations developed by public and private entities for public and private food establishments for preparing allergen-free foods in pursuing this revision.

SEC. 210. RECOMMENDATIONS REGARDING RESPONDING TO FOOD-RELATED ALLERGIC RESPONSES.

The Secretary of Health and Human Services shall, in providing technical assistance relating to trauma care and emergency medical services to State and local agencies under section 1202(b)(3) of the Public Health Service Act (42 U.S.C. 300d–2(b)(3)), include technical assistance relating to the use of different modes of treatment for and prevention of allergic responses to foods.

Passed the Senate March 8, 2004.

Attest:

Secretary.

108TH CONGRESS
2D SESSION

S. 741

AN ACT

To amend the Federal Food, Drug, and Cosmetic Act with regard to new animal drugs, and for other purposes.