

MINOR USE AND MINOR SPECIES ANIMAL HEALTH ACT
 OF 2004; FOOD ALLERGEN LABELING AND CONSUMER
 PROTECTION ACT OF 2004

JULY 15, 2004.—Committed to the Committee of the Whole House on the State of
 the Union and ordered to be printed

Mr. BARTON of Texas, from the Committee on Energy and
 Commerce, submitted the following

R E P O R T

[To accompany S. 741]

[Including cost estimate of the Congressional Budget Office]

The Committee on Energy and Commerce, to whom was referred
 the bill (S. 741) to amend the Federal Food, Drug, and Cosmetic
 Act with regard to new animal drugs, and for other purposes, hav-
 ing considered the same, report favorably thereon without amend-
 ment and recommend that the bill do pass.

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PURPOSE AND SUMMARY

Title I of S. 741 addresses the critical shortage of animal drugs available for minor species, which are defined as animals other than humans that are not major species (cattle, horses, swine, chickens, turkeys, dogs, and cats), and for minor uses for major species, which are defined as the use of a drug in a major species for a disease that occurs infrequently in a small number of animals, or in limited geographic areas in a small number of animals annually. The bill does so by creating new ways for animal drugs to be legally marketed.

Title II of S. 741 is the Food Allergen Labeling and Consumer Protection Act. It lays out a number of new requirements for the labeling of food in order to protect consumers with food allergies. Specifically, food that contains one of the eight major food allergens (milk, eggs, fish, Crustacean shellfish, tree nuts, peanuts, wheat, and soybeans) must list the food source from which the major food allergen is derived either immediately after the list of ingredients or in parentheses following an ingredient that contains a food allergen.

BACKGROUND AND NEED FOR LEGISLATION

TITLE I

Congress has recognized for some time that there are not adequate market incentives for manufacturers to produce animal drugs for minor species and for minor uses in major species. Therefore veterinarians, animal owners, and livestock producers may have limited options for treating these animals if they become ill. Veterinarians are often forced to treat these animals with unapproved drugs, or to treat these animals with the off-label use of an approved animal drug.

Congress approved the Animal Medicinal Drug Use Clarification Act (AMDUCA) of 1994 (Public Law 103-396), which expanded the ability of veterinarians to use approved animal drugs for unapproved purposes. However, this legislation did not create new avenues for FDA approval of new animal drugs for minor uses and minor species.

Congress responded to this shortage by approving the Animal Drug Availability Act (ADAA) of 1996 (Public Law 104-250). Section 2(f) of ADAA directed the Secretary of Health and Human Services to “consider legislative and regulatory options for facilitating the approval under section 512 of the Federal Food, Drug, and Cosmetic Act of animal drugs intended for minor species and for minor uses and, within 18 months after the date of enactment of this Act, announce proposals for legislative or regulatory change to the approval process under such section for animal drugs intended for use in minor species or for minor uses.” The FDA responded to this directive by forming the ADAA Minor Use/Minor Species Working Group, which issued a report entitled “Proposals to Increase the Legal Availability of Animal Drugs for Minor Species and Minor Uses.” This report was made available through a Federal Register notice on October 29, 1998 (63 FR 58058). Included in the report’s recommendations were proposals to create a conditional approval process for new animal drugs and a mecha-

nism to index legally marketed, unapproved new animal drugs. Both of these proposals are contained in S. 741.

TITLE II

Currently, approximately 2 percent of adults and 5 percent of children are allergic to various types of foods. Eight major food allergens (fish, Crustacean shellfish, milk, eggs, peanuts, tree nuts, soybeans, and wheat) cause over percent of food allergies in the United States. Since there is currently no cure for food allergies, consumers need to be empowered to know whether or not food allergies are present in the food they consume. There are no labeling standards currently in place for food allergies. S. 741 fills this gap by ensuring that the food source from which a major food allergen is derived is clearly labeled in plain English.

The Committee expects, consistent with the November 30, 1987 Memorandum of Understanding, that the Alcohol and Tobacco Tax and Trade Bureau (TTB) of the Department of Treasury will pursuant to the Federal Alcohol Administration Act determine how, as appropriate, to apply allergen labeling of beverage alcohol products and the labeling requirements for those products. The Committee expects that the TTB and the FDA will work together in promulgation of allergen regulations, with respect to those products.

HEARINGS

The Committee on Energy and Commerce has not held hearings on the legislation.

COMMITTEE CONSIDERATION

On Tuesday, June 15, 2004, the Subcommittee on Health met in open markup session and approved S. 741 for Full Committee consideration by a voice vote, a quorum being present. On Thursday, June 24, 2004, the Full Committee met in open markup session and favorably ordered S. 741 reported by a voice vote, a quorum being present.

COMMITTEE VOTES

There were no record votes taken in connection with ordering S. 741 reported. A motion by Mr. Pickering to order S. 741 reported to the House, as amended, was agreed to by a voice vote.

COMMITTEE OVERSIGHT FINDINGS

Pursuant to clause 3(c)(1) of rule XIII of the Rules of the House of Representatives, the Committee has not held oversight or legislative hearings on this legislation.

STATEMENT OF GENERAL PERFORMANCE GOALS AND OBJECTIVES

The first goal of S. 741 is to address the critical shortage of animal drugs available for minor species, and drugs for minor uses for major species. The second goal is to protect consumers with food allergies by implementing new requirements for the labeling of food.

NEW BUDGET AUTHORITY, ENTITLEMENT AUTHORITY, AND TAX
EXPENDITURES

In compliance with clause 3(c)(2) of rule XIII of the Rules of the House of Representatives, the Committee finds that S. 741, Minor Use and Minor Species Animal Health Act, would result in no new or increased budget authority, entitlement authority, or tax expenditures or revenues.

COMMITTEE COST ESTIMATE

The Committee adopts as its own the cost estimate prepared by the Director of the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974.

CONGRESSIONAL BUDGET OFFICE ESTIMATE

Pursuant to clause 3(c)(3) of rule XIII of the Rules of the House of Representatives, the following is the cost estimate provided by the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974:

U.S. CONGRESS,
CONGRESSIONAL BUDGET OFFICE,
Washington, DC, July 2, 2004.

Hon. JOE BARTON,
*Chairman, Committee on Energy and Commerce,
House of Representatives, Washington, DC.*

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the enclosed cost estimate for S. 741, an act to amend the Federal Food, Drug, and Cosmetic Act with regard to new animal drugs, and for the other purposes.

If you wish further details on this estimate, we will be pleased to provide them. The CBO staff contacts are Julia Christensen (for animal drugs) and Niall Brennan (for food allergens).

Sincerely,

ELIZABETH M. ROBINSON
(For Douglas Holtz-Eakin).

Enclosure.

S. 741—An act to amend the Federal Food, Drug, and Cosmetic Act with regard to new animal drugs, and for other purposes

Summary: S. 741 aims to increase the market availability of new animal drugs for minor species and for minor uses in major species of animals. It would amend the Federal Food, Drug, and Cosmetic Act (FFDCA) to authorize the Food and Drug Administration (FDA) to establish a conditional approval process for such drugs and to create an index of legally marketed unapproved drugs to treat certain minor species. It also would authorize grants to help defray a portion of the cost associated with the development of designated drugs and would award seven years of marketing exclusivity to products meeting certain criteria.

S. 741 also would require that labels for food products indicate in plain English the presence of any of the eight major food allergens, and would direct the Secretary of Health and Human Serv-

ices to engage in a number of activities to increase scientific and public understanding of issues related to food allergies.

CBO estimates that implementing S. 741 would cost \$6 million in 2006 and \$60 million over the 2005–2009 period, assuming appropriation of the necessary funds.

The legislation would not affect direct spending. There would be potential for higher revenues through penalties imposed on sponsors of misbranded or illegally marketed drugs or of mislabeled food products. However, the FDA generally issues warning letters to violators and works with them to correct the violation. For chronic violators or for serious offenses, the FDA generally pursues injunctions or seizes products; prosecution, which can involve penalties, generally is a last resort. Therefore, CBO expects that revenues from such penalties would be negligible.

S. 741 contains no intergovernmental mandates as defined in the Unfunded Mandates Reform Act (UMRA). The act's provisions would increase the availability and broaden the potential uses of certain drugs used to treat minor species animals and also to treat minor conditions in major species. State and local conservation programs, zoos, and animal shelters could take advantage of those new drugs or uses, and the impact on their budgets would likely be positive.

S. 741 would impose a private-sector mandate on the manufacturers, packagers, and labelers of processed foods by requiring them to display on the label the names of the major food allergens from which the ingredients are derived. It also would impose mandates on some manufacturers of generic animal drugs for minor uses or use in minor species by potentially delaying the time at which their products could enter the market. CBO estimates that the direct cost of these mandates would not exceed the threshold established by UMRA (\$120 million in 2004, adjusted annually for inflation) in any of the first five years the mandates would be effective.

Estimated cost to the Federal Government: The estimated budgetary impact of S. 741 is shown in the following table. The costs of this legislation fall within budget function 550 (health).

	By fiscal year, in millions of dollars—				
	2005	2006	2007	2008	2009
CHANGES IN SPENDING SUBJECT TO APPROPRIATION					
Title I: Minor Use and Minor Species Animal Health Act of 2004:					
Estimated Authorization Level	1	1	2	3	4
Estimated Outlays	1	1	2	3	3
Title II: Food Allergen Labeling and Consumer Protection Act of 2004:					
Estimated Authorization Level	12	12	12	12	12
Estimated Outlays	5	10	11	12	12
Net Effect on Spending by the Food and Drug Administration ¹ :					
Estimated Authorization Level	13	13	14	15	16
Estimated Outlays	6	11	13	15	15

¹ CBO assumes that a portion of the costs associated with the conditional approval process proposed under S. 741 would be covered by user fees collected from sponsors seeking approval to market animal drugs. (User fees are collected and made available for obligation only to the extent, and in the amount, provided in advance in appropriation acts.) We estimate that additional collections associated with activities required by the act would total less than \$500,000 annually.

Basis of Estimate: For this estimate, CBO assumes that S. 741 will be enacted this fall and that the amounts necessary to implement the act will be appropriated for each year.

Spending subject to appropriation

S. 741 would increase the availability of approved or legally marketed animal drugs for minor species and for minor uses in major species and would modify food labeling requirements regarding food allergens. CBO estimates that implementing S. 741 would cost the FDA \$6 million in 2005 and \$60 million over the 2005–2009 period, subject to the availability of appropriated funds.

Title I: Minor Use and Minor Species Animal Health Act of 2004. S. 741 would create two procedures within the FDA to allow sponsors to lawfully market animal drugs without final approval for use in minor species and for minor uses in major species. (Minor species are species other than cattle, horses, swine, chickens, turkey, dogs, and cats. A minor use in a major species refers to the intended use of a drug in a major species for a disease that occurs in a small number of animals and occurs either infrequently or in limited geographic areas.) The act also would authorize grants and award market exclusivity to encourage the development of new drugs for animals, and it would establish a new office within the FDA to administer activities related to regulating animal drugs for minor uses and minor species.

New procedures for legal marketing of animal drugs. Under current law, the FDA will approve drugs for marketing only after the sponsor has demonstrated that the drug is both safe and effective. S. 741 would require the Secretary of the Health and Human Services to establish a process for granting conditional approval of new animal drugs intended for minor uses and for use in minor species. Conditional approval would be granted for one year at a time, and could be renewed for a total of five years.

S. 741 also would require the Secretary to establish a process for listing on an index unapproved drugs that may be marketed legally for use in certain minor species. Eligibility for listing on the index would apply to drugs for animals that are not consumed by humans or food-producing animals, or for use in a non-food life stage of a minor species (such as the larval form of shellfish) in a contained man-made structure (such as a hatchery pond or tank). The Secretary could place a drug on the index if the sponsor demonstrates that the drug meets certain safety criteria and if an expert panel concludes that the benefits of using the drug outweigh its risks to the target animal.

Based on information from the FDA, CBO anticipates that the cost to the FDA associated with implementing those procedures to allow sponsors to lawfully market animal drugs without final approval would total less than \$500,000 annually. CBO assumes a portion of the costs associated with the conditional approval process would be covered by higher user fees collected from sponsors seeking approval to market animal drugs, but we estimate that additional collections associated with activities required under S. 741 would be negligible.

Incentives to develop new drugs for animals. The act would provide two incentives to encourage development of new animal drugs for minor uses and for minor species through the awarding of grants and of market exclusivity to qualifying sponsors of designated drugs.

First, the act would direct the FDA to award market exclusivity for seven years on the approved indication of certain designated

drugs. As a result, a sponsor could sell its product without competition in the market and recover a portion of the research and development costs. CBO anticipates that the cost to the FDA associated with implementing this provision would be negligible.

Second, S. 741 would authorize the appropriation of specific amounts for making grants to sponsors of designated drugs in the two fiscal years following the issuance of final regulations for the new program and would authorize the appropriation of such sums as necessary in later years. Grants awarded under the program would defray some of the costs for qualified safety and effectiveness testing and for certain manufacturing expenses associated with developing the qualifying drug. Based on the time frame outlined in the act, CBO assumes that funding for grants would not be authorized until fiscal year 2007. We estimate that outlays for the new grant program would total \$4 million over the 2007–2009 period, assuming the availability of appropriated funds.

New Office. S. 741 would establish a new Office of Minor Use and Minor Species Animal Drug Development within the Center for Veterinary Medicine at the FDA. The office would designate minor use and minor species drugs, administer grants authorized under the act, and review requests for listing of drugs on the newly created index. S. 741 would authorize the appropriation of \$1.2 million in 2004 and such sums as necessary in later years. Assuming the appropriation of the necessary amounts, CBO estimates that creating and funding the new office would cost \$1 million in 2005 and \$6 million over the 2005–2009 period.

Title II: Food Allergen Labeling and Consumer Protection Act of 2004. Title II of the act would direct the Secretary to engage in a number of activities to increase scientific and public understanding of issues related to food allergies. CBO estimates that implementing title II would cost \$5 million in 2005 and \$50 million over the 2005–2009 period, assuming the appropriation of the necessary amounts.

S. 741 would amend the FFDCA to require that any food that contains a major food allergen be labeled in such a way that the presence of the food allergen is easily visible to consumers. Major food allergens are defined as “milk, egg, fish, crustacean shellfish, tree nuts, wheat, peanuts, and soybeans.” Section 203 also would provide for an appeal process whereby an individual or company could petition the Secretary to exempt a food ingredient from that labeling requirement. The Secretary would be required to approve or deny the petition within 180 days of receiving such an appeal. Based on information from the FDA, CBO estimates that spending by the FDA to carry out those responsibilities would amount to \$1 million in 2005 and \$5 million over the 2005–2009 period, assuming appropriation of the necessary funds.

The act also would direct the Secretary, through the Centers for Disease Control and Prevention (CDC), to engage in the collection of, and publication of data on the prevalence of food allergies, the incidence of serious adverse events related to food allergies, and the treatment and prevention of food allergies. Because true food allergy events are relatively rare (in contrast to food poisoning events), CBO expects that the CDC would engage in multiple strategies to identify and collect useful data, such as:

- Analyzing existing data, including questions recently added to the National Health Interview Survey (NHIS) to better assess the prevalence of known food allergies.
- Adding laboratory tests to the National Health and Nutrition Examination Survey (NHANES) to identify conditions that may be unknown to the survey participant.
- Testing stored blood specimens that were collected in a previous cycle of the NHANES, and stored for future analysis, to estimate the prevalence of food allergy reactivity in the U.S. population.
- Improving the ability of the nation's vital statistics system to monitor food allergy-related deaths by using intelligent automated systems to help physicians more accurately record cause of death, and by working with physicians' organizations to improve education on recording cause of death.
- Increasing the precision of surveys of health care providers, and improving the quality of information recorded by providers, so that comparatively small numbers of events could be better detected.

Based on information from the FDA and CDC, CBO estimates that federal spending to develop and operate the system for collecting data on food allergies would total \$3 million in 2005 and \$41 million over the 2005–2009 period, subject to appropriation of the necessary amounts.

S. 741 would require the Secretary to submit a report to the Congress within 18 months of enactment. That report should analyze the extent to which foods are unintentionally contaminated with major food allergens during the manufacturing process, recommend manufacturing practices that would reduce the incidence of such contamination, and describe the types of advisory labeling currently being used by food producers, the extent to which such labeling is being used, and the preferences of those likely to be affected by food allergies regarding labeling information. Assuming the availability of appropriated funds, CBO estimates that the FDA would spend less than \$500,000 in 2005 and a total of \$1 million over the 2005–2009 period to produce that report.

S. 741 would require the Secretary to conduct inspections of food and manufacturing, processing, and packing facilities to ensure that such entities are engaging in efforts to reduce the possibility of food allergen contamination and to ensure that food allergens are being appropriately labeled. Based on information provided by the FDA, CBO expects those tasks would be accomplished without increasing the number of inspections of food facilities and without having a significant effect on the cost of those inspections.

The act also would require the Secretary to develop guidelines for preparing allergen-free foods in food establishments (such as restaurants, bakeries, delicatessens, and cafeterias), and to issue regulations to define and permit the use of the term “gluten-free” on the labeling of foods. Based on information from the FDA about the cost of similar activities, CBO estimates that spending by the FDA to carry out those responsibilities would total \$1 million in 2005 and \$3 million over the 2005–2009 period.

Estimated impact on state, local, and tribal governments: S. 741 contains no intergovernmental mandates as defined in UMRA. The act's provisions would increase the availability and broaden the po-

tential uses of certain drugs used to treat minor species animals and also to treat minor conditions in major species. State and local conservation programs, zoos, and animal shelters could take advantage of those new drugs or uses, and the impact on their budgets would likely be positive.

Estimated impact on the private sector: S. 741 would impose private-sector mandates, as defined in UMRA, on the manufacturers, packagers and labelers of processed foods regulated by the Food and Drug Administration and on the manufacturers of certain animal drugs. CBO estimates that the direct cost of these mandates would not exceed the threshold established by UMRA (\$120 million in 2004, adjusted annually for inflation) in any of the first five years the mandates would be effective.

Section 203 would require the labels of processed foods containing major food allergens to display the names of those allergens from which ingredients are derived. According to industry sources, the majority of the approximately 300,000 food labels regulated by the FDA are currently in compliance with the requirement of S. 741. Moreover, the requirement would not become effective until January 1, 2006, allowing many food processors to incorporate the required changes during planned label revisions, further decreasing the cost of the mandate. This compliance period also would provide food processors with sufficient time to exhaust most label inventories, resulting in small costs due to lost inventories. Based on information provided by the FDA and industry sources, CBO estimates that the administrative, printing, analytical, and label inventory costs associated with this mandate would total less than \$75 million through fiscal year 2006, and would be negligible in later years.

Section 102 also would impose private-sector mandates, as defined in UMRA, on some manufacturers of generic animal drugs for minor uses or use in minor species by providing additional market exclusivity to innovators. This additional exclusivity would potentially delay the time at which the generic products of some animal drug manufacturers could enter the market. Based on information provided by the FDA and the Department of Agriculture, CBO estimates the cost of these mandates to be small.

Previous CBO estimate: On July 1, 2004, CBO transmitted a cost estimate for S. 741 as passed by the Senate on March 8, 2004. The two versions of the legislation are identical, as are CBO's two estimates.

Estimate prepared by: Federal Costs: Niall Brennan and Julia Christensen; Impact on State, Local, and Tribal Governments: Leo Lex; and Impact on the Private Sector: Daniel Wilmoth.

Estimate approved by: Peter H. Fontaine, Deputy Assistant Director for Budget Analysis.

FEDERAL MANDATES STATEMENT

The Committee adopts as its own the estimate of Federal mandates prepared by the Director of the Congressional Budget Office pursuant to section 423 of the Unfunded Mandates Reform Act.

ADVISORY COMMITTEE STATEMENT

No advisory committees within the meaning of section 5(b) of the Federal Advisory Committee Act were created by this legislation.

CONSTITUTIONAL AUTHORITY STATEMENT

Pursuant to clause 3(d)(1) of rule XIII of the Rules of the House of Representatives, the Committee finds that the Constitutional authority for this legislation is provided in Article I, section 8, clause 3, which grants Congress the power to regulate commerce with foreign nations, among the several States, and with the Indian tribes.

APPLICABILITY TO LEGISLATIVE BRANCH

The Committee finds that the legislation does not relate to the terms and conditions of employment or access to public services or accommodations within the meaning of section 102(b)(3) of the Congressional Accountability Act.

SECTION-BY-SECTION ANALYSIS OF THE LEGISLATION

TITLE I

Section 101. Short title

Section 101 designates the short title of Title I of this bill as the “Minor Use and Minor Species Animal Health Act of 2004.”

Section 102(a). Findings

Section 102(a) includes a number of Congressional findings regarding the need for new procedures to increase the number of new animal drugs available for minor species and for minor uses for major species.

Section 102(b). Amendments to the Federal Food, Drug, and Cosmetic Act

Section (b)(1) amends section 201 of the Federal Food, Drug, and Cosmetic Act (FFDCA) to include definitions for major species, minor species, and minor use. Section (b)(2) amends sections 512(c)(2)(F)(ii), (iii), and (v) to create a new exclusivity provision. Residue depletion studies will be considered “significant new data” for granting three years of market exclusivity for minor species or minor use approvals. Currently, only effectiveness and target animal safety studies qualify to get this marketing exclusivity. Subsection (b)(3) creates a new subsection (d)(5) to clarify that in reviewing an application to add an intended use for a minor use or a minor species, the Secretary of Health and Human Services shall reevaluate only the information needed to determine whether the application can be approved. This review of only the information relevant to whether the application can be approved should not be construed to constitute reaffirmation of the original new drug application.

Subsection (b)(4) adds new sections 571, 572, and 573 to FFDCA.

New Section 571. Conditional approval of new animal drugs for minor use and minor species

Subsection (a)(1) permits any person to file an application for conditional approval of a new animal drug intended for a minor use or a minor species.

Subsection (a)(2) describes the information an applicant is required to submit to the Secretary as part of an application for conditional approval of a new animal drug. Included as part of an application is a commitment that an applicant will perform the research necessary to secure approval as a new animal drug under section 512(d) within five years of the Secretary's original conditional approval.

Subsection (a)(3) lists a number of reasons that would prevent a person from submitting an application for conditional approval of a new animal drug under section 571. Conditional approval of a new animal drug that is contained in, or is a product of, a transgenic animal is prohibited under this subsection.

Subsection (b) directs the Secretary to either approve an application for conditional approval of a new animal drug within 180 days of the filing of an application (or after a period of time agreed to by both the Secretary and the applicant) or notify the applicant of the opportunity for an informal hearing on the question of whether or not the conditional approval should be granted.

Subsection (c) lists circumstances under which the Secretary should refuse to conditionally approve an application submitted under subsection (a). If the application fails to meet the criteria established under sections 512(d)(1)(A) through (D) or (F) through (I), then the Secretary is directed to refuse to conditionally approve the application. Additionally, the Secretary may not conditionally approve an application if the applicant presents insufficient evidence to show that there is a reasonable expectation that the drug will be effective. Finally, an application may not be conditionally approved if another application has been approved under section 512 for the same drug, for the same dosage, for the same intended use, and there are sufficient quantities of the drug available. If none of these categories apply, then the Secretary is directed to conditionally approve the new animal drug and publish a notice in the Federal Register indicating as much.

Subsection (d) states that a conditional approval is effective for one year, renewable for up to four additional years. The Secretary may grant a 90-day extension to review the renewal request. The request shall be deemed to be approved unless the applicant failed to submit a timely application; the application fails to demonstrate that the applicant is making sufficient progress towards gaining full approval under section 512(d), that there is a large enough quantity of the drug available, or that the same drug in the same dosage form for the same intended use has not received approval under section 512; and the applicant is not able to prove that the drug does not violate sections 512(e)(1)(A) through (B) or (D) through (F). If the Secretary declines to renew the conditional approval, then the Secretary shall provide an opportunity for the applicant to engage in an informal hearing to discuss whether the conditional approval should be reinstated.

Subsection (e)(1) directs the Secretary to withdraw any conditional approval if the Secretary finds that another applicant has re-

ceived approval for the same drug in the same dosage form for the same intended use and there is sufficient quantity of the drug to meet the needs for which the drug is intended. Under subsection (e)(2), the Secretary is required to withdraw the conditional approval of an application if the Secretary finds that any of the provisions of section 512(e)(1)(A) through (B) or (D) through (F) or if the Secretary believes that there is not a reasonable expectation that the drug will have the effect for which it was originally approved.

Subsection (f) describes labeling requirements for conditionally approved new animal drugs. A label on a conditionally approved new animal drug must read “conditionally approved by FDA pending a full demonstration of effectiveness under application _____” and must include other information specified by the Secretary. Additionally, an intended use that is the subject of a conditional approval is not to be included as part of a product label under section 512.

Subsection (g) states that a new animal drug that has been conditionally approved may not be amended or supplemented to add a new indication for use.

Subsection (h) states that 180 days prior to the termination date established for a conditionally approved animal drug the applicant should have all materials submitted to the Secretary to make a decision whether or not to fully approve the drug under section 512(d).

Subsection (i) establishes that the decision of the Secretary to refuse or withdraw conditional approval of an application constitutes final agency action subject to judicial review.

Subsection (j) defines the term “transgenic animal.”

New Section 572. Index of legally marketed unapproved new animal drugs for minor species

New subsection (a) directs the Secretary to establish an index of legally marketed, unapproved new animal drugs for 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 (new subsection (a)(1)(A)), and for 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 (new subsection (a)(1)(B)). In the latter case, the law requires that safety for humans is demonstrated in accordance with section 512(d) of the FFDCA. New animal drugs that are contained in, or are a product of, a transgenic animal are not eligible for inclusion in the index.

New subsection (b) states that any entity intending to file a request under this new section 572 shall be entitled to one or more conferences to discuss the requirements for indexing a new animal drug.

New subsection (c) provides for a mechanism whereby an entity can request that the Secretary make a decision regarding the eligibility of a particular new animal drug for inclusion in the index. After submitting a request to the Secretary, the Secretary will make a determination of eligibility within 90 days for new animal drugs requesting inclusion in the index under new subsection (a)(1)(A) and 180 days for new animal drugs requesting inclusion

in the index under new subsection (a)(1)(B). The Secretary may approve the eligibility request if: the same drug in the same dosage form for the same intended use is not approved under section 512 or conditionally approved under section 571; the proposed use of the drug meets the conditions of subsections (a)(1)(A) or (a)(1)(B), as appropriate; 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; the new animal drug will not significantly affect the human environment; and 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.

New subsection (d) provides for a mechanism whereby an entity may request that the Secretary add a new animal drug to the index of legally marketed unapproved new animal drugs for minor species. The entity requesting inclusion in the index must provide the Secretary with a number of items that are described in subsection (d)(1). Among those items is a report described in subsection (d)(2), which must be authored by a qualified expert panel as defined in subsection (d)(3). Included in the report is an evaluation of all available target animal safety and effectiveness information, including anecdotal information. The report must 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 caused by the absence of an approved or conditionally approved new animal drug for the minor species in question. The Committee notes that while the focus of the expert panel is on the benefits and risks to the target animal, the Secretary will have already determined that the new animal drug in question is either not going to be used on animals that humans or food-producing animals will consume, or is in full compliance with the human safety standards described in section 512(d) of the FDCA. The report must also include information from which labeling can be written and a recommendation regarding whether the new animal drug should be limited to use under the professional supervision of a licensed veterinarian. Subsection (d)(3) describes the requirements for a "qualified expert panel." The panel must operate external to the FDA and be composed of experts qualified by scientific training and experience to evaluate the target animal safety and effectiveness of the new animal drug under consideration. Qualified expert panels are not subject to the Federal Advisory Committee Act, 5 U.S.C. App. 2. The Secretary by regulation shall define the criteria for selection of a qualified expert panel and the procedures for the operation of the panel.

Subsection (d)(4) requires the Secretary to grant or deny a request for inclusion in the index of legally marketed unapproved new animal drugs for minor species within 180 days of receipt of the information required in subsection (d)(2). 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 provide the entity with the opportunity for an informal conference. The decision of the Secretary following an informal conference shall constitute final agency action subject to judicial review.

New subsection (e) describes the information that must be included for each new animal drug listed under the index. This includes the name and address of the person who holds the index listing; the name of the drug and the intended use and conditions of use for which it is being indexed; product labeling; and conditions and any limitations that the Secretary deems necessary regarding use of the drug. The Secretary is directed to publish the index, and revise it periodically; additionally, the Secretary may establish a process for reporting changes in the conditions of manufacturing or labeling of indexed products.

New subsection (f) lists a number of circumstances whereby the Secretary may remove a new animal drug from the index. New subsection (f)(1) provides the Secretary with a number of justifications for removing a new animal drug from the index. New subsection (f)(2) provides the Secretary with additional authority to remove a new animal drug from the index. Under new subsection (f)(2), the Secretary must only find 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 must give the entity listed in the index the opportunity for an informal conference if he or she uses the authority available under new subsections (f)(1) and (f)(2) to remove a new animal drug from the index. The decision of the Secretary following an informal conference shall constitute final agency action subject to judicial review.

New subsection (g) directs the Secretary to promulgate regulations (to the extent consistent with the public health) to exempt 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 from the safety and effectiveness standards described in section 512 of the FFDCA.

New subsection (h) describes labeling requirements for new animal drugs included in the index of legally marketed unapproved new animal drugs for minor species. Specifically, the labeling of such a drug shall read "NOT APPROVED BY FDA.—Legally marketed as an FDA indexed product. Extra-label use is prohibited." Additionally, the labeling shall include the following statement 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." The Secretary may require other information in the index listing.

New subsection (i) requires that the entity who has a new animal drug included in the index shall establish and maintain such

records, and make such reports to the Secretary that he or she determines, either through regulation or by order with respect to a particular listing, is needed to determine whether there is or may be ground for using new subsection (f) to remove a new animal drug from the index.

Finally, new subsection (j) requires that 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 be made available to the public under certain circumstances.

New Section 573. Designated new animal drugs for minor use or minor species

New section 573(a) provides the Secretary with the authority to declare a new animal drug to be a “designated new animal drug.” A designated new animal drug is eligible for two different kinds of incentives to encourage the development of new animal drugs for minor use or minor species. Under new section 573(b), the Secretary may award grants and enter into contracts with public and private entities to subsidize the costs incurred by qualified safety and effectiveness testing and manufacturing expenses. Qualified safety and effectiveness testing is defined as testing that occurs after a new animal drug is declared to be a designated new animal drug and is carried out under an investigational exemption under section 512(j) of the FDCA. Manufacturing expenses are defined as expenses incurred in developing processes and procedures associated with manufacture of the designated new animal drug which occur after the new animal drug is declared to be a designated new animal drug and before the sponsor files an application for approval under section 512 or conditional approval under new section 571. Under new section 573(c), if the Secretary approves an application for approval under section 512 or for conditional approval under new section 571, the sponsor of the new animal drug will receive seven years of marketing exclusivity. During this time, the Secretary may not approve or conditionally approve another application for a new animal drug with the same intended use as the designated new animal drug unless the Secretary finds that the holder of the approved application cannot assure the availability of sufficient quantities of the drug or the holder provides written consent to the Secretary for the approval or conditional approval of a new animal drug. The Secretary may terminate the designation of a new animal drug if the sponsor of the drug in question discontinues active pursuit of a full approval under section 512 or conditional approval under section 571. In addition, 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. 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.

Subsection (b)(5) makes a number of technical and conforming changes to the FDCA.

Subsection (b)(6) lists the timelines for implementing regulations for new sections 571, 572, and 573.

Subsection (b)(7) creates an Office of Minor Use and Minor Species Animal Drug Development at the Center for Veterinary Medi-

cine at the Food and Drug Administration. \$1.2 million is authorized to be appropriated for the office in fiscal year 2004, and such sums as may be necessary for each fiscal year thereafter.

Subsection (b)(8) authorizes \$1 million for the grants for designated new animal drugs for the fiscal year following publication of the final regulations implementing section 573(b), \$2 million for the subsequent fiscal year, and such sums as may be necessary for each fiscal year thereafter.

TITLE II

Section 201. Short title

Section 201 designates the short title of Title II of this bill as the “Food Allergen Labeling and Consumer Protection Act of 2004.”

Section 202. Findings

Section 202 makes a number of findings regarding the prevalence of food allergies. Specifically, approximately 2 percent of adults and 5 percent of children suffer from food allergies—further, eight major foods or food groups account for 90 percent of food allergies. These eight are milk, eggs, fish, Crustacean shellfish, tree nuts, peanuts, wheat, and soybeans.

Section 203. Food labeling; requirement of information regarding allergenic substances

Section 203(a) creates a new section 403(w) in the FFDC. New section 403(w)(1) states that a food shall be deemed to be misbranded if it, or one of its ingredients, is a major food allergen, unless the food allergen is properly labeled. First, under new section 403(w)(1)(A), the manufacturer may include a list, either immediately after or adjacent to the list of ingredients, which identifies the food source from which the major food allergen is derived. Second, under new section 403(w)(1)(B), the manufacturer may include the common or usual name of the major food allergen in the list of ingredients followed in parentheses by the name of the food source from which the major food allergen is derived. There are two exceptions to this provision. The manufacturer is not required to include the food source from which the major food allergen is derived if the common or usual name of the ingredient uses the name of the food source from which the major food allergen is derived. For example, if “milk casing” is included in the list of ingredients, it is not necessary for the manufacturer to include the word “milk” in parentheses following this ingredient. Additionally, the manufacturer is not required to include the name of the food source from which the major food allergen is derived if the name of the food source appears elsewhere in the list of ingredients. For example, if the list of ingredients includes “milk casing,” then it is not necessary to include the word “milk” in parentheses after “whey.” However, this exception does not hold when the name of the food source that appears elsewhere in the list of ingredients is not a major food allergen. For example, peanut oil is a highly refined oil and does not cause food allergies. In this case, the list of ingredients would have to include “peanuts” in parentheses after an ingredient that includes peanuts.

Under new section 403(w)(2), the definition of “major food allergen,” which is defined under new section 201(q)(q) of the FFDCFA, means that in the case of a tree nut, fish, or Crustacean shellfish, the specific tree nut (pecans), fish (salmon), or Crustacean shellfish (lobster) must be listed.

New section 403(w)(3) holds that this labeling information required under new section 403(w) 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. The Secretary must publish any such finding in the Federal Register as a notice. The finding will be effective as of the date the notice is published.

New section 403(w)(4) states that notwithstanding the provision in current law for flavorings, coloring, or incidental additives that exempts them from other food labeling requirements, a flavoring, coloring, or incidental additive that is or contains a major food allergen shall be subject to the labeling requirements 403(w)(1).

New section 403(w)(5) gives the Secretary the authority to modify the food labeling requirements of subparagraph (A) or (B) of new section 403(w)(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 one of the new food labeling requirements is necessary to protect the public health.

New section 403(w)(6) creates a procedure by which any entity may petition the Secretary to exempt a food ingredient from the new food allergen labeling requirements created under section 403(w)(1). Within 180 days, the Secretary will be required to approve or deny such petition or the petition shall be deemed denied, unless the Secretary and the petitioner mutually agree upon an extension of time. The burden is on the entity filing the petition to provide scientific evidence that the food ingredient does not cause an allergic response that poses a risk to human health.

New section 403(w)(7) provides industry with a different process for securing an exemption from the food allergen labeling requirements. An entity may file a notification with the Secretary stating that scientific evidence demonstrates that the food ingredient does not contain allergenic protein or that the ingredient does not cause an allergic response that poses a risk to human health. An entity filing a notification may use the food ingredient in question 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 decides to not approve the notification. Note that in the case of a petition, the petition is deemed denied unless the Secretary affirmatively approves the petition; in the case of a notification, the burden is on the Secretary to explicitly deny the notification request. While the Committee recognizes that thresholds for the eight major allergens have not yet been established by the scientific community, if they are established, ingredients containing allergenic proteins below the established threshold would be eligible for the notification procedure.

New section 403(x) states that the exemption from current law food labeling requirements for spices, flavorings, colorings, or incidental additives does not apply in cases where these ingredients contain a food allergen that is not a major food allergen. In such

a case, the food allergen shall be disclosed in a manner specified by the Secretary by regulation.

Section 203(b) states that the labeling requirements established under new section 403(w) do not prevent the Secretary from requiring labels or labeling changes for other food allergens that are not major food allergens.

Section 203(c) adds a new section 201qq to the FFDCA. New section 201qq defines a “major food allergen” to be milk, egg, fish, Crustacean shellfish, tree nuts, wheat, peanuts, and soybeans. Included in the definition are food ingredients that contain proteins derived from one of the eight major food allergens, with two exceptions. First, any highly refined oil or ingredient derived from a highly refined oil is exempted from the food allergy labeling requirements. Second, any food ingredient that is exempted through either the petition or notification procedures is not included in the definition of major food allergens.

The requirements of section 203 will take effect on January 1, 2006.

Section 204. Report on food allergies

Section 204 directs the Secretary to produce a report on a number of issues related to food allergies within 18 months of enactment of S. 741. In reference to paragraph 4, it is the Committee’s intention that the Secretary focus on which types of advisory labeling are effective in alerting consumers with food allergies or their caregivers about the risk of cross-contact. Appropriate survey mechanisms would be a particularly useful way to gather this information.

Section 205. Inspections relating to food allergens

Section 205 directs the Secretary to continue conducting inspections under section 704 of the FFDCA to ensure that manufacturers, processors, and packagers are taking appropriate steps to reduce or eliminate cross-contact between food ingredients that are major food allergens and food ingredients that are not major food allergens. In addition, the Secretary is to use these inspections to ensure that major food allergens are properly labeled.

Section 206. Gluten labeling

Section 206 directs the Secretary to issue a proposed rule to define, and permit use of the term “gluten-free” on the labeling of foods within two years of enactment of S. 741. The Secretary is required to consult with appropriate experts and stakeholders before promulgating this proposed rule. The Secretary shall issue a final rule to define, and permit the use of, the term “gluten-free” on the labeling of foods within four years of the enactment of S. 741. Given the devastating nature of celiac disease, the Committee urges the Secretary to move expeditiously in implementing the requirements of this section.

Section 207. Improvement and publication of data on food-related allergic responses

Section 207 directs the Secretary, acting through the Centers for Disease Control and Prevention and in consultation with the Food and Drug Administration, to improve the national data on the

prevalence of food allergies; the incidence of clinically significant or serious adverse events related to food allergies; and the use of different modes of treatment for and prevention of allergic responses to foods. There are authorized such sums as may be necessary to carry out this section.

Section 208. Food allergies research

Section 208 directs the Secretary, acting through the Director of the National Institutes of Health, to 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. The Committee encourages the panel to review existing scientific data on food allergy reaction thresholds for each of the major food allergens. It is the Committee's hope that this information will be helpful to the FDA as it continues to review scientific data on food allergy reaction thresholds. The panel shall make recommendations to the Secretary for enhancing and coordinating research activities concerning food allergies not later than one year after the enactment of S. 741. The Secretary shall make these recommendations public.

Section 209. Food allergies in the food code

Section 209 directs the Secretary, in the Conference for Food Protection, to 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 is directed to 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, including guidelines and recommendations preventing unintentional cross-contact with major food allergens.

Section 210. Recommendation regarding responding to food-related allergic responses

Section 210 directs the Secretary to include technical assistance relating to the use of different modes of treatment for and prevention of allergic responses to foods when providing technical assistance relating to trauma care and emergency medical services to State and local agencies.

CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

In compliance with clause 3(e) of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italics, existing law in which no change is proposed is shown in roman):

FEDERAL FOOD, DRUG, AND COSMETIC ACT

* * * * *

CHAPTER II—DEFINITIONS

SEC. 201. For the purposes of this Act—

(a) * * *

* * * * *

(u) The term “safe,” as used in paragraph (s) of this section and in sections 409, 512, 571, and 721, has reference to the health of man or animal.

(v) The term “new animal drug” means any drug intended for use for animals other than man, including any drug intended for use in animal feed but not including such animal feed—

(1) * * *

* * * * *

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.

* * * * *

(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.

(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).

CHAPTER III—PROHIBITED ACTS AND PENALTIES

PROHIBITED ACTS

SEC. 301. The following acts and the causing thereof are hereby prohibited:

(a) * * *

* * * * *

(e) The refusal to permit access to or copying of any record as required by section 412, 414, 504, 564, 703, or 704(a); or the failure to establish or maintain any record, or make any report, required under section 412, 414(b), 504, 505 (i) or (k), [512(a)(4)(C), 512 (j), (l) or (m)] 512(a)(4)(C), 512 (j), (l) or (m), 572(i), 515(f), 519, or 564

or the refusal to permit access to or verification or copying of any such required record.

* * * * *

(j) The using by any person to his own advantage, or revealing, other than to the Secretary or officers or employees of the Department, or to the courts when relevant in any judicial proceeding under this Act, any information acquired under authority of section 404, 409, 412, 414, 505, 510, 512, 513, 514, 515, 516, 518, 519, 520, 571, 572, 573., 704, 708, or 721 concerning any method or process which as a trade secret is entitled to protection; or the violating of section 408(i)(2) or any regulation issued under that section. This paragraph does not authorize the withholding of information from either House of Congress or from, to the extent of matter within its jurisdiction, any committee or subcommittee of such committee or any joint committee of Congress or any subcommittee of such joint committee.

* * * * *

CHAPTER IV—FOOD

* * * * *

MISBRANDED FOOD

SEC. 403. A food shall be deemed to be misbranded—

(a) * * *

* * * * *

(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.*

SEC. 403A. (a) Except as provided in subsection (b), no State or political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food in interstate commerce—

(1) * * *

(2) any requirement for the labeling of food of the type required by section 403(c), 403(e), [or 403(i)(2)] 403(i)(2), 403(w), or 403(x) that is not identical to the requirement of such section, except that this paragraph does not apply to a requirement of a State or political subdivision of a State that is of the type required by section 403(c) and that is applicable to maple syrup,

* * * * *

CHAPTER V—DRUGS AND DEVICES

SUBCHAPTER A—DRUGS AND DEVICES

* * * * *

MISBRANDED DRUGS AND DEVICES

SEC. 502. A drug or device shall be deemed to be misbranded—
(a) * * *

* * * * *

(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).*

EXEMPTIONS AND CONSIDERATION FOR CERTAIN DRUGS, DEVICES, AND BIOLOGICAL PRODUCTS

SEC. 503. (a) * * *

* * * * *

(f)(1)(A) A drug intended for use by animals other than man, 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, which—

(i) * * *

(ii) is limited by an approved application under subsection (b) of section 512, *a conditionally-approved application under section 571, or an index listing under section 572* to use under the professional supervision of a licensed veterinarian,

* * * * *

(3) The Secretary may by regulation exempt drugs for animals other than man subject to section 512, *571, or 572* from the requirements of paragraph (1) when such requirements are not necessary for the protection of the public health.

* * * * *

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), *a conditionally-approved application filed pursuant to section 571, or an index listing pursuant to section 572* 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 a 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) * * *

(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), *or the index listing pursuant to section 572(e)*.

* * * * *

(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 the index listing pursuant to section 572(e)* or fails to contain the general cautionary statement prescribed by the Secretary.

* * * * *

NEW ANIMAL DRUGS

SEC. 512. (a)【(1) A new animal drug shall, with respect to any particular use or intended use of such drug, be deemed unsafe for the purposes of section 501(a)(5) and section 402(a)(2)(D) 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

【(B) such drug, its labeling, and such use conform to such approved application.

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 the purposes of section 501(a)(6) unless—

[(A) there is in effect an approval of an application filed pursuant to subsection (b) with respect to such drug, as used in such animal feed,

[(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, and

[(C) such animal feed and its labeling, distribution, holding, and use conform to the conditions and indications of use published pursuant to subsection (i).] *(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.

* * * * *
 (b)(1) * * * * *
 * * * * *

(3) Any person intending to file an application [under paragraph (1) or a request for an investigational exemption under subsection (j)] under paragraph (1), section 571, or a request for an investigational exemption under subsection (j) shall be entitled to one or more conferences prior to such submission to reach an agreement acceptable to the Secretary establishing a submission or an investigational requirement, which may include a requirement for a field investigation. A decision establishing a submission or an investigational requirement shall bind the Secretary and the applicant or requestor unless (A) the Secretary and the applicant or requestor mutually agree to modify the requirement, or (B) the Secretary by written order determines that a substantiated scientific requirement essential to the determination of safety or effectiveness of the animal drug involved has appeared after the conference. No later than 25 calendar days after each such conference, the Secretary shall provide a written order setting forth a scientific justification specific to the animal drug and intended uses under consideration if the agreement referred to in the first sentence requires more than one field investigation as being essential to provide substantial evidence of effectiveness for the intended uses of the drug. Nothing in this paragraph shall be construed as compelling the Secretary to require a field investigation.

(c)(1) * * * * *
 (2)(A) * * * * *
 * * * * *
 (F)(i) * * * * *

(ii) If an application submitted under subsection (b)(1) for a drug, which includes an active ingredient (including any ester or salt of the active ingredient) that has been approved in another application approved under such subsection, is approved after the date of enactment of this paragraph and if such application contains substantial evidence of the effectiveness of the drug involved, any studies of animal safety, or, in the case of food producing animals,

human food safety studies [(other than bioequivalence or residue studies)] (*other than bioequivalence studies or residue depletion studies, except residue depletion studies for minor uses or minor species*) required for the approval of the application and conducted or sponsored by the applicant, the Secretary may not make the approval of an application submitted under subsection (b)(2) for the conditions of approval of such drug in the subsection (b)(1) application effective before the expiration of 3 years from the date of the approval of the application under subsection (b)(1) for such drug.

(iii) If a supplement to an application approved under subsection (b)(1) is approved after the date of enactment of this paragraph and the supplement contains substantial evidence of the effectiveness of the drug involved, any studies of animal safety, or, in the case of food producing animals, human food safety studies [(other than bioequivalence or residue studies)] (*other than bioequivalence studies or residue depletion studies, except residue depletion studies for minor uses or minor species*) required for the approval of the supplement and conducted or sponsored by the person submitting the supplement, the Secretary may not make the approval of an application submitted under subsection (b)(2) for a change approved in the supplement effective before the expiration of 3 years from the date of the approval of the supplement.

* * * * *

(v) If an application (including any supplement to a new animal drug application) submitted under subsection (b)(1) for a new animal drug for a food-producing animal use, which includes an active ingredient (including any ester or salt of the active ingredient) which has been the subject of a waiver under clause (iv) is approved after the date of enactment of this paragraph, and if the application contains substantial evidence of the effectiveness of the drug involved, any studies of animal safety, or human food safety studies [(other than bioequivalence or residue studies)] (*other than bioequivalence studies or residue depletion studies, except residue depletion studies for minor uses or minor species*) required for the new approval of the application and conducted or sponsored by the applicant, the Secretary may not make the approval of an application (including any supplement to such application) submitted under subsection (b)(2) for the new conditions of approval of such drug in the subsection (b)(1) application effective before the expiration of five years from the date of approval of the application under subsection (b)(1) for such drug. The provisions of this paragraph shall apply only to the first approval for a food-producing animal use for the same applicant after the waiver under clause (iv).

* * * * *

(d)(1) * * *

* * * * *

(4) In a case in which an animal drug contains more than one active ingredient, or the labeling of the drug prescribes, recommends, or suggests use of the drug in combination with one or more other animal drugs, and the active ingredients or drugs intended for use in the combination [(have previously been separately approved)] *have previously been separately approved pursuant to an application submitted under section 512(b)(1) for particular uses*

and conditions of use for which they are intended for use in the combination—

(A) * * *

* * * * *

(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 re-evaluate 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.*

* * * * *

(f) Whenever the Secretary finds that the facts so require, he shall revoke any previous order under **subsection (d), (e), or (m)** subsection (d), (e), or (m), or section 571 (c), (d), or (e) refusing, withdrawing, or suspending approval of an application and shall approve such application or reinstate such approval, as may be appropriate.

(g) Orders of the Secretary issued under this section, or section 571 (other than orders issuing, amending, or repealing regulations) shall be served (1) in person by any officer or employee of the department designated by the Secretary or (2) by mailing the order by registered mail or by certified mail addressed to the applicant or respondent at his last known address in the records of the Secretary.

* * * * *

(i) When a new animal drug application filed pursuant to subsection (b) or section 571 is approved, the Secretary shall by notice, which upon publication shall be effective as a regulation, publish in the Federal Register the name and address of the applicant and the conditions and indications of use of the new animal drug covered by such application, including any tolerance and withdrawal period or other use restrictions and, if such new animal drug is intended for use in animal feed, appropriate purposes and conditions of use (including special labeling requirements 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) applicable to any animal feed for use in which such drug is approved, and such other information, upon the basis of which such application was approved, as the Secretary deems necessary to assure the safe and effective use of such drug. Upon withdrawal of approval of such new animal drug application or upon its suspension or upon failure to renew a conditional approval under section 571, the Secretary shall forthwith revoke or suspend, as the case may be, the regulation published pursuant to this subsection (i) insofar as it is based on the approval of such application.

* * * * *

(l)(1) In the case of any new animal drug for which an approval of an application filed pursuant to subsection (b) or section 571 is in effect, the applicant shall establish and maintain such records, and make such reports to the Secretary, of data relating to experi-

ence, including experience with uses authorized under subsection (a)(4)(A), and other data or information, received or otherwise obtained by such applicant 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 application, 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 (e) or subsection (m)(4) of this section. 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.

* * * * *

(m)(1) Any person may file with the Secretary an application for a license to manufacture animal feeds bearing or containing new animal drugs. Such person shall submit to the Secretary as part of the application (A) a full statement of the business name and address of the specific facility at which the manufacturing is to take place and the facility's registration number, (B) the name and signature of the responsible individual or individuals for that facility, (C) a certification that the animal feeds bearing or containing new animal drugs are manufactured and labeled in accordance with the **[applicable regulations published pursuant to subsection (i)]** *applicable regulations published pursuant to subsection (i) or for indexed new animal drugs in accordance with the index listing published pursuant to section 572(e)(2) and the labeling requirements set forth in section 572(h)*, and (D) a certification that the methods used in, and the facilities and controls used for, manufacturing, processing, packaging, and holding such animal feeds are in conformity with current good manufacturing practice as described in section 501(a)(2)(B).

* * * * *

(3) If the Secretary, after due notice to the applicant in accordance with paragraph (2) and giving the applicant an opportunity for a hearing in accordance with such paragraph, finds, on the basis of information submitted to the Secretary as part of the application, on the basis of a preapproval inspection, or on the basis of any other information before the Secretary—

(A) * * *

* * * * *

(C) that the facility manufactures animal feeds bearing or containing new animal drugs in a manner that does not accord with the specifications for manufacture or labels animal feeds bearing or containing new animal drugs in a manner that does not accord with the conditions or indications of use that are published pursuant to subsection (i) *or an index listing pursuant to section 572(e)*,

the Secretary shall issue an order refusing to approve the application. If, after such notice and opportunity for hearing, the Secretary finds that subparagraphs (A) through (C) do not apply, the Secretary shall issue an order approving the application. An order under this subsection approving an application for a license to

manufacture animal feeds bearing or containing new animal drugs shall permit a facility to manufacture only those animal feeds bearing or containing new animal drugs for which there are in effect regulations pursuant to subsection (i) *or an index listing pursuant to section 572(e)* relating to the use of such drugs in or on such animal feed.

* * * * *

(p)(1) Safety and effectiveness data and information which has been submitted in an application filed under subsection (b)(1) *or section 571(a)* for a drug and which has not previously been disclosed to the public shall be made available to the public, upon request, unless extraordinary circumstances are shown—

(A) * * *

* * * * *

(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, outside the United States, the drug identified in the application filed under subsection (b)(1) *or section 571(a)*, and

* * * * *

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 sub-

section 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 containing 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 ap-

proved 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, outside 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 section 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.

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SECTION 108 OF THE ANIMAL DRUG AMENDMENTS OF 1968

(Public Law 90-399)

EFFECTIVE DATE AND TRANSITIONAL PROVISIONS

SEC. 108. (a) * * *
(b)(1) * * *

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(3) In the case of any drug (other than a drug subject to section 512(n) of the basic Act as amended by this Act) intended for use in animals other than man which, on October 9, 1962, (A) was commercially used or sold in the United States, (B) was not a new drug as defined by section 201(p) of the basic Act as then in force, and (C) was not covered by an effective application under section 505 of that Act, the words "effectiveness" and "effective" contained in **[section 201(w) as added by this Act]** *section 201(v)* to the basic Act shall not apply to such drug when intended solely for use under conditions prescribed, recommended, or suggested in labeling with respect to such drug on that day.

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