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## AN ACT

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

1       *Be it enacted by the Senate and House of Representa-*  
2       *tives of the United States of America in Congress assembled,*

3       **TITLE I—MINOR USE AND MINOR**  
4       **SPECIES HEALTH**

5       **SECTION 101. SHORT TITLE.**

6       This title may be cited as the “Minor Use and Minor  
7       Species Animal Health Act of 2004”.

1 **SEC. 102. MINOR USE AND MINOR SPECIES ANIMAL**  
2 **HEALTH.**

3 (a) FINDINGS.—Congress makes the following find-  
4 ings:

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

7 (2) There is a severe shortage of approved new  
8 animal drugs for treating animal diseases and condi-  
9 tions that occur infrequently or in limited geographic  
10 areas.

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

16 (4) Because the populations for which such new  
17 animal drugs are intended may be small and condi-  
18 tions of animal management may vary widely, it is  
19 often difficult to design and conduct studies to es-  
20 tablish drug safety and effectiveness under tradi-  
21 tional new animal drug approval processes.

22 (5) It is in the public interest and in the inter-  
23 est of animal welfare to provide for special proce-  
24 dures to allow the lawful use and marketing of cer-  
25 tain new animal drugs for minor species and minor  
26 uses that take into account these special cir-

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

3            (6) Exclusive marketing rights for clinical test-  
 4        ing expenses have helped encourage the development  
 5        of “orphan” drugs for human use, and comparable  
 6        incentives should encourage the development of new  
 7        animal drugs for minor species and minor uses.

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

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

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

16        “(oo) The term ‘minor species’ means animals other  
 17        than humans that are not major species.

18        “(pp) The term ‘minor use’ means the intended use  
 19        of a drug in a major species for an indication that occurs  
 20        infrequently and in only a small number of animals or in  
 21        limited geographical areas and in only a small number of  
 22        animals annually.”.

23            (2) THREE-YEAR EXCLUSIVITY FOR MINOR USE  
 24        AND MINOR SPECIES APPROVALS.—Section  
 25        512(c)(2)(F) (ii), (iii), and (v) of the Federal Food,

1 Drug, and Cosmetic Act is amended by striking  
2 “(other than bioequivalence or residue studies)” and  
3 inserting “(other than bioequivalence studies or res-  
4 idue depletion studies, except residue depletion stud-  
5 ies for minor uses or minor species)” every place it  
6 appears.

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

12 “(5) In reviewing an application that proposes  
13 a change to add an intended use for a minor use or  
14 a minor species to an approved new animal drug ap-  
15 plication, the Secretary shall reevaluate only the rel-  
16 evant information in the approved application to de-  
17 termine whether the application for the minor use or  
18 minor species can be approved. A decision to ap-  
19 prove the application for the minor use or minor  
20 species is not, implicitly or explicitly, a reaffirmation  
21 of the approval of the original application.”.

22 (4) MINOR USE AND MINOR SPECIES NEW ANI-  
23 MAL DRUGS.—Chapter V of the Federal Food, Drug,  
24 and Cosmetic Act (21 U.S.C. 351 et seq.) is amend-  
25 ed by adding at the end the following:

1 **“Subchapter F—New Animal Drugs for Minor**  
2 **Use and Minor Species**

3 **“SEC. 571. CONDITIONAL APPROVAL OF NEW ANIMAL**  
4 **DRUGS FOR MINOR USE AND MINOR SPECIES.**

5 “(a)(1) Except as provided in paragraph (3) of this  
6 section, any person may file with the Secretary an applica-  
7 tion for conditional approval of a new animal drug in-  
8 tended for a minor use or a minor species. Such an appli-  
9 cation may not be a supplement to an application ap-  
10 proved under section 512. Such application must comply  
11 in all respects with the provisions of section 512 of this  
12 Act except sections 512(a)(4), 512(b)(2), 512(c)(1),  
13 512(c)(2), 512(c)(3), 512(d)(1), 512(e), 512(h), and  
14 512(n) unless otherwise stated in this section, and any ad-  
15 ditional provisions of this section. New animal drugs are  
16 subject to application of the same safety standards that  
17 would be applied to such drugs under section 512(d) (in-  
18 cluding, for antimicrobial new animal drugs, with respect  
19 to antimicrobial resistance).

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

23 “(A) all information necessary to meet the re-  
24 quirements of section 512(b)(1) except section  
25 512(b)(1)(A);

1           “(B) full reports of investigations which have  
2           been made to show whether or not such drug is safe  
3           under section 512(d) (including, for an antimicrobial  
4           new animal drug, with respect to antimicrobial re-  
5           sistance) and there is a reasonable expectation of ef-  
6           fectiveness for use;

7           “(C) data for establishing a conditional dose;

8           “(D) projections of expected need and the jus-  
9           tification for that expectation based on the best in-  
10          formation available;

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

14          “(F) a commitment that the applicant will con-  
15          duct additional investigations to meet the require-  
16          ments for the full demonstration of effectiveness  
17          under section 512(d)(1)(E) within 5 years.

18          “(3) A person may not file an application under para-  
19          graph (1) if—

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

23               “(B) the person has previously filed an applica-  
24               tion for conditional approval under paragraph (1)  
25               for the same drug in the same dosage form for the

1 same intended use whether or not subsequently con-  
2 ditionally approved by the Secretary under sub-  
3 section (b), or

4 “(C) the person obtained the application, or  
5 data or other information contained therein, directly  
6 or indirectly from the person who filed for condi-  
7 tional approval under paragraph (1) for the same  
8 drug in the same dosage form for the same intended  
9 use whether or not subsequently conditionally ap-  
10 proved by the Secretary under subsection (b).

11 “(b) Within 180 days after the filing of an applica-  
12 tion pursuant to subsection (a), or such additional period  
13 as may be agreed upon by the Secretary and the applicant,  
14 the Secretary shall either—

15 “(1) issue an order, effective for one year, con-  
16 ditionally approving the application if the Secretary  
17 finds that none of the grounds for denying condi-  
18 tional approval, specified in subsection (c) of this  
19 section applies and publish a Federal Register notice  
20 of the conditional approval, or

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

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

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

3           “(2) the information submitted to the Secretary  
4           as part of the application and any other information  
5           before the Secretary with respect to such drug, is in-  
6           sufficient to show that there is a reasonable expecta-  
7           tion that the drug will have the effect it purports or  
8           is represented to have under the conditions of use  
9           prescribed, recommended, or suggested in the pro-  
10          posed labeling thereof; or

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

17 the Secretary shall issue an order refusing to conditionally  
18 approve the application. If, after such notice and oppor-  
19 tunity for an informal hearing, the Secretary finds that  
20 paragraphs (1) through (3) do not apply, the Secretary  
21 shall issue an order conditionally approving the application  
22 effective for one year and publish a Federal Register no-  
23 tice of the conditional approval. Any order issued under  
24 this subsection refusing to conditionally approve an appli-  
25 cation shall state the findings upon which it is based.



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

9               “(1) No later than 90 days from the end of the  
10       1-year period for which the original or renewed con-  
11       ditional approval is effective, the applicant may sub-  
12       mit a request to renew a conditional approval for an  
13       additional 1-year term.

14              “(2) A conditional approval shall be deemed re-  
15       newed at the end of the 1-year period, or at the end  
16       of a 90-day extension that the Secretary may, at the  
17       Secretary’s discretion, grant by letter in order to  
18       complete review of the renewal request, unless the  
19       Secretary determines before the expiration of the 1-  
20       year period or the 90-day extension that—

21                   “(A) the applicant failed to submit a time-  
22       ly renewal request;

23                   “(B) the request fails to contain sufficient  
24       information to show that—

1 “(i) the applicant is making sufficient  
2 progress toward meeting approval require-  
3 ments under section 512(d)(1)(E), and is  
4 likely to be able to fulfill those require-  
5 ments and obtain an approval under sec-  
6 tion 512 before the expiration of the 5-year  
7 maximum term of the conditional approval;

8 “(ii) the quantity of the drug that has  
9 been distributed is consistent with the con-  
10 ditionally approved intended use and condi-  
11 tions of use, unless there is adequate ex-  
12 planation that ensures that the drug is  
13 only used for its intended purpose; or

14 “(iii) the same drug in the same dos-  
15 age form for the same intended use has  
16 not received approval under section 512, or  
17 if such a drug has been approved, that the  
18 holder of the approved application is un-  
19 able to assure the availability of sufficient  
20 quantities of the drug to meet the needs  
21 for which the drug is intended; or

22 “(C) any of the provisions of section  
23 512(e)(1) (A) through (B) or (D) through (F)  
24 are applicable.

1           “(3) If the Secretary determines before the end  
2           of the 1-year period or the 90-day extension, if  
3           granted, that a conditional approval should not be  
4           renewed, the Secretary shall issue an order refusing  
5           to renew the conditional approval, and such condi-  
6           tional approval shall be deemed withdrawn and no  
7           longer in effect. The Secretary shall thereafter pro-  
8           vide an opportunity for an informal hearing to the  
9           applicant on the issue whether the conditional ap-  
10          proval shall be reinstated.

11          “(e)(1) The Secretary shall issue an order with-  
12       drawing conditional approval of an application filed pursu-  
13       ant to subsection (a) if the Secretary finds that another  
14       person has received approval under section 512 for the  
15       same drug in the same dosage form for the same intended  
16       use and that person is able to assure the availability of  
17       sufficient quantities of the drug to meet the needs for  
18       which the drug is intended.

19          “(2) The Secretary shall, after due notice and oppor-  
20       tunity for an informal hearing to the applicant, issue an  
21       order withdrawing conditional approval of an application  
22       filed pursuant to subsection (a) if the Secretary finds  
23       that—

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

4           “(B) on the basis of new information before the  
5           Secretary with respect to such drug, evaluated to-  
6           gether with the evidence available to the Secretary  
7           when the application was conditionally approved,  
8           that there is not a reasonable expectation that such  
9           drug will have the effect it purports or is rep-  
10          resented to have under the conditions of use pre-  
11          scribed, recommended, or suggested in the labeling  
12          thereof.

13          “(3) The Secretary may also, after due notice and  
14          opportunity for an informal hearing to the applicant, issue  
15          an order withdrawing conditional approval of an applica-  
16          tion filed pursuant to subsection (a) if the Secretary finds  
17          that any of the provisions of section 512(e)(2) are applica-  
18          ble.

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

21                 “(A) bear the statement, ‘conditionally ap-  
22                 proved by FDA pending a full demonstration of ef-  
23                 fectiveness under application number’; and

24                 “(B) contain such other information as pre-  
25                 scribed by the Secretary.

1       “(2) An intended use that is the subject of a condi-  
2       tional approval under this section shall not be included  
3       in the same product label with any intended use approved  
4       under section 512.

5       “(g) A conditionally approved new animal drug appli-  
6       cation may not be amended or supplemented to add indi-  
7       cations for use.

8       “(h) 180 days prior to the termination date estab-  
9       lished under subsection (d) of this section, an applicant  
10      shall have submitted all the information necessary to sup-  
11      port a complete new animal drug application in accordance  
12      with section 512(b)(1) or the conditional approval issued  
13      under this section is no longer in effect. Following review  
14      of this information, the Secretary shall either—

15               “(1) issue an order approving the application  
16              under section 512(c) if the Secretary finds that none  
17              of the grounds for denying approval specified in sec-  
18              tion 512(d)(1) applies, or

19               “(2) give the applicant an opportunity for a  
20              hearing before the Secretary under section 512(d)  
21              on the question whether such application can be ap-  
22              proved.

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

1 issued an order under section 512(c) approving such appli-  
 2 cation prior to the termination date established under sub-  
 3 section (d) of this section, the conditional approval issued  
 4 under this section is no longer in effect unless the Sec-  
 5 retary grants an extension of an additional 180-day period  
 6 so that the Secretary can complete review of the applica-  
 7 tion. The decision to grant an extension is committed to  
 8 the discretion of the Secretary and not subject to judicial  
 9 review.

10 “(i) The decision of the Secretary under subsection  
 11 (c), (d), or (e) of this section refusing or withdrawing con-  
 12 ditional approval of an application shall constitute final  
 13 agency action subject to judicial review.

14 “(j) In this section and section 572, the term  
 15 ‘transgenic animal’ means an animal whose genome con-  
 16 tains a nucleotide sequence that has been intentionally  
 17 modified in vitro, and the progeny of such an animal; Pro-  
 18 vided that the term ‘transgenic animal’ does not include  
 19 an animal of which the nucleotide sequence of the genome  
 20 has been modified solely by selective breeding.

21 **“SEC. 572. INDEX OF LEGALLY MARKETING UNAPPROVED**  
 22 **NEW ANIMAL DRUGS FOR MINOR SPECIES.**

23 “(a)(1) The Secretary shall establish an index limited  
 24 to—

1           “(A) new animal drugs intended for use in a  
2       minor species for which there is a reasonable cer-  
3       tainty that the animal or edible products from the  
4       animal will not be consumed by humans or food-pro-  
5       ducing animals; and

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

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

16          “(b) Any person intending to file a request under this  
17      section shall be entitled to one or more conferences to dis-  
18      cuss the requirements for indexing a new animal drug.

19          “(c)(1) Any person may submit a request to the Sec-  
20      retary for a determination whether a new animal drug  
21      may be eligible for inclusion in the index. Such a request  
22      shall include—

23           “(A) information regarding the need for the  
24      new animal drug, the species for which the new ani-  
25      mal drug is intended, the proposed intended use and

1 conditions of use, and anticipated annual distribu-  
2 tion;

3 “(B) information to support the conclusion that  
4 the proposed use meets the conditions of subpara-  
5 graph (A) or (B) of subsection (a)(1) of this section;

6 “(C) information regarding the components and  
7 composition of the new animal drug;

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

11 “(E) an environmental assessment that meets  
12 the requirements of the National Environmental Pol-  
13 icy Act of 1969, as amended, and as defined in 21  
14 CFR Part 25, as it appears on the date of enact-  
15 ment of this provision and amended thereafter or in-  
16 formation to support a categorical exclusion from  
17 the requirement to prepare an environmental assess-  
18 ment;

19 “(F) information sufficient to support the con-  
20 clusion that the proposed use of the new animal  
21 drug is safe under section 512(d) with respect to in-  
22 dividuals exposed to the new animal drug through  
23 its manufacture or use; and



1           “(G) such other information as the Secretary  
2           may deem necessary to make this eligibility deter-  
3           mination.

4           “(2) Within 90 days after the submission of a request  
5           for a determination of eligibility for indexing based on sub-  
6           section (a)(1)(A) of this section, or 180 days for a request  
7           submitted based on subsection (a)(1)(B) of this section,  
8           the Secretary shall grant or deny the request, and notify  
9           the person who requested such determination of the Sec-  
10          retary’s decision. The Secretary shall grant the request if  
11          the Secretary finds that—

12           “(A) the same drug in the same dosage form  
13           for the same intended use is not approved or condi-  
14           tionally approved;

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

18           “(C) the person requesting the determination  
19           has established appropriate specifications for the  
20           manufacture and control of the new animal drug  
21           and has demonstrated an understanding of the re-  
22           quirements of current good manufacturing practices;

23           “(D) the new animal drug will not significantly  
24           affect the human environment; and

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

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

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

15           “(A) a copy of the Secretary’s determination of  
16 eligibility issued under subsection (c);

17           “(B) a written report that meets the require-  
18 ments in subsection (d)(2) of this section;

19           “(C) a proposed index entry;

20           “(D) facsimile labeling;

21           “(E) anticipated annual distribution of the new  
22 animal drug;

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

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

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

6               “(H) upon specific request of the Secretary, in-  
7       formation submitted to the expert panel described in  
8       paragraph (3); and

9               “(I) any additional requirements that the Sec-  
10      retary may prescribe by general regulation or spe-  
11      cific order.

12      “(2) The report required in paragraph (1) shall—

13              “(A) be authored by a qualified expert panel;

14              “(B) include an evaluation of all available tar-  
15      get animal safety and effectiveness information, in-  
16      cluding anecdotal information;

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

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

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

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

7           “(A) is composed of experts qualified by sci-  
8           entific training and experience to evaluate the target  
9           animal safety and effectiveness of the new animal  
10          drug under consideration;

11          “(B) operates external to FDA; and

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

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

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

1 target animal, taking into account the harm caused by the  
2 absence of an approved or conditionally-approved new ani-  
3 mal drug for the minor species in question. If the Sec-  
4 retary denies the request, the Secretary shall thereafter  
5 provide due notice and the opportunity for an informal  
6 conference. The decision of the Secretary following an in-  
7 formal conference shall constitute final agency action sub-  
8 ject to judicial review.

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

12 “(A) the name and address of the person who  
13 holds the index listing;

14 “(B) the name of the drug and the intended  
15 use and conditions of use for which it is being in-  
16 dexed;

17 “(C) product labeling; and

18 “(D) conditions and any limitations that the  
19 Secretary deems necessary regarding use of the  
20 drug.

21 “(2) The Secretary shall publish the index, and revise  
22 it periodically.

23 “(3) The Secretary may establish by regulation a  
24 process for reporting changes in the conditions of manu-  
25 facturing or labeling of indexed products.

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

4           “(A) the expert panel failed to meet the re-  
5 quirements as set forth by the Secretary by regula-  
6 tion;

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

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

15          “(D) the manufacture of the new animal drug  
16 is not in accordance with current good manufac-  
17 turing practices;

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

21          “(F) the conditions and limitations of use asso-  
22 ciated with the index listing have not been followed;  
23 or

24          “(G) the request for indexing contains any un-  
25 true statement of material fact,

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

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

9 “(A) suspend the listing of such drug imme-  
10 diately;

11 “(B) give the person listed in the index prompt  
12 notice of the Secretary’s action; and

13 “(C) afford that person the opportunity for an  
14 informal conference.

15 The decision of the Secretary following an informal con-  
16 ference shall constitute final agency action subject to judi-  
17 cial review.

18 “(g) For purposes of indexing new animal drugs  
19 under this section, to the extent consistent with the public  
20 health, the Secretary shall promulgate regulations for ex-  
21 empting from the operation of section 512 minor species  
22 new animal drugs and animal feeds bearing or containing  
23 new animal drugs intended solely for investigational use  
24 by experts qualified by scientific training and experience  
25 to investigate the safety and effectiveness of minor species

1 animal drugs. Such regulations may, at the discretion of  
2 the Secretary, among other conditions relating to the pro-  
3 tection of the public health, provide for conditioning such  
4 exemption upon the establishment and maintenance of  
5 such records, and the making of such reports to the Sec-  
6 retary, by the manufacturer or the sponsor of the inves-  
7 tigation of such article, of data (including but not limited  
8 to analytical reports by investigators) obtained as a result  
9 of such investigational use of such article, as the Secretary  
10 finds will enable the Secretary to evaluate the safety and  
11 effectiveness of such article in the event of the filing of  
12 a request for an index listing pursuant to this section.

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

16 “(1) ‘NOT APPROVED BY FDA.—Legally mar-  
17 keted as an FDA indexed product. Extra-label use  
18 is prohibited.’;

19 “(2) except in the case of new animal drugs in-  
20 dexed for use in an early life stage of a food-pro-  
21 ducing animal, ‘This product is not to be used in  
22 animals intended for use as food for humans or  
23 other animals.’; and

24 “(3) such other information as may be pre-  
25 scribed by the Secretary in the index listing.



1       “(i)(1) In the case of any new animal drug for which  
2 an index listing pursuant to subsection (a) is in effect,  
3 the person who has an index listing shall establish and  
4 maintain such records, and make such reports to the Sec-  
5 retary, of data relating to experience, and other data or  
6 information, received or otherwise obtained by such person  
7 with respect to such drug, or with respect to animal feeds  
8 bearing or containing such drug, as the Secretary may by  
9 general regulation, or by order with respect to such listing,  
10 prescribe on the basis of a finding that such records and  
11 reports are necessary in order to enable the Secretary to  
12 determine, or facilitate a determination, whether there is  
13 or may be ground for invoking subsection (f). Such regula-  
14 tion or order shall provide, where the Secretary deems it  
15 to be appropriate, for the examination, upon request, by  
16 the persons to whom such regulation or order is applica-  
17 ble, of similar information received or otherwise obtained  
18 by the Secretary.

19       “(2) Every person required under this subsection to  
20 maintain records, and every person in charge or custody  
21 thereof, shall, upon request of an officer or employee des-  
22 ignated by the Secretary, permit such officer or employee  
23 at all reasonable times to have access to and copy and  
24 verify such records.

1       “(j)(1) Safety and effectiveness data and information  
2 which has been submitted in support of a request for a  
3 new animal drug to be indexed under this section and  
4 which has not been previously disclosed to the public shall  
5 be made available to the public, upon request, unless ex-  
6 traordinary circumstances are shown—

7               “(A) if no work is being or will be undertaken  
8 to have the drug indexed in accordance with the re-  
9 quest,

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

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

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

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

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

1 side the United States, the drug identified in the re-  
 2 quest for indexing; and

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

8 **“SEC. 573. DESIGNATED NEW ANIMAL DRUGS FOR MINOR**  
 9 **USE OR MINOR SPECIES.**

10 “(a) DESIGNATION.—

11 “(1) The manufacturer or the sponsor of a new  
 12 animal drug for a minor use or use in a minor spe-  
 13 cies may request that the Secretary declare that  
 14 drug a ‘designated new animal drug’. A request for  
 15 designation of a new animal drug shall be made be-  
 16 fore the submission of an application under section  
 17 512(b) or section 571 for the new animal drug.

18 “(2) The Secretary may declare a new animal  
 19 drug a ‘designated new animal drug’ if—

20 “(A) it is intended for a minor use or use  
 21 in a minor species; and

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

1           “(3) Regarding the termination of a designa-  
2           tion—

3                   “(A) the sponsor of a new animal drug  
4                   shall notify the Secretary of any decision to dis-  
5                   continue active pursuit of approval under sec-  
6                   tion 512 or 571 of an application for a des-  
7                   ignated new animal drug. The Secretary shall  
8                   terminate the designation upon such notifica-  
9                   tion;

10                   “(B) the Secretary may also terminate des-  
11                   ignation if the Secretary independently deter-  
12                   mines that the sponsor is not actively pursuing  
13                   approval under section 512 or 571 with due  
14                   diligence;

15                   “(C) the sponsor of an approved des-  
16                   ignated new animal drug shall notify the Sec-  
17                   retary of any discontinuance of the manufac-  
18                   ture of such new animal drug at least one year  
19                   before discontinuance. The Secretary shall ter-  
20                   minate the designation upon such notification;  
21                   and

22                   “(D) the designation shall terminate upon  
23                   the expiration of any applicable exclusivity pe-  
24                   riod under subsection (c).

1           “(4) Notice respecting the designation or termi-  
2           nation of designation of a new animal drug shall be  
3           made available to the public.

4           “(b) GRANTS AND CONTRACTS FOR DEVELOPMENT  
5 OF DESIGNATED NEW ANIMAL DRUGS.—

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

13          “(2) For purposes of paragraph (1) of this sec-  
14          tion—

15                 “(A) The term ‘qualified safety and effec-  
16                 tiveness testing’ means testing—

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

22                         “(ii) which is carried out under an in-  
23                         vestigational exemption under section  
24                         512(j).

1           “(B) The term ‘manufacturing expenses’  
2           means expenses incurred in developing proc-  
3           esses and procedures associated with manufac-  
4           ture of the designated new animal drug which  
5           occur after the new animal drug is designated  
6           under this section and before the date on which  
7           an application with respect to such new animal  
8           drug is submitted under section 512 or 571.

9           “(c) EXCLUSIVITY FOR DESIGNATED NEW ANIMAL  
10        DRUGS.—

11           “(1) Except as provided in subsection (c)(2), if  
12           the Secretary approves or conditionally approves an  
13           application for a designated new animal drug, the  
14           Secretary may not approve or conditionally approve  
15           another application submitted for such new animal  
16           drug with the same intended use as the designated  
17           new animal drug for another applicant before the ex-  
18           piration of seven years from the date of approval or  
19           conditional approval of the application.

20           “(2) If an application filed pursuant to section  
21           512 or section 571 is approved for a designated new  
22           animal drug, the Secretary may, during the 7-year  
23           exclusivity period beginning on the date of the appli-  
24           cation approval or conditional approval, approve or  
25           conditionally approve another application under sec-

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

“(A) the Secretary finds, after providing  
the holder of such an approved application no-  
tice and opportunity for the submission of  
views, that in the granted exclusivity period the  
holder of the approved application cannot as-  
sure 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 expira-  
tion of such exclusivity period.”.

(5) CONFORMING AMENDMENTS.—

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

(B) Section 201(v) of the Federal Food,  
Drug, and Cosmetic Act is amended by insert-  
ing the following after paragraph (2): “Pro-  
vided 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

1 through notice and comment rulemaking find-  
 2 ing that the criteria of paragraphs (1) and (2)  
 3 have not been met (or that the exception to the  
 4 criterion in paragraph (1) has been met) is a  
 5 new animal drug.”.

6 (C) Section 301(e) of the Federal Food,  
 7 Drug, and Cosmetic Act is amended by striking  
 8 “512(a)(4)(C), 512(j), (l) or (m)” and inserting  
 9 “512(a)(4)(C), 512 (j), (l) or (m), 572(i).”

10 (D) Section 301(j) of the Federal Food,  
 11 Drug, and Cosmetic Act is amended by striking  
 12 “520” and inserting “520, 571, 572, 573.”

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

16 “(w) If it is a new animal drug—

17 “(1) that is conditionally approved under sec-  
 18 tion 571 and its labeling does not conform with the  
 19 approved application or section 571(f), or that is not  
 20 conditionally approved under section 571 and its  
 21 label bears the statement set forth in section  
 22 571(f)(1)(A); or

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



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

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

5 (i) in paragraph (1)(A)(ii) by striking  
6 “512” and inserting “512, a conditionally-  
7 approved application under section 571, or  
8 an index listing under section 572”; and

9 (ii) in paragraph (3) by striking “sec-  
10 tion 512” and inserting “section 512, 571,  
11 or 572”.

12 (G) Section 504(a)(1) of the Federal Food,  
13 Drug, and Cosmetic Act is amended by striking  
14 “512(b)” and inserting “512(b), a condi-  
15 tionally-approved application filed pursuant to  
16 section 571, or an index listing pursuant to sec-  
17 tion 572”.

18 (H) Sections 504(a)(2)(B) and 504(b) of  
19 the Federal Food, Drug, and Cosmetic Act are  
20 amended by striking “512(i)” each place it ap-  
21 pears and inserting “512(i), or the index listing  
22 pursuant to section 572(e)”.

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

1 paragraphs (1) and (2) and inserting the fol-  
2 lowing:

3 “(1) A new animal drug shall, with respect to any  
4 particular use or intended use of such drug, be deemed  
5 unsafe for purposes of section 501(a)(5) and section  
6 402(a)(2)(C)(ii) unless—

7 “(A) there is in effect an approval of an appli-  
8 cation filed pursuant to subsection (b) with respect  
9 to such use or intended use of such drug, and such  
10 drug, its labeling, and such use conform to such ap-  
11 proved application;

12 “(B) there is in effect a conditional approval of  
13 an application filed pursuant to section 571 with re-  
14 spect to such use or intended use of such drug, and  
15 such drug, its labeling, and such use conform to  
16 such conditionally approved application; or

17 “(C) there is in effect an index listing pursuant  
18 to section 572 with respect to such use or intended  
19 use of such drug in a minor species, and such drug,  
20 its labeling, and such use conform to such index list-  
21 ing.

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

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

10 “(2) An animal feed bearing or containing a new ani-  
 11 mal drug shall, with respect to any particular use or in-  
 12 tended use of such animal feed be deemed unsafe for pur-  
 13 poses of section 501(a)(6) unless—

14 “(A) there is in effect—

15 “(i) an approval of an application filed  
 16 pursuant to subsection (b) with respect to such  
 17 drug, as used in such animal feed, and such  
 18 animal feed and its labeling, distribution, hold-  
 19 ing, and use conform to such approved applica-  
 20 tion;

21 “(ii) a conditional approval of an applica-  
 22 tion filed pursuant to section 571 with respect  
 23 to such drug, as used in such animal feed, and  
 24 such animal feed and its labeling, distribution,

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

3 “(iii) an index listing pursuant to section  
4 572 with respect to such drug, as used in such  
5 animal feed, and such animal feed and its label-  
6 ing, distribution, holding, and use conform to  
7 such index listing; and

8 “(B) such animal feed is manufactured at a site  
9 for which there is in effect a license issued pursuant  
10 to subsection (m)(1) to manufacture such animal  
11 feed.”.

12 (J) Section 512(b)(3) of the Federal Food,  
13 Drug, and Cosmetic Act is amended by striking  
14 “under paragraph (1) or a request for an inves-  
15 tigational exemption under subsection (j)” and  
16 inserting “under paragraph (1), section 571, or  
17 a request for an investigational exemption  
18 under subsection (j)”.

19 (K) Section 512(d)(4) of the Federal  
20 Food, Drug, and Cosmetic Act is amended by  
21 striking “have previously been separately ap-  
22 proved” and inserting “have previously been  
23 separately approved pursuant to an application  
24 submitted under section 512(b)(1)”.

1           (L) Section 512(f) of the Federal Food,  
2           Drug, and Cosmetic Act is amended by striking  
3           “subsection (d), (e), or (m)” and inserting  
4           “subsection (d), (e), or (m), or section 571 (c),  
5           (d), or (e)”.

6           (M) Section 512(g) of the Federal Food,  
7           Drug, and Cosmetic Act is amended by striking  
8           “this section” and inserting “this section, or  
9           section 571”.

10          (N) Section 512(i) of the Federal Food,  
11          Drug, and Cosmetic Act is amended by striking  
12          “subsection (b)” and inserting “subsection (b)  
13          or section 571” and by inserting “or upon fail-  
14          ure to renew a conditional approval under sec-  
15          tion 571” after “or upon its suspension”.

16          (O) Section 512(l)(1) of the Federal Food,  
17          Drug, and Cosmetic Act is amended by striking  
18          “subsection (b)” and inserting “subsection (b)  
19          or section 571”.

20          (P) Section 512(m)(1)(C) of the Federal  
21          Food, Drug, and Cosmetic Act is amended by  
22          striking “applicable regulations published pur-  
23          suant to subsection (i)” and inserting “applica-  
24          ble regulations published pursuant to subsection  
25          (i) or for indexed new animal drugs in accord-

1           ance with the index listing published pursuant  
 2           to section 572(e)(2) and the labeling require-  
 3           ments set forth in section 572(h)”.

4           (Q) Section 512(m)(3) of the Federal  
 5           Food, Drug, and Cosmetic Act is amended by  
 6           inserting “or an index listing pursuant to sec-  
 7           tion 572(e)” after “subsection (i)” each place it  
 8           appears.

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

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

17          (T) Section 108(b)(3) of Public Law 90–  
 18          399 is amended by striking “section 201(w) as  
 19          added by this Act” and inserting “section  
 20          201(v)”.

21          (6) REGULATIONS.—On the date of enactment  
 22          of this Act, the Secretary of Health and Human  
 23          Services shall implement sections 571 and 573 of  
 24          the Federal Food, Drug, and Cosmetic Act and sub-  
 25          sequently publish implementing regulations. Not

1 later than 12 months after the date of enactment of  
2 this Act, the Secretary shall issue proposed regula-  
3 tions to implement section 573 of the Federal Food,  
4 Drug, and Cosmetic Act (as added by this Act), and  
5 not later than 24 months after the date of enactment  
6 of this Act, the Secretary shall issue final regulations  
7 implementing section 573 of the Federal Food, Drug,  
8 and Cosmetic Act. Not later than 18 months after  
9 the date of enactment of this Act, the Secretary shall  
10 issue proposed regulations to implement section 572  
11 of the Federal Food, Drug, and Cosmetic Act (as  
12 added by this Act), and not later than 36 months  
13 after the date of enactment of this Act, the Secretary  
14 shall issue final regulations implementing section 572  
15 of the Federal Food, Drug, and Cosmetic Act. Not  
16 later than 30 months after the date of enactment of  
17 this Act, the Secretary shall issue proposed regula-  
18 tions to implement section 571 of the Federal Food,  
19 Drug, and Cosmetic Act (as added by this Act), and  
20 not later than 42 months after the date of enactment  
21 of this Act, the Secretary shall issue final regulations  
22 implementing section 571 of the Federal Food, Drug,  
23 and Cosmetic Act. These timeframes shall be ex-  
24 tended by 12 months for each fiscal year, in which

1 the funds authorized to be appropriated under sub-  
2 section (i) are not in fact appropriated.

3 (7) OFFICE.—The Secretary of Health and  
4 Human Services shall establish within the Center for  
5 Veterinary Medicine (of the Food and Drug Admin-  
6 istration), an Office of Minor Use and Minor Species  
7 Animal Drug Development that reports directly to  
8 the Director of the Center for Veterinary Medicine.  
9 This office shall be responsible for overseeing the de-  
10 velopment and legal marketing of new animal drugs  
11 for minor uses and minor species. There is author-  
12 ized to be appropriated to carry out this subsection  
13 \$1,200,000 for fiscal year 2004 and such sums as  
14 may be necessary for each fiscal year thereafter.

15 (8) AUTHORIZATION OF APPROPRIATIONS.—  
16 There is authorized to be appropriated to carry out  
17 section 573(b) of the Federal Food, Drug, and Cos-  
18 metic Act (as added by this section) \$1,000,000 for  
19 the fiscal year following publication of final imple-  
20 menting regulations, \$2,000,000 for the subsequent  
21 fiscal year, and such sums as may be necessary for  
22 each fiscal year thereafter.



1 **TITLE II—FOOD ALLERGEN LA-**  
2 **BELING AND CONSUMER PRO-**  
3 **TECTION**

4 **SEC. 201. SHORT TITLE.**

5 This title may be cited as the “Food Allergen Label-  
6 ing and Consumer Protection Act of 2004”.

7 **SEC. 202. FINDINGS.**

8 Congress finds that—

9 (1) it is estimated that—

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

14 (B) each year, roughly 30,000 individuals  
15 require emergency room treatment and 150 in-  
16 dividuals die because of allergic reactions to  
17 food;

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

22 (B) at present, there is no cure for food aller-  
23 gies; and

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

1           (3)(A) in a review of the foods of randomly se-  
2       lected manufacturers of baked goods, ice cream, and  
3       candy in Minnesota and Wisconsin in 1999, the  
4       Food and Drug Administration found that 25 per-  
5       cent of sampled foods failed to list peanuts or eggs  
6       as ingredients on the food labels; and

7           (B) nationally, the number of recalls because of  
8       unlabeled allergens rose to 121 in 2000 from about  
9       35 a decade earlier;

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

14          (5)(A) ingredients in foods must be listed by  
15       their “common or usual name”;

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

21          (C) in other cases, the ingredients may be de-  
22       clared as a class, including spices, flavorings, and  
23       certain colorings, or are exempt from the ingredient  
24       labeling requirements, such as incidental additives;  
25       and

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

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

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

10 **SEC. 203. FOOD LABELING; REQUIREMENT OF INFORMA-**  
 11 **TION REGARDING ALLERGENIC SUBSTANCES.**

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

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

18                   “(A) the word ‘Contains’, followed by the name  
 19                   of the food source from which the major food aller-  
 20                   gen is derived, is printed immediately after or is ad-  
 21                   jacent to the list of ingredients (in a type size no  
 22                   smaller than the type size used in the list of ingredi-  
 23                   ents) required under subsections (g) and (i); or

24                   “(B) the common or usual name of the major  
 25                   food allergen in the list of ingredients required under

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

5 “(i) the common or usual name of the in-  
6 gredient uses the name of the food source from  
7 which the major food allergen is derived; or

8 “(ii) the name of the food source from  
9 which the major food allergen is derived ap-  
10 pears elsewhere in the ingredient list, unless the  
11 name of the food source that appears elsewhere  
12 in the ingredient list appears as part of the  
13 name of a food ingredient that is not a major  
14 food allergen under section 201(qq)(2)(A) or  
15 (B).

16 “(2) As used in this subsection, the term ‘name of  
17 the food source from which the major food allergen is de-  
18 rived’ means the name described in section 201(qq)(1);  
19 provided that in the case of a tree nut, fish, or Crustacean  
20 shellfish, the term ‘name of the food source from which  
21 the major food allergen is derived’ means the name of the  
22 specific type of nut or species of fish or Crustacean shell-  
23 fish.

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

1 only if the Secretary finds that such other labeling is suffi-  
2 cient to protect the public health. A finding by the Sec-  
3 retary under this paragraph (including any change in an  
4 earlier finding under this paragraph) is effective upon  
5 publication in the Federal Register as a notice.

6 “(4) Notwithstanding subsection (g), (i), or (k), or  
7 any other law, a flavoring, coloring, or incidental additive  
8 that is, or that bears or contains, a major food allergen  
9 shall be subject to the labeling requirements of this sub-  
10 section.

11 “(5) The Secretary may by regulation modify the re-  
12 quirements of subparagraph (A) or (B) of paragraph (1),  
13 or eliminate either the requirement of subparagraph (A)  
14 or the requirements of subparagraph (B) of paragraph  
15 (1), if the Secretary determines that the modification or  
16 elimination of the requirement of subparagraph (A) or the  
17 requirements of subparagraph (B) is necessary to protect  
18 the public health.

19 “(6)(A) Any person may petition the Secretary to ex-  
20 empt a food ingredient described in section 201(qq)(2)  
21 from the allergen labeling requirements of this subsection.

22 “(B) The Secretary shall approve or deny such peti-  
23 tion within 180 days of receipt of the petition or the peti-  
24 tion shall be deemed denied, unless an extension of time

1 is mutually agreed upon by the Secretary and the peti-  
2 tioner.

3 “(C) The burden shall be on the petitioner to provide  
4 scientific evidence (including the analytical method used  
5 to produce the evidence) that demonstrates that such food  
6 ingredient, as derived by the method specified in the peti-  
7 tion, does not cause an allergic response that poses a risk  
8 to human health.

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

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

15 “(7)(A) A person need not file a petition under para-  
16 graph (6) to exempt a food ingredient described in section  
17 201(qq)(2) from the allergen labeling requirements of this  
18 subsection, if the person files with the Secretary a notifica-  
19 tion containing—

20 “(i) scientific evidence (including the analytical  
21 method used) that demonstrates that the food ingre-  
22 dient (as derived by the method specified in the noti-  
23 fication, where applicable) does not contain aller-  
24 genic protein; or

1           “(ii) a determination by the Secretary that the  
2           ingredient does not cause an allergic response that  
3           poses a risk to human health under a premarket ap-  
4           proval or notification program under section 409.

5           “(B) The food ingredient may be introduced or deliv-  
6           ered for introduction into interstate commerce as a food  
7           ingredient that is not a major food allergen 90 days after  
8           the date of receipt of the notification by the Secretary,  
9           unless the Secretary determines within the 90-day period  
10          that the notification does not meet the requirements of  
11          this paragraph, or there is insufficient scientific evidence  
12          to determine that the food ingredient does not contain al-  
13          lergenic protein or does not cause an allergenic response  
14          that poses a risk to human health.

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

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

1 (b) EFFECT ON OTHER AUTHORITY.—The amend-  
 2 ments made by this section that require a label or labeling  
 3 for major food allergens do not alter the authority of the  
 4 Secretary of Health and Human Services under the Fed-  
 5 eral Food, Drug, and Cosmetic Act (21 U.S.C. 301 et  
 6 seq.) to require a label or labeling for other food allergens.

7 (c) CONFORMING AMENDMENTS.—

8 (1) Section 201 of the Federal Food, Drug, and  
 9 Cosmetic Act (21 U.S.C. 321) (as amended by sec-  
 10 tion 102(b)) is amended by adding at the end the  
 11 following:

12 “(qq) The term ‘major food allergen’ means any of  
 13 the following:

14 “(1) Milk, egg, fish (e.g., bass, flounder, or  
 15 cod), Crustacean shellfish (e.g., crab, lobster, or  
 16 shrimp), tree nuts (e.g., almonds, pecans, or wal-  
 17 nuts), wheat, peanuts, and soybeans.

18 “(2) A food ingredient that contains protein de-  
 19 rived from a food specified in paragraph (1), except  
 20 the following:

21 “(A) Any highly refined oil derived from a  
 22 food specified in paragraph (1) and any ingre-  
 23 dient derived from such highly refined oil.

24 “(B) A food ingredient that is exempt  
 25 under paragraph (6) or (7) of section 403(w).”.



1           (2) Section 403A(a)(2) of the Federal Food,  
 2           Drug, and Cosmetic Act (21 U.S.C. 343–1(a)(2)) is  
 3           amended by striking “or 403(i)(2)” and inserting  
 4           “403(i)(2), 403(w), or 403(x)”.

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

8           **SEC. 204. REPORT ON FOOD ALLERGENS.**

9           Not later than 18 months after the date of enactment  
 10          of this Act, the Secretary of Health and Human Services  
 11          (in this section referred to as the “Secretary”) shall sub-  
 12          mit to the Committee on Health, Education, Labor, and  
 13          Pensions of the Senate and the Committee on Energy and  
 14          Commerce of the House of Representatives a report  
 15          that—

16               (1)(A) analyzes—

17                       (i) the ways in which foods, during manu-  
 18                       facturing and processing, are unintentionally  
 19                       contaminated with major food allergens, includ-  
 20                       ing contamination caused by the use by manu-  
 21                       facturers of the same production line to produce  
 22                       both products for which major food allergens  
 23                       are intentional ingredients and products for  
 24                       which major food allergens are not intentional  
 25                       ingredients; and

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

4           (B) estimates how common the practices de-  
5           scribed in subparagraph (A) are in the food indus-  
6           try, with breakdowns by food type as appropriate;

7           (2) advises whether good manufacturing prac-  
8           tices or other methods can be used to reduce or  
9           eliminate cross-contact of foods with the major food  
10          allergens;

11          (3) describes—

12               (A) the various types of advisory labeling  
13               (such as labeling that uses the words “may con-  
14               tain”) used by food producers;

15               (B) the conditions of manufacture of food  
16               that are associated with the various types of ad-  
17               visory labeling; and

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

20          (4) describes how consumers with food allergies  
21          or the caretakers of consumers would prefer that in-  
22          formation about the risk of cross-contact be commu-  
23          nicated on food labels as determined by using appro-  
24          priate survey mechanisms;

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

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

9           (B) the nature of the violations found; and

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

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

16 **SEC. 205. INSPECTIONS RELATING TO FOOD ALLERGENS.**

17       The Secretary of Health and Human Services shall  
18       conduct inspections consistent with the authority under  
19       section 704 of the Federal Food, Drug, and Cosmetic Act  
20       (21 U.S.C. 374) of facilities in which foods are manufac-  
21       tured, processed, packed, or held—

22          (1) to ensure that the entities operating the fa-  
23       cilities comply with practices to reduce or eliminate  
24       cross-contact of a food with residues of major food

1 allergens that are not intentional ingredients of the  
2 food; and

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

5 **SEC. 206. GLUTEN LABELING.**

6 Not later than 2 years after the date of enactment  
7 of this Act, the Secretary of Health and Human Services,  
8 in consultation with appropriate experts and stakeholders,  
9 shall issue a proposed rule to define, and permit use of,  
10 the term “gluten-free” on the labeling of foods. Not later  
11 than 4 years after the date of enactment of this Act, the  
12 Secretary shall issue a final rule to define, and permit use  
13 of, the term “gluten-free” on the labeling of foods.

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

16 (a) IN GENERAL.—The Secretary of Health and  
17 Human Services, acting through the Director of the Cen-  
18 ters for Disease Control and Prevention and in consulta-  
19 tion with the Commissioner of Food and Drugs, shall im-  
20 prove (including by educating physicians and other health  
21 care providers) the collection of, and publish as it becomes  
22 available, national data on—

23 (1) the prevalence of food allergies;

24 (2) the incidence of clinically significant or seri-  
25 ous adverse events related to food allergies; and

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

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

6   **SEC. 208. FOOD ALLERGIES RESEARCH.**

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

13          (b) RECOMMENDATIONS.—Not later than 1 year  
14          after the date of enactment of this Act, the panel shall  
15          make recommendations to the Secretary for enhancing  
16          and coordinating research activities concerning food aller-  
17          gies, which the Secretary shall make public.

18   **SEC. 209. FOOD ALLERGENS IN THE FOOD CODE.**

19          The Secretary of Health and Human Services shall,  
20          in the Conference for Food Protection, as part of its ef-  
21          forts to encourage cooperative activities between the  
22          States under section 311 of the Public Health Service Act  
23          (42 U.S.C. 243), pursue revision of the Food Code to pro-  
24          vide guidelines for preparing allergen-free foods in food  
25          establishments, including in restaurants, grocery store

1 delicatessens and bakeries, and elementary and secondary  
2 school cafeterias. The Secretary shall consider guidelines  
3 and recommendations developed by public and private en-  
4 tities for public and private food establishments for pre-  
5 paring allergen-free foods in pursuing this revision.

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

8       The Secretary of Health and Human Services shall,  
9 in providing technical assistance relating to trauma care  
10 and emergency medical services to State and local agencies  
11 under section 1202(b)(3) of the Public Health Service Act  
12 (42 U.S.C. 300d–2(b)(3)), include technical assistance re-  
13 lating to the use of different modes of treatment for and  
14 prevention of allergic responses to foods.



Union Calendar No. 366

108<sup>TH</sup> CONGRESS  
2<sup>D</sup> Session

**S. 741**

[Report No. 108–608]

**AN ACT**

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

JULY 15, 2004

Committed to the Committee of the Whole House on the State of the Union and ordered to be printed