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MINOR USE AND MINOR SPECIES ANIMAL HEALTH ACT OF 2003

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Mr. GREGG, from the Committee on Health, Education, Labor, and Pensions, submitted the following

R E P O R T

[To accompany S. 741]

The Committee on Health, Education, Labor, and Pensions, to which 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, having considered the same, reports favorably thereon with an amendment and recommends that the bill (as amended) do pass.

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I. PURPOSE AND SUMMARY OF LEGISLATION

Title I of S. 741, the Minor Use and Minor Species Animal Health (MUMS) Act, is intended to amend the Federal Food, Drug, and Cosmetic Act (FFDCA) to address the critical shortage of approved animal drugs for minor species (species other than cattle, horses, swine, chickens, turkeys, dogs, and cats) and for minor uses in major species (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). Title I is intended to increase the availability of new animal drugs for minor species and for minor uses, while still ensuring appropriate safeguards for animal and human health.

Title I establishes two new ways to lawfully market new animal drugs. First, it establishes a conditional approval mechanism for new animal drugs for minor uses and minor species. Conditionally-approved new animal drugs must meet the same new animal drug approval requirements for safety as new animal drugs approved under section 512 of the FFDCA (21 U.S.C. 360b). However, the effectiveness standard for conditionally-approved drugs differs from the effectiveness standard for new animal drugs approved under section 512. An application for a conditional approval must include data to demonstrate that there is a "reasonable expectation of effectiveness" rather than "substantial evidence of effectiveness." If an application for conditional approval is approved, the conditional approval will be in effect for one year, renewable for a maximum of four additional one-year terms. During this period, which ends 5 years from the date of conditional approval, the applicant is expected to conduct effectiveness studies and to demonstrate by "substantial evidence" that the animal drug is effective for its intended use. The conditional approval is intended to allow sponsors to recoup some development costs through marketing of the product prior to full, unconditional approval.

Second, Title I provides for an index of legally-marketed unapproved new animal drugs for non-food minor species and non-food life stages of food producing minor species under limited circumstances. The index is intended to provide a way to lawfully market those minor species drugs for which there is unlikely to be sufficient financial incentive to seek a full or conditional approval. A new animal drug deemed by the Food and Drug Administration (FDA) to be eligible for listing on the index will be added to the index if the drug meets certain safety criteria; and if the benefits of using the drug outweigh the risks to the target animal, taking into account the harm caused by the absence of an approved or conditionally-approved drug for the use in question. The addition of a new animal drug to the index will be based, in part, on the report of an expert panel based on its review of all available safety and effectiveness information. Title I also provides a process for classifying certain new animal drugs for minor uses and minor species as designated new animal drugs. Persons gathering data to support approval of a designated new animal drug may qualify for either or both of two incentives. The first incentive is the availability of grants for development of certain designated new animal drugs. The second incentive is an extension of marketing exclusivity to seven years.

Title I would preserve all FDA requirements for the approval of an antimicrobial. Section 512 of the FFDCA requires that any new animal drug submitted for approval under the MUMS Act, must meet all human safety requirements, including drug residue and microbial safety criteria. In accordance with this requirement, all such antimicrobials would be evaluated under FDA's Guidance for Industry #152, Evaluating the Safety of Antimicrobial New Animal Drugs with Regard to Their Microbiological Effects on Bacteria of

Human Health Concern (as well as other subsequent guidance or regulation). Guidance #152 requires the completion of a qualitative risk assessment that among other things, would examine whether the use of an antimicrobial in animals, including aquaculture, could lead to drug resistance affecting humans. Additionally, antimicrobials, as well as all other drugs submitted under the provisions of the MUMS Act, will continue to be subject to an extensive environmental assessment prior to approval or legal marketing.

Title II of S. 741 responds to the seven million Americans who suffer from food allergies, approximately 2 percent of whom are adults and 5 percent of whom are infants and young children. Eight major foods or food groups—milk, eggs, fish, Crustacean shellfish, tree nuts, peanuts, wheat, and soybeans—account for 90 percent of food allergies. Peanut or tree nut allergy is reported by over three million Americans and appears to be increasing in prevalence—the rate of peanut allergy is reported to almost double among children in the U.S. between 1997 and 2002. There is currently no cure for food allergies. Instead, people with a food allergy must avoid the food to which they are allergic.

The Federal Food, Drug, and Cosmetic Act (FFDCA) requires, with some exceptions, a complete listing of all the ingredients in a food on the food label. Currently, the FFDCA does not require the eight major food allergens to be identified, using plain English, on the food label when ingredients contain allergenic substances. The names of some ingredients do not clearly identify in plain English that the ingredient is the source of an allergen. For example, whey and casein are required to be identified in the food ingredient list as whey and casein despite the fact that these ingredients are derived from milk and may cause allergic reactions in those allergic to milk. Use of plain English in food labels to identify the presence of the eight major food allergens will make the food label much more useful to consumers with food allergies.

There are also two exemptions from the requirement that each ingredient be listed in the food ingredient label. One exemption allows for collective naming of flavors, certain colors, and spices. These terms are not completely descriptive, however; in particular, they do not identify if any components of flavors or colors are allergens. Under the second exemption, incidental additives, which are food substances that are used in insignificant amounts and that do not have any technical or functional effect in the food, need not be identified in the food label. Although additives that are, or that contain, a major food allergen are not considered to be incidental, these ingredients are nonetheless sometimes inadvertently left off of the food label. Requiring the use of plain English to identify the presence of the eight major food allergens used in flavors and certain colors will also make the food label more useful to allergic consumers.

Food allergens sometimes inadvertently find their way into a food because of a firm's production practices; such as rework addition or product carryover due to use of common equipment or production scheduling. Such practices present an unintentional opportunity for a product that contains an allergen to come into cross-contact with a product that does not contain that particular allergen as an ingredient or as a component of an ingredient. In some

instances it may not be possible to eliminate the possibility of cross-contact following good manufacturing practice. In such instances, it may be appropriate for food manufacturers to use advisory labeling (such as "may contain") to indicate the possible presence of food allergens in a food product. Many food manufacturers currently use such advisory language. However, "cross-contact" deserves further study by both FDA and the food industry.

Celiac disease is an immune-mediated disease and is distinct from food allergy. When gluten from certain cereal grains is ingested by individuals with celiac disease, damage to the gastrointestinal tract, central nervous system, and other organs may occur over time. The current treatment for individuals with celiac disease is avoidance of glutens in foods that are associated with celiac disease. Permitting a "gluten-free" claim to appear on the labels of food products will assist individuals with celiac disease to avoid the glutens associated with the disease.

The major purpose of this legislation is to ensure that the major food allergens are identified in plain English on food product labels. Members of this committee have worked in a bi-partisan fashion to ensure that this legislation will provide reliable, accurate, and clear allergen information on the food label. Title II of S. 741, "The Food Allergen Labeling and Consumer Protection Act of 2003" will assist food allergic consumers in identifying foods that contain major food allergens.

II. Committee Action

Title I, the Minor Use and Minor Species Animal Health (MUMS) Act of 2003 (S. 741) was introduced by Senator Sessions for himself and for Mr. Bingaman, Mr. Gregg, Mr. Miller, Mr. Allard, Mrs. Lincoln, Mr. Ensign, Ms. Collins, Mr. Crapo, Mr. Craig, and Mr. Harkin on March 27, 2003 and subsequently marked up as an original bill at the Committee on Health, Education, Labor, and Pensions Executive Session on November 21, 2003. At that time, Senator Gregg offered an amendment in the nature of a substitute that included technical changes and a new Title II, the Food Allergens Labeling and Consumer Protection Act. The chairman's mark was accepted by unanimous consent and reported favorably from the committee by voice vote.

III. Background and Need for Legislation

TITLE I

Because the markets are small and profit margins low for new animal drugs intended for minor uses in major species or for minor species, there are often insufficient economic incentives to motivate sponsors to develop the data necessary to support FDA approvals. In addition, some minor species populations are too small or their management systems too diverse to make it practical to conduct traditional studies to demonstrate safety and effectiveness. Consequently, manufacturers have not, in many cases, been willing to fund research to collect these data. Accordingly, very few new animal drugs intended for minor uses or for minor species have been approved and are legally marketed.

Because of the limited availability of approved new animal drugs intended for minor uses or minor species, veterinarians, animal

owners, and livestock producers have limited options for treating these sick animals. In many cases, the choices are to leave a sick animal untreated or to treat the animal with an unapproved drug.

Failure to treat sick animals appropriately may increase public health hazards. For example, the transmission of disease from animals to humans or the shedding of disease-producing organisms by untreated animals into the environment may increase health risks to humans as well as other animals. Treating an animal with an unapproved drug introduces questions of effectiveness and safety to the animal, to the environment and to the public.

FDA has attempted to encourage the submission of New Animal Drug Applications (NADA) for minor uses and minor species within the confines of the FFDCA. The FDA's efforts have been met, thus far, with only limited success.

The Animal Medicinal Drug Use Clarification Act (AMDUCA) was enacted in 1994 (Public Law 103–396). AMDUCA and the final implementing regulations permit veterinarians to use approved new animal drugs for unapproved therapeutic uses in certain instances. Although AMDUCA does give veterinarians more legal treatment options, it does not, and was not intended to, facilitate the approval of new animal drugs for minor uses or minor species. Because the best drug for a minor use or minor species often is not available in an appropriate approved formulation or dosage form, or the best drug is not approved for use in any species, AMDUCA provides few additional legal treatment options for minor species and minor uses. In any case, drug approval is preferable to extra-label use because it makes dosage information and drug withdrawal periods (for food-producing animals) more readily available to the veterinarian or producer.

The Animal Drug Availability Act (ADAA) was enacted on October 9, 1996 (Public Law 104–250). The ADAA reflected Congress's concerns about the lack of availability of approved new animal drugs. Among other things, the legislation recognized particular problems relating to the availability of approved new animal drugs for minor uses in major species and for use in minor species. Section 2(f) of the ADAA directed the Secretary of Health and Human Services (the Secretary) to consider legislative and regulatory options for facilitating approval under section 512 of the FFDCA (21 U.S.C. 360b) of new animal drugs intended for use in minor species or for minor uses. The ADAA further required the Secretary to announce proposals for legislative or regulatory change to the approval process for new animal drugs intended for use in minor species or for minor uses.

FDA worked to develop proposals and to make them available for public comment throughout the process. On October 29, 1998 (63 FR 58056), FDA published a Federal Register notice announcing the availability of "Proposals to Increase the Legal Availability of Animal Drugs for Minor Species and Minor Uses, ADAA Minor Use/Minor Species Working Group" to fulfill that statutory obligation.

After closely examining the existing statutes, FDA determined that they simply fail to provide adequate options to fully serve the needs of hundreds of minor animal species. Congress recognized the possibility that statutory changes might be needed to fulfill its charge at Section 2(f) of the ADAA. To achieve the goal of increas-

ing the availability of safe and effective drugs for minor species and minor uses, FDA concluded that Federal statutes should be amended. FDA's proposals provide a conceptual basis for the Minor Use and Minor Species Animal Health Act of 2003.

TITLE II

The intent of Title II of S. 741 is to require plain English ingredient labeling of products that contain milk, eggs, fish, Crustacean shellfish, tree nuts, peanuts, wheat, and soybeans—collectively referred to as the eight major food allergens. This legislation amends the FFDCA to require that food ingredient statements identify in plain English when the food contains a major food allergen, including when a major food allergen is contained in flavorings, colorings, and incidental additives.

The legislation requires the Secretary of Health and Human Services (the Secretary) to issue a report to Congress about food allergen cross-contact, advisory labeling and food allergen inspections. The Secretary is required to conduct food allergen inspections under existing authority under the FFDCA.

This legislation provides for enhanced surveillance and for recommendations related to research concerning food allergens. The Centers for Disease Control and Prevention (CDC) is called upon to track food-allergic-related deaths and other clinically significant and serious adverse events. Additionally, the National Institutes of Health (NIH) is directed to convene a panel of experts to develop recommendations for research activities concerning food allergies.

This legislation directs the Secretary to pursue revision of the Food Code to provide guidelines for preparing allergen-free foods in food establishments. It also directs the Secretary to provide technical assistance relating to emergency treatment of allergic responses to foods.

Further, this legislation requires the Secretary to define by regulation the term "gluten-free" for voluntary use in food labeling.

IV. Explanation of Bill and Committee Views

Requirement of plain English labeling of the eight major food allergens

The legislation amends section 201 of the FFDCA to define the term "major food allergen." It is defined to mean the eight most significant food allergens—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—and any food that contains protein derived from one of these eight food allergens (except for highly refined oils, ingredients derived from highly refined oils, and other food ingredients that are exempt under the legislation). Fish, Crustacean shellfish, and tree nuts are collective names that include a variety of different items. For example, the term "tree nuts" refers to a variety of individual nuts, including almonds, Brazil nuts, cashews, chestnuts, filberts/hazelnuts, macadamia nuts, pecans, pine nuts, pistachios, and walnuts. The term "Crustacean shellfish" refers to crabs, crawfish/crayfish, lobster, prawns, and shrimp. The term "fish" refers to a variety of different species of fish.

The committee has provided that food ingredients containing protein derived from milk, eggs, fish, shellfish, peanuts, tree nuts, wheat, or soybeans may nevertheless be excluded from the definition of "major food allergen" under one of three exceptions. First, highly refined oils and ingredients derived from highly refined oils are excluded from the definition of "major food allergen." "Highly refined oils" are intended to signify refined, bleached, deodorized (RBD) oils. The committee notes, however, that the legislation does not change the common or usual name of highly refined oils; that is, highly refined oils would still be required to be identified by their common and usual name in the ingredient list, e.g., "peanut oil." Second, the committee has also excluded from the definition of "major food allergen" food ingredients for which the Secretary has determined, based on scientific evidence presented in a petition, that the food ingredient does not cause an allergic response that pose a risk to human health.

Finally, the committee has provided for a notification process to exclude from the definition of a major food allergen those food ingredients that contain protein derived from one of the major eight protein sources but do not contain the allergenic protein and for food ingredients for which the Secretary has previously made a determination that the use of 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 of the FFDCA. The committee recognizes that the GRAS notification process is not included as part of this exception. The committee encourages FDA to adopt a reasonable standard for determining whether a food ingredient "does not contain an allergenic protein." For example, while the committee recognizes that thresholds for the major eight 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.

The committee intends that the Secretary will provide guidance to industry on the information that would be useful for making a determination that foods that contain protein derived from one of the eight food allergens do not cause an allergic response that poses a risk to human health. The committee also intends that the Secretary provide an appropriate process for providing such information to the Secretary that minimizes the burden on the food manufacturer.

The legislation requires FDA to post the petitions and notifications for exemption from allergen labeling to a public site as well as FDA's responses to such petitions and notifications. In instances when FDA concludes that a notification or petition has provided data demonstrating that the food ingredient should be exempt from the definition of "major food allergen," the exemption will apply to any product bearing or containing the ingredient under the same conditions of use described in the notification or petition.

The legislation also amends section 403 of the FFDCA to provide two new misbranding provisions. The first of these, section 403(w), requires that the eight major food allergens be labeled on foods that are not raw agricultural products. Under section 403(w), manufacturers will have two options as to how they must label the eight major food allergens on such foods. Under either plain

English allergen labeling option, the term for a major food allergen—milk, egg, wheat, peanuts, soybeans, or, in the case of the collective terms "fish," "Crustacean shellfish," or "tree nuts," the common or usual name for the relevant specific members of the class, such as "cod," "shrimp," or "almond"—will appear in the food label if the food is, or it bears or contains, a major food allergen as defined in section 201(qq). These plain English allergen labeling requirements apply only to foods for which an ingredient list is required in a label or labeling under the FFDCA.

Manufacturers may choose to summarize the allergen information using the terms for the major food allergens from which any ingredients in the food are derived in a statement at the end of, or immediately adjacent to, the ingredient list. This information must appear in a type size no smaller than the type size used in the ingredient list.

Alternatively, manufacturers may place the term for the appropriate major food allergen in parentheses within the ingredient list after the common or usual name of the ingredient derived from that major food allergen. There are two exceptions to this requirement. First, the listing of the term for the food allergen is not required to appear in parentheses after an ingredient name if the ingredient name uses the term for the major food allergen (for example, "milk" need not appear in parentheses after "milk" or "milk byproduct," nor need "almond" appear after "almond"). Second, the term for a food allergen need not be placed after an ingredient if the term for that food allergen appears elsewhere in the ingredient list; the food allergen term need only appear once in the ingredient statement, 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 excluded from the definition of a major food allergen. For example, if a food contained highly refined peanut oil and a natural flavoring containing peanut as a constituent, the term "peanut" would have to appear in parentheses after "natural flavoring" in the ingredient list, because peanut oil is not a "major food allergen" under this legislation.

These two options can be illustrated by an example. If a food were to have as ingredients semolina, rice flour, rolled oats, pine nuts, tomato juice, whey, sodium caseinate, and natural flavoring, with the natural flavoring including peanuts as a constituent, the major food allergens in the food could be labeled in two ways. First, the following statement could appear at the end of, or immediately adjacent to, the list of ingredients: "Contains wheat, milk, pine nuts, and peanuts." Second, the ingredient list could read: "Ingredients: semolina (wheat), rice flour, rolled oats, pine nuts, tomato juice, whey (milk), sodium caseinate, and natural flavoring (peanuts)."

These two examples illustrate several aspects of the allergen labeling requirements. In the second example, "milk" does not appear in parentheses after "sodium caseinate" because it has already appeared after "whey." In the examples, the natural flavoring includes peanuts as a constituent and so peanut is labeled as an allergen in the food. In other words, the food allergen labeling requirement applies to flavorings, colorings, and incidental additives. Only the peanut constituent of the natural flavoring ingredient is identified, however; the other constituents of the flavoring—or in-

deed of any coloring or incidental additive—are not required to be listed under either plain English labeling option permitted under the legislation.

The term "pine nuts" is in the summary of allergy information in the first example, but it need not appear after "pine nut" in the ingredient list in the second example because the repetition is unnecessary. The first example illustrates the committee's intent that the term for the relevant specific member of the class "fish" or "Crustacean shellfish" or "tree nuts" is required to be used whenever an ingredient is, or is derived from, an example from one of these food categories. The second example illustrates the committee's intent that an ingredient whose common or usual name uses the term for the major food allergen—in the example, "pine nuts" clearly uses the term for pine nuts—need not be followed by a parenthetical repeating the term. Finally, all major food allergens are required to be labeled consistently on the food label: either in the summary of allergen information at the end of, or immediately adjacent to, the ingredient list, or using parentheses after ingredients.

The committee intends that the use of the term "milk" in either of these examples does not violate the standard of identity for milk established under FDA regulations. Used in this context, the term "milk" is used to identify a major food allergen and not the identity of the ingredient or the food.

The legislation gives FDA the authority to modify or eliminate these requirements by regulation. This authority is limited in a few respects, however. First, FDA may modify one or both labeling options. Second, FDA may not eliminate all major food allergen labeling by eliminating both labeling options; rather, FDA may eliminate only one of the approaches. Third, and most significantly, FDA must demonstrate in the regulation that modification or elimination of an allergen labeling requirement is necessary to protect public health. The committee considers this standard to impose a high burden on the Secretary to justify changing these requirements of the legislation.

In addition, the legislation amends section 403A of the FFDCA to give the modification to the ingredient label required by section 403(w) the same preemptive effect over State and local ingredient labeling that the current ingredient labeling has.

The committee understands that many manufacturers have already labeled their foods in conformity with one of the plain English allergen labeling options, and it expects that most foods will be labeled in compliance with these requirements before January 1, 2006. In any case, all foods that contain an ingredient that is or that contains a major food allergen must be labeled by January 1, 2006. This fixed date by which all affected foods must be labeled in accordance with these requirements will give consumers greater certainty that they will be able to rely on food labels as of that date. Importantly, this requirement does not require the relieving of food products that are in the marketplace before the effective date. In other words, this legislation does not require food products to be pulled from the marketplace and relabeled in conformance with the requirements of this legislation if they were labeled before January 1, 2006.

The committee intends the requirements of section 403(w) to be self-implementing. FDA will not be required to issue regulations to implement section 403(w). FDA may issue guidance, should the agency find that guidance would assist manufacturers or distributors, particularly small businesses, to comply with the requirements in this legislation.

The legislation also adds a second misbranding provision to account for other food allergens. In particular, section 403(x) provides that FDA has the authority to require by regulation appropriate labeling of any spice, flavoring, coloring, or incidental additive ingredient that is, or includes as a constituent, a food allergen that is not a major food allergen. The committee does not intend the listing of all spices or flavorings in a product but intends that the Secretary will require the food allergen to be identified on the label in a manner consistent with this legislation. In addition, the legislation provides that the amendments made by it do not otherwise alter FDA's authority to require the labeling of other food allergens that are not major food allergens. Finally, the legislation amends section 403A of the FFDCA to give requirements under section 403(x)—which provides for an exception to a current labeling exemption for spices, flavorings, colorings, and incidental additives that has preemptive effect over State and local labeling requirements—the same preemptive effect over State and local labeling requirements that the current exemption has.

Food allergy surveillance, research, and response

The committee is concerned that the prevalence of food allergies is uncertain and the incidence of clinically significant and serious adverse events is not being systematically monitored. In response to these concerns, the legislation requires the Centers for Disease Control and Prevention to better capture information 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. In addition, the legislation requires the National Institutes of Health to convene a panel of nationally recognized experts to review current clinical research efforts and develop recommendations for enhancing and coordinating research activities concerning food allergies.

The legislation directs the Secretary, in the Conference for Food Protection, to pursue revision of the Food Code to provide recommendations and guidance on preparing allergen-free foods in food establishments. The Secretary should refer to private guidelines, including the Food Allergy and Anaphylaxis Network and Food Allergy Initiative's document entitled: Food Allergy Training Guide for Restaurants and Food Services, as a model during development.

Finally, the legislation directs the Secretary to provide technical assistance to States and localities about treatment of food allergic responses by trauma care and emergency medical services. Currently, the preferred treatment for anaphylaxis from food allergy is an auto-injector epinephrine device. The legislation does not specify this treatment, so that the Secretary will continue to provide such technical assistance as new treatments are developed.

Celiac disease and gluten labeling

The legislation directs the Secretary, after consulting with appropriate experts and stakeholders, to promulgate a regulation to define and permit the use of the term "gluten-free" as a voluntary claim on the food label. The committee intends that this "gluten-free" claim not be a claim for special dietary use, a nutrient content claim, or a health claim. The legislation requires that the proposed rule regarding this claim be issued not later than 2 years after the date of enactment of the legislation, and that the final rule be issued not later than 4 years after the date of enactment of the legislation.

V. Cost Estimate

Due to time constraints, the Congressional Budget Office estimate was not included in the report. When received by the committee, it will appear in the Congressional Record.

VI. Application of Law to the Legislative Branch

Section 102(b) (3) of Public Law 104–1, the Congressional Accountability Act (CAA), requires a description of the application of this bill to the legislative branch. Title I, the Minor Use and Minor Species Animal Health Act of 2003 would amend the Federal FFDCA by creating a program authorizing FDA to establish a conditional approval mechanism for animal drugs, an index of legally-marketed unapproved new animal drugs for certain uses in some minor species, and up to seven years of marketing exclusivity for some new animal drugs approved or conditionally approved for minor uses or minor species. As such, the legislation would not apply to the legislative branch.

Title II of S. 741 adds two misbranding provisions to section 403 of the FFDCA to provide, first, that food labels include plain English labeling of the eight major food allergens and second, that food allergens other than the eight major food allergens can be identified when they are contained in flavorings, colorings, or other incidental additives. It also requires certain other actions by the Department of Health and Human Services relating to food allergens and gluten. As such, it has no application to the legislative branch.

VII. Regulatory Impact Statement

Title I would establish a new Office of Minor Use and Minor Species Animal Drug Development within the FDA's Center for Veterinary Medicine. This office will be responsible for designating minor use and minor species animal drugs, for administering grants and contracts under section 573 of the FFDCA, for reviewing minor species drug index listing requests, and for serving as liaison to other government agencies interested in minor use and minor species animal drug development. This legislation requires the Secretary to issue proposed and final regulations to implement section 573 no later than 12 months and 24 months after the date of enactment of this act, respectively. The Secretary is also required to publish proposed and final regulations to implement section 572 no later than 18 months and 36 months after the date of enactment of this

act, respectively. Finally, the Secretary is required to issue proposed and final regulations implementing section 571 no later than 30 months and 42 months after enactment of this act, respectively. Accordingly, this legislation is expected to increase costs to government minimally.

Title II requires foods that contain one or more of the eight major food allergens to be labeled so as to disclose the presence of those allergens in plain English. Because many in the food industry have already begun the process of labeling their products to disclose these allergens, and because the legislation requires food manufacturers to comply with this requirement by January 1, 2006, by which time most in the food industry may be expected to produce new labels for their foods notwithstanding the requirements of this legislation, the costs to most members of the food industry and to the food industry in aggregate of this requirement will be minimized. Accordingly, this legislation is not expected to increase costs to government.

VIII. SECTION-BY-SECTION ANALYSIS

TITLE I

Sec. 101. Short title

Section 101 provides that the short title of Title I of this bill is the Minor Use and Minor Species Animal Health Act of 2003.

Sec. 102(a). Findings

Section 102(a) sets forth Congressional findings regarding the need for incentives and new ways to lawfully market new animal drugs for minor species and minor uses.

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

Subsection (b)(1) amends the FFDCA to add relevant definitions. New section 201(nn) of the FFDCA defines "major species" as cattle, horses, swine, chickens, turkeys, dogs, and cats. The FDA is authorized to amend this definition to add species to the major species list through rulemaking. New section 201(oo) defines "minor species" as species other than humans or major species. Minor species are defined by exclusion consistent with the existing definition in the Code of Federal Regulations (21 CFR 514.1(d)(1)). New section 201(pp) of the FFDCA defines "minor use" as 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 geographic areas and in only a small number of animals annually. This definition incorporates the existing definition in the Code of Federal Regulations (21 CFR 514.1(d)(1)) with a further limitation to small numbers to assure that such intended uses will not be extended to a wider use. The Secretary is expected to further clarify this definition in regulations implementing this section. FDA is given broad latitude in determining what constitutes a minor use in a major species. The Congress intends for FDA to make the determination of minor use by evaluating, in the context of the drug development process, whether the incidence of the disease or condition occurs so infrequently that the sponsor of a drug intended for such use has no reasonable expectation of its sales generating suffi-

cient revenues to offset the costs of development. The Congress does not intend for FDA to establish a test of commercial value, but rather directs FDA to determine whether the expected low use of a drug would discourage its development. FDA will make this determination, in part, based upon documentation from the drug sponsor demonstrating that the disease or condition occurs infrequently and in a small number of animals, or occurs in limited geographic areas and in a small number of animals annually. FDA may initially make such determinations on a case-by-case basis. These initial determinations may form the basis for establishing or revising regulations which clarify the grounds or the process for determining whether a new animal drug is intended for a "minor use".

Subsection (b)(2) of this bill amends section 512(c) of the FFDCA to allow FDA to award three years of market exclusivity in connection with the approval of a minor use or minor species NADA or supplemental NADA when the approval is based on a residue depletion study that is used to calculate a withdrawal time. The typical minor species supplement to an approved application for a new animal drug intended for use in a food-producing animal uses or incorporates by reference most of the human food safety data from the approved application. The exception is the residue depletion study or studies (e.g., tissue, milk, eggs) which the sponsor must conduct in the target minor species to support approval. Such studies are not granted exclusivity under the current statute. These studies must be done using Good Laboratory Practices (21 CFR 58), and can be as costly as target animal safety or effectiveness studies which, under current law, can serve as the basis for the exclusivity period. Granting marketing exclusivity based on a residue depletion study or studies is intended to encourage sponsors to conduct such studies to support minor species supplements.

Subsection (b)(3) adds new section 512(d)(5) to the FFDCA to direct FDA to review only the existing information in the approved NADA that is relevant to a minor use or minor species supplemental NADA. Animal drug manufacturers have been concerned that filing a supplemental NADA to add a claim for a minor use or use in a minor species could lead to automatic reevaluation of the underlying major species approval, thereby putting the entire NADA in jeopardy. This concern has served as a disincentive to the filing of minor use and minor species supplemental NADAs. This section is intended to mitigate that concern. Therefore, the legislation provides that FDA's review of a supplemental application for a minor use or minor species approval does not constitute a reaffirmation of the approval(s) for the major species. Section 512(d)(5) does not in any way change FDA's current authority to reevaluate any application at any time under section 512 of the FFDCA.

Subsection (b)(4) adds a new subchapter (F) to the FFDCA consisting of sections 571 to 573.

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

Section 571(a)(1) establishes a conditional approval process for minor use and minor species new animal drugs.

Subsection (a)(2) establishes the information that sponsors must submit as part of an application for conditional approval.

Subsection (a)(2)(A) indicates that the standards and requirements for conditional approval of new animal drugs are identical to those for new animal drugs approved under section 512 except with respect to effectiveness.

Under subsection (a)(2)(B), the drug sponsor must provide information to establish that the drug is safe (including, for an antimicrobial new animal drug, with respect to antimicrobial resistance) and that there is a reasonable expectation that the drug is effective for use. Data from such sources as pilot studies, investigations using surrogate endpoints, short-term investigations, pharmacokinetic extrapolations, or investigations of closely-related diseases may be used to demonstrate a reasonable expectation of effectiveness. Data from some of these sources may also be used to meet the "substantial evidence" standard of effectiveness under section 512 of the FFDCA. Under section 512, a sponsor must have a sufficient number of "adequate and well-controlled" studies to demonstrate by substantial evidence that a new animal drug is effective. But, to meet the conditional approval standard, the studies need not be of the same quality or quantity as studies that meet the "substantial evidence" standard. Within five years of the date of the conditional approval, the sponsor must conduct a sufficient number of adequate and well-controlled studies to demonstrate by "substantial evidence" that the new animal drug is effective under section 512(d)(1)(E).

Subsection (a)(2)(C) requires submission of data to establish a conditional dose.

Subsections (a)(2)(D) and (E) require sponsors to provide projections and justification for the expected need for the drug and an estimate of the quantity of drug to be distributed on an annual basis to meet that need. Information to support these projections could include market research, surveys of veterinarians, producers, or academic institutions, or statistics compiled by private or government agencies. Regulations will specify ways that sponsors may adjust distribution amounts based on changes in demand prior to the submission of a renewal request. Subsection (a)(2)(F) requires a sponsor to commit to conducting additional investigations to meet the full requirements for the demonstration of effectiveness under section 512 (d)(1)(e) within five years.

Subsection (a)(3)(A) prohibits a person from filing an application for conditional approval for a new animal drug that is contained in or the product of a transgenic animal.

Subsection (a)(3)(B) prohibits persons from filing an application for conditional approval of the same drug, in the same dosage form, for the same intended use as a product for which they have previously filed an application for conditional approval. The Secretary has discretion to define the term "same drug" as used here and throughout section 571. In defining "same drug," the Secretary should take into account that the purpose of this legislation is to promote the development of minor use and minor species new animal drugs. A sponsor should be able to reap a conditional approval's benefit, recouping some development costs through marketing of a product prior to full approval, only once per product. This section, therefore, is intended to limit conditional approval applications to products that differ materially from products for which a sponsor has previously filed a conditional approval application. So,

for example, where two products differ only with respect to one or more inactive ingredients, they are the "same drug" for purposes of this section.

Similarly, subsection (a)(3)(C) prevents a sponsor from marketing in excess of the five years it is given to get full approval of a conditionally approved drug by preventing the sponsor from reapplying or transferring the conditional approval to someone else who will apply for a new conditional approval for the drug. A sponsor change (e.g., as the result of a sale or merger) does not require a new application. The new sponsor assumes all the existing deadlines and requirements inherent to the existing application.

Subsection (b) provides the Secretary 180 days (or an agreed upon timeframe) after the filing of an application pursuant to subsection (a) to issue an order either to conditionally approve a new animal drug for one year or give the sponsor notice of an opportunity for an informal hearing on whether the application can be conditionally approved. If any of the provisions of section 512(d) except (d)(1)(E) are applicable, or insufficient information is available to show that there is a reasonable expectation that the drug will be effective for its intended purpose, the Secretary will issue an order under section 571(c) refusing to conditionally approve the application. The Secretary will also refuse to conditionally approve a new animal drug for a minor use or a minor species if 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.

Subsection (d) establishes that a conditional approval is renewable annually for up to four additional one-year terms upon submission of a request for renewal. A conditional approval cannot be in effect for more than five years from the date of the original conditional approval, unless the Secretary extends its review of effectiveness information. If the sponsor files a timely request for renewal, i.e. no later than 90 days prior to the end of the one-year conditional approval, the application will be renewed automatically at the expiration of the one-year term, unless the Secretary issues a written order denying the renewal. The Secretary may grant an extension of 90 additional days to complete review of the renewal request if necessary. The renewal, if granted, will expire one year from the end of the previous one-year term, not one year from the end of a 90-day extension.

Under subsection (e)(1), the Secretary will withdraw conditional approval of a new animal drug 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.

Subsection (e)(2) requires the Secretary, after an opportunity for an informal hearing to the applicant, to withdraw a conditional approval if any of the provisions of section 512(e)(1) except 512(e)(1)(C), which relates to effectiveness, are applicable, or if new information becomes available to suggest that there is not a reasonable expectation that the drug will have its purported effect.

Subsection (e)(3) also allows the Secretary to withdraw a conditional approval, after an opportunity for an informal hearing, if any of the provisions of section 512(e)(2) are applicable. Subsection (f) establishes labeling requirements for conditionally-approved new

animal drugs. Labeling for a conditionally-approved new animal drug must bear a statement identifying the new animal drug as conditionally approved. A conditionally-approved indication cannot be included on the same label as a fully-approved indication. Multiple conditionally-approved indications may appear on the same printed label. However, the sponsor must remove indications from the label of a conditionally-approved product when they are either fully approved under section 512 or withdrawn for any reason.

Subsection (g) prohibits amending or supplementing a conditionally-approved new animal drug application to add indications for use. To get approval for a different/new indication, a sponsor must submit a new animal drug application or another application for conditional approval for the new intended use. However, such application may incorporate information from an existing application by right of reference.

Subsection (h) provides that if a conditionally-approved new animal drug is not approved under section 512(c) within five years of the conditional approval, the conditional approval is no longer in effect, unless extended by the Secretary for an additional 180 days to complete review of the application.

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 Sec. 572. Index of legally-marketed unapproved new animal drugs for minor species

Section 572(a)(1) of the FFDCA requires the Secretary to establish an index of legally-marketed new animal drugs for minor species. New animal drugs intended for minor uses in major species do not qualify to be indexed. The index is limited to animal drugs for 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, as well as new animal drugs intended for use in an appropriately contained non-food early life stage of a food-producing minor species, where safety of the indexed drug is demonstrated in accordance with the standard of section 512(d) (including, for an antimicrobial new animal drug, with respect to antimicrobial resistance). The index is primarily intended to benefit zoo and wildlife species, aquarium fish, reptiles, caged birds, small pet mammals, and wildlife, some commercially-produced species, such as crickets and earthworms, and non-food life stages of some minor human food species, such as shellfish and some finfish. For most of these species, it is highly unlikely there will ever be sufficient economic incentive for the development of data packages to support full or conditional approvals. The index established by this section provides an alternative process for making drug products legally available for these species.

Subsection (a)(2) precludes the indexing of a new animal drug that is contained in or the product of a transgenic animal.

Subsection (b) provides that anyone interested in indexing a new animal drug is entitled to one or more conferences with the Secretary to discuss indexing requirements.

Subsection (c) entitles any person to submit a request to the Secretary to determine whether a new animal drug is eligible for in-

clusion in the index. This request will include information to support the need for the drug, conditions of its intended use, and the expected annual distribution. Information also must be provided to support safety for humans (if applicable), and details of the drug's chemistry and manufacturing processes. In addition, a request must include an environmental assessment that meets the requirements of the National Environmental Policy Act, or information to support a categorical exclusion from the requirement to prepare an environmental assessment. Finally, occupational and user safety must be addressed, as well as any other issue the Secretary deems necessary. The Secretary has 90 days to determine whether the new animal drug is eligible for inclusion in the index. However, the Secretary has 180 days to grant or deny the request in the case where the request is for indexing of a new animal drug which is intended for use in an early life stage of a minor species food animal. The additional 90 days allows the Secretary sufficient time to ensure that the drug is safe for humans under section 512(d) (including, with respect to a new antimicrobial drug, antimicrobial safety); that the same drug in the same dosage form for the same intended use is not approved or conditionally approved; the sponsor has established appropriate specifications for the manufacture and control of the new animal drug; the person requesting the index listing has demonstrated that the drug is safe for users; and the requirements of the National Environmental Policy Act have been met. The Secretary will grant the eligibility request only if the foregoing requirements are satisfied. As in section 571, the Secretary has discretion to define the term "same drug" as used in this section. In defining "same drug" the Secretary should take into account the intent of limiting the index to drugs which are materially different from drugs that have previously been approved or conditionally approved. So, for example, where two products differ only with respect to one or more inactive ingredients, they are the "same drug" for purposes of this section. If the Secretary denies the request for eligibility, the sponsor may request an informal conference. Such a conference will be conducted in a more informal manner than a hearing conducted under 21 CFR part 16. The record compiled for the informal conference will form the record for judicial review.

If the Secretary makes a determination that a drug is eligible for inclusion in the index, new section 572(d) permits the person who made the request for index eligibility to ask the Secretary to add the drug to the index. The request for indexing must include: the Secretary's determination of eligibility; the report of a panel of qualified experts operating external to FDA and not subject to the Federal Advisory Committee Act; a proposed index entry; facsimile product labeling; anticipated annual distribution; and written commitments to manufacture the product in accordance with good manufacturing practices and to label, distribute and promote the product only in accordance with the index entry. Upon request of the Secretary, the information provided to the expert panel must also be provided. The report of the expert panel must address all available target animal safety and effectiveness information, including anecdotal information. The report of the expert panel must include the panel's opinion regarding whether the benefits of using the new animal drug for the proposed use in a minor species out-

weigh 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. Many of the species for which indexing is the only viable option are either too valuable or too rare to be used in controlled investigations. Thus, the recommendations of experts with extensive experience in the care of these species are an important source of information regarding whether or not to include a drug in the index. The report must also include information on the basis of which product labeling can be written, including a recommendation regarding whether the drug should be limited to use under the supervision of a veterinarian. The Secretary may request copies of the information provided to the expert panel, and any other information prescribed by general regulation or specific order. The Secretary will establish by regulation the criteria for selection of members, and the procedures for operation of the expert panel. The Secretary has 180 days to grant or deny a request for listing a drug on the index, based upon whether the request continues to meet the eligibility criteria in subsection (a), and the Secretary finds, on the basis of the expert panel report and any other information available, that the benefits of using the product for the proposed use in the minor species outweigh its risks to the target animal, taking into account the harm caused by the absence of an approved or conditionally-approved drug for the minor species in question.

Subsection (e) requires that the index include 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 any other conditions and limitations that are necessary regarding use of the drug. Although an index listing is specific to its sponsor, more than one person can obtain an index listing for the same drug in the same dosage form for the same intended use. There is no marketing exclusivity provision for indexed drugs. The Secretary will publish the index and update it periodically. The Secretary may establish by regulation a process for minor changes in the conditions of manufacturing or labeling of indexed products. Subsection (f) lists the bases on which the Secretary must remove a drug from the index after the opportunity for an informal conference. The Secretary may immediately suspend the index listing of a new animal drug if the Secretary finds that there is a reasonable probability that the use of the indexed product would present a risk to the health of humans or other animals. Subsection (g) requires the Secretary to promulgate regulations to permit the investigational use of new animal drugs intended to be indexed.

Subsection (h) requires that the labeling of a new animal drug listed in the index include, prominently and conspicuously, the statement: "Not approved by FDA. Legally marketed as an FDA indexed product. Extra-label use is prohibited." Except in the case of a product indexed for use in an early life-stage of a minor species food-producing animal, the label of the indexed product must also bear the statement: "This product is not to be used in animals intended for use as food for humans or other animals."

Subsection (i) gives the Secretary the authority to impose recordkeeping and reporting requirements, either by general regulation or by specific order. These requirements may include reporting to

the Secretary the quantity of the drug manufactured and distributed.

The Secretary has the authority to inspect and copy any records required to be maintained. Subsection (j) provides for safety and effectiveness data to be made public under specified conditions or circumstances. Section 572 of the FFDCA contains no provision parallel to current section 512(n) that would permit index listing to serve as the basis for the submission of an abbreviated new animal drug application or a subsequent index listing based on a demonstration of bioequivalence to an indexed product.

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

Section 573(a) establishes a designation procedure. Under subsection (a), the manufacturer or sponsor of a new animal drug may request that the Secretary declare the drug a "designated new animal drug." The decision to request the designation is entirely within the discretion of the manufacturer or sponsor. A request for designation must be made before the submission of a new animal drug application under section 512 or submission of an application for a new animal drug under section 571 seeking conditional approval. Once the Secretary determines that a drug is a "designated new animal drug," individuals or entities pursuing legal marketing of such drug may be eligible for grants for qualified safety and effectiveness testing of the drug, and for manufacturing expenses incurred in connection with the development of such drug. A designated new animal drug will qualify for an extended period of marketing exclusivity upon approval.

Whether a new animal drug is designated depends on its intended use. A new animal drug will be designated only if the drug is intended for use in a minor species or for minor use in a major species and the same new animal drug in the same dosage form for the same intended use has not previously been approved or conditionally approved for such use and is not currently designated. The Secretary has discretion to define the term "same drug" as used in this section. In defining "same drug" the Secretary should take into account the purpose of this legislation to promote the development of minor use and minor species new animal drugs. A sponsor should be able to reap the benefits of designation only for products that are materially different from products that have already been approved, conditionally approved, or designated. So, for example, where two products differ only with respect to one or more inactive ingredients, they are the "same drug" for purposes of this section.

The goal of designation is to facilitate the approval of new animal drugs for minor species and minor uses in major species. Thus, the Secretary will terminate a designation if the sponsor discontinues active pursuit of approval so that other sponsors can seek designation and pursue approval of the new animal drug. Notice of designation and termination of designation of a new animal drug will be made available to the public.

Subsection (b) gives the Secretary the authority to make grants to and enter into contracts with public and private entities and individuals to assist in defraying the costs of safety and effectiveness testing and manufacturing costs relating to the development of designated new animal drugs. Such grants and contracts may only be

used to defray costs that are incurred after the date the new animal drug is designated and before the date on which the application under section 512 is submitted.

Subsection (c) provides for a period of marketing exclusivity for designated new animal drugs from the date of approval. If the Secretary approves or conditionally approves an application for a designated new animal drug, the Secretary cannot approve or conditionally approve another application for such new animal drug for the same intended use as the designated new animal drug before the expiration of seven years from the date of the approval or conditional approval of the designated new animal drug. By providing for a period of exclusive marketing, i.e., exclusivity, this bill gives sponsors a period in which they can recoup research and development costs without competition.

In certain circumstances, the Secretary can approve or conditionally approve a new animal drug during the exclusivity period for the same use for which the designated new animal drug was approved. One circumstance is when the Secretary finds that at any time during the exclusivity period the holder of the approved application cannot assure the availability of sufficient quantities of the drug to meet the need for the drug. The Secretary must provide the holder of the approved application with notice and an opportunity for submission of views before taking this action. A second circumstance is when the holder of the approved application gives written consent to the Secretary for the approval or conditional approval of other applications before the expiration of the exclusivity period.

Sec. 5. Conforming amendments

This section makes conforming amendments to the FFDCA. An amendment to section 201(v) of the FFDCA makes any drug intended for minor uses or for use in minor species animals a new animal drug unless it is the subject of a final regulation issued by the Secretary finding that the drug: (1) is generally recognized as safe and effective for use under the conditions prescribed, recommended, or suggested in the drug's labeling and has been used to a material extent and for a material time under such conditions; or (2) has been "grandfathered" under the provisions of section 201(v)(1) of the FFDCA or section 108 of Public Law 90–399. The purpose of this provision is to facilitate enforcement actions against illegally-marketed minor use or minor species animal drugs. A major disincentive to the submission of NADAs for minor uses and minor species is a prospective sponsor's knowledge that due to limited resources the Secretary is unable to pursue enforcement actions against all firms that market competing illegal animal drugs. Under the Act, as amended, the Secretary will be able to show that such a product is an unapproved new animal drug by demonstrating that it is not approved, conditionally approved, indexed, or the subject of a final regulation finding that it meets the criteria of section 201(v) of the FFDCA for the use or uses for which it is intended. This will allow the Secretary to remove from the market in a timely manner unapproved products marketed for the same claim as approved or indexed products.

An amendment to section 502 of the FFDCA adds new subsection (u). New section 502(u) deems any conditionally-approved new ani-

mal drug misbranded if its labeling does not conform to its approved application or does not bear the statements required under new section 571(f). A new animal drug is also deemed misbranded if its labeling bears the statement set forth in new section 571(f)(1)(A) saying it is conditionally approved when it is not conditionally approved. An indexed drug is deemed misbranded if its labeling does not conform to its index listing or does not bear the statements required under new section 572(h). A drug is also deemed misbranded if its labeling bears the statement set forth in new section 572(h) saying it is indexed when it is not.

Amendments to sections 503 and 504 of the FFDCA describe when new animal drugs that are conditionally approved or indexed must be approved as prescription or veterinary feed directive drugs, respectively.

Amendments to section 512(a)(1) and (2) of the FFDCA provide for lawful marketing of conditionally-approved new animal drugs and animal feed bearing or containing conditionally-approved new animal drugs, and of indexed new animal drugs and animal feed bearing or containing indexed new animal drugs. Any new animal drug or feed bearing or containing a new animal drug that is not approved, conditionally approved, or listed in the index is deemed unsafe and would therefore be adulterated.

An amendment to section 512(d)(4) of the FFDCA clarifies that a new animal drug that has been individually conditionally approved may not be approved for use in combination under this section, either in combination with a fully-approved drug, or with another conditionally-approved drug. Section 512(d)(4) of the FFDCA provides a modified approval process for certain combinations of new animal drugs that were previously separately approved under section 512. One of the underlying bases for permitting use of the modified combination approval process is that the individual drugs to be used in combination have been shown to be safe and effective for their intended uses. Conditionally-approved new animal drugs do not qualify because they have not been demonstrated by substantial evidence to be effective. An amendment to section 512(m)(1)(C) of the FFDCA describes the conditions that must be met for the use of indexed drugs in medicated feeds.

Sec. 6. Regulations

This section requires FDA to issue proposed and final implementing regulations. Section 571, conditional approval, and section 573, designation, will be implemented immediately upon the enactment of this legislation. FDA cannot implement section 572, indexing, of the FFDCA until final regulations become effective.

Sec. 7. Office

This section establishes an Office of Minor Use and Minor Species Animal Drug Development, reporting directly to the Director of the Center for Veterinary Medicine of FDA. This office will be responsible for designating minor use and minor species animal drugs, for administering grants and contracts under section 573 of the FFDCA, for reviewing minor species drug index listing requests, and for serving as liaison to other government agencies interested in minor use and minor species animal drug development. This office is not responsible for reviewing minor use or minor spe-

cies approval or conditional approval applications. This section also authorizes the appropriation of 1.2 million dollars for this office for the first year, to be adjusted to meet actual needs for subsequent years.

Sec. 8. Authorization of appropriations

This section provides authorization for the appropriation of funds to carry out section 573(b). This will provide funding for grants for designated new animal drugs for minor species and minor uses.

TITLE II

Sec. 201. Short title of title II

The "Food Allergen Labeling and Consumer Protection Act of 2003."

Sec. 202. Findings

Establishes a series of findings, which point to the critical need for plain English food allergen labeling on packaged food products.

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

Amends section 201 of the FFDCA to define the term "major food allergen" to mean one of the 8 major food allergens (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) and any food that contains a protein derived from one of these eight food allergens, except highly refined oils, ingredients derived from highly refined oils, and other food ingredients that are exempt from the labeling under this legislation.

Section 203 amends section 403 of the FFDCA to provide that a food is misbranded 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 its label identifies the ingredient that is or that bears or contains the major food allergen. This information is required to appear consistently within each such food's label in one of two ways, either within the ingredient list in parentheses after the first ingredient that contains the allergen, or in summary form at the end of, or immediately adjacent to, the ingredient list. Section 203 requires that food ingredient statements identify in one of these ways when a major food allergen is used in flavorings, colorings, or incidental additives. All foods, other than raw agricultural commodities, that contain ingredients that are, or that bear or contain, major food allergens must be labeled by January 1, 2006. Section 203 also amends section 403A of the FFDCA to give the allergen labeling the same preemptive effect over State and local ingredient labeling as current ingredient labeling.

Section 203 provides that FDA has the authority to require by regulation appropriate labeling of any spice, flavoring, coloring, or incidental additive that is, or that bears or contains, a food allergen that is not a major food allergen. Section 203 also provides that this regulatory exception to the current labeling exemption for spices, flavorings, colorings, and incidental additives has the same preemptive effect over State and local labeling requirements as the current exemption. In addition, section 203 provides that the

amendments made by it do not otherwise alter FDA's authority to require the labeling of other food allergens that are not major food allergens.

Section 204. Report on food allergens

Requires the Secretary to issue a report to Congress not later than 18 months after the date of enactment of this Act, analyzing the ways in which foods, during manufacturing and processing, can be unintentionally contaminated with major food allergens (cross-contact); estimating how common these practices are; advising whether methods can be used to reduce or eliminate cross-contact of foods with the major food allergens; describing the types of advisory labeling used by the food industry, the conditions of manufacture associated with use of advisory labeling, and the extent of use of advisory labeling; determining how consumers with food allergies or the caretakers of consumers would prefer information about the risk of cross-contact be communicated on food labels; stating the number of inspections of food manufacturing and processing facilities conducted in the previous 2 years and discussing the findings of these inspections; and assessing the extent to which cross-contact issues have been addressed by the Secretary and the food industry.

Section 205. Inspections relating to food allergens

Requires the Secretary to conduct inspections under its existing authority under Section 704 to ensure that food facilities comply with practices to reduce or eliminate cross-contact of a food with major food allergen residues and that food allergens are properly labeled.

Sec. 206. Gluten labeling

Requires the Secretary to issue a proposed rule no later than 2 years, and a final rule no later than 4 years, after the date of enactment of this legislation to define, and permit the use of, the term "gluten-free" on the labeling of foods.

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

Requires the CDC to improve the collection of 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, and publish it as it becomes available. Section 207 authorizes the appropriation of such sums as may be necessary to carry out its purposes.

Sec. 208. Food allergies research

Directs the NIH to convene a panel of nationally recognized experts in allergy and immunology to review current basic and clinical research efforts related to food allergies and to make recommendations—which the Secretary will make public—to enhance and coordinate research activities concerning food allergies not later than 1 year after the date of enactment of the legislation.

Sec. 209. Food allergens in the Food Code

Directs the Secretary, in the Conference for Food Protection, as part of its cooperative activities between the States under section 311 of the Public Health Service Act, 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.

Sec. 210. Recommendations regarding responding to food-related allergic responses

Directs the Secretary to provide technical assistance relating to the use of different modes of treatment for and prevention of allergic responses to foods when it provides technical assistance relating to trauma care and emergency medical services under section 1202(b)(3) of the Public Health Service Act.

IX. CHANGES IN EXISTING LAW

In compliance with rule XXVI paragraph 12 of the Standing Rules of the Senate, the following provides a print of the statute or the part or section thereof to be amended or replaced (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italic, 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)(1) * * *

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

(v) * * *

* * * * * * *

(2) * * *

* * * * * * *

Provided that any drug intended for minor use or use in a minor species that is not the subject of a final regulation published by the Secretary through notice and comment rulemaking finding that the criteria of paragraphs (1) and (2) have not been met (or that the exception to the criterion in paragraph (1) has been met) is a new animal drug.

* * * * * * *

(mm)(1) * * *

(2) * * *

(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] *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.

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FOOD ALLERGEN LABELING AND CONSUMER PROTECTION ACT OF 2003

* * * * * * *

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 same 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) * * *

* * * * * * *

(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

ADULTERATED DRUGS AND DEVICES

SEC. 501. A drug or device shall be deemed to be adulterated—
(a)(1) * * *

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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 751 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] *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] *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)] *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).

* * * * * * *

(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)] *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)] *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 for 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) * * *

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(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.

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(c)(1) * * *

(2)(A) * * *

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(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 bioequivalance 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 sup-

plement 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.

(iv) * * *

(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) * * *

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(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—

* * * * * * *

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

* * * * * * *

(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] *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)] *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)] *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 experience, 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) * * *

(A) * * *

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(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)] *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—

* * * * * * *

(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 iden-

tified in the application filed under [subsection (b)(1)] *subsection (b)(1) or section 571(a)*, and

* * * * * * *

SEC. 564. AUTHORIZATION FOR MEDICAL PRODUCTS FOR USE IN EMERGENCIES.

(a) IN GENERAL.—

(1) EMERGENCY USES.— * * *

* * * * * * *

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

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

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

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

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

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

(C) data for establishing a conditional dose;

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

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

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

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

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

(B) the person has previously filed an application for conditional approval under paragraph (1) for the same drug in the same dosage form for the same intended use whether or not subsequently conditionally approved by the Secretary under subsection (b), or

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

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

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

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

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

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

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

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

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

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

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

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

the Secretary determines before the expiration of the 1-year period or the 90-day extension that—

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

(B) the request fails to contain sufficient information 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 extensions, 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 approved or conditionally approved new animal drug for the minor species in question;

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

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

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

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

(B) operates external to FDA; and

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

The Secretary shall define the criteria for section of a qualified expert panel and the procedure 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 informal 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 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 be-

fore 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 "manufactured 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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Public Law 90–399—July 13, 1968

EFFECTIVE DATE AND TRANSITIONAL PROVISIONS

SEC. 108. (a) * * *

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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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