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[Report No. 108-226]

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

IN THE SENATE OF THE UNITED STATES

MARCH 27, 2003

Mr. SESSIONS (for himself, Mr. BINGAMAN, Mr. GREGG, Mr. MILLER, Mr. ALLARD, Mrs. LINCOLN, Mr. ENSIGN, Ms. COLLINS, Mr. CRAPO, Mr. CRAIG, Mr. HARKIN, Mr. SHELBY, Mr. DOMENICI, Mr. ENZI, Mr. SMITH, Mrs. MURRAY, Mr. HATCH, Ms. LANDRIEU, Mr. WYDEN, Mr. PRYOR, and Mr. DURBIN) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

FEBRUARY 18, 2004

Reported under authority of the order of the Senate of February 12, 2004,
by Mr. GREGG, with an amendment

[Strike out all after the enacting clause and insert the part printed in italic]

A BILL

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,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Minor Use and Minor
3 Species Animal Health Act of 2003”.

4 **SEC. 2. FINDINGS.**

5 Congress makes the following findings:

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

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

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

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

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

1 uses that take into account these special cir-
2 cumstances and that ensure that such drugs do not
3 endanger animal or public health.

4 (6) Exclusive marketing rights and tax credits
5 for clinical testing expenses have helped encourage
6 the development of “orphan” drugs for human use,
7 and comparable incentives should encourage the de-
8 velopment of new animal drugs for minor species
9 and minor uses.

10 **SEC. 3. AMENDMENTS TO THE FEDERAL FOOD, DRUG, AND**
11 **COSMETIC ACT.**

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

15 “(kk) The term ‘major species’ means cattle, horses,
16 swine, chickens, turkeys, dogs, and cats, except that the
17 Secretary may revise this definition by regulation.

18 “(ll) The term ‘minor species’ means animals other
19 than humans that are not major species.

20 “(mm) The term ‘minor use’ means the intended use
21 of a drug in a major species for an indication that occurs
22 infrequently or in limited geographical areas.”

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

1 Act is amended by striking “(other than bioequivalence or
2 residue studies)” and inserting “(other than bioequiva-
3 lence studies or residue depletion studies, except residue
4 depletion studies for minor uses or minor species)” every
5 place it appears.

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

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

20 (d) MINOR USE AND MINOR SPECIES NEW ANIMAL
21 DRUGS.—Chapter V of the Federal Food, Drug, and Cos-
22 metic Act (21 U.S.C. 351 et seq.) is amended by adding
23 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(e)(1),
13 512(e)(2), 512(e)(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.

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

19 “(A) all information necessary to meet the re-
20 quirements of section 512(b)(1) except section
21 512(b)(1)(A);

22 “(B) full reports of investigations which have
23 been made to show whether or not such drug is safe
24 and there is a reasonable expectation of effectiveness
25 for use;

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

2 “(D) projections of expected need and the jus-
3 tification for that expectation based on the best in-
4 formation available;

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

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

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

14 “(A) the person has previously filed an applica-
15 tion for conditional approval under paragraph (1)
16 for the same drug in the same dosage form for the
17 same intended use whether or not subsequently con-
18 ditionally approved by the Secretary under sub-
19 section (b); or

20 “(B) the person obtained the application, or
21 data or other information contained therein, directly
22 or indirectly from the person who filed for condi-
23 tional approval under paragraph (1) for the same
24 drug in the same dosage form for the same intended

1 use whether or not subsequently conditionally ap-
2 proved by the Secretary under subsection (b).

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

7 “(1) issue an order, effective for one year, con-
8 ditionally approving the application if the Secretary
9 finds that none of the grounds for denying condi-
10 tional approval, specified in subsection (c) of this
11 section applies, or

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

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

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

19 “(2) the information submitted to the Secretary
20 as part of the application and any other information
21 before the Secretary with respect to such drug, is in-
22 sufficient to show that there is a reasonable expecta-
23 tion that the drug will have the effect it purports or
24 is represented to have under the conditions of use

1 prescribed, recommended, or suggested in the pro-
2 posed labeling thereof; or

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

9 the Secretary shall issue an order refusing to conditionally
10 approve the application. If, after such notice and oppor-
11 tunity for an informal hearing, the Secretary finds that
12 paragraphs (1) through (3) do not apply, the Secretary
13 shall issue an order conditionally approving the application
14 effective for one year. Any order issued under this sub-
15 section refusing to conditionally approve an application
16 shall state the findings upon which it is based.

17 ~~“(d) A conditional approval under this section is ef-~~
18 ~~fective for a 1-year period and is thereafter renewable by~~
19 ~~the Secretary annually for up to 4 additional 1-year terms.~~
20 ~~A conditional approval shall be in effect for no more than~~
21 ~~5 years from the date of approval under subsection (b)(1)~~
22 ~~or (c) of this section unless extended as provided for in~~
23 ~~subsection (h) of this section. The following shall also~~
24 ~~apply:~~

1 “(1) No later than 90 days from the end of the
2 1-year period for which the original or renewed con-
3 ditional approval is effective, the applicant may sub-
4 mit a request to renew a conditional approval for an
5 additional 1-year term.

6 “(2) A conditional approval shall be deemed re-
7 newed at the end of the 1-year period, or at the end
8 of a 90-day extension that the Secretary may, at the
9 Secretary’s discretion, grant by letter in order to
10 complete review of the renewal request, unless the
11 Secretary determines before the expiration of the 1-
12 year period or the 90-day extension that—

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

15 “(B) the request fails to contain sufficient
16 information to show that—

17 “(i) the applicant is making sufficient
18 progress toward meeting approval require-
19 ments under section 512(d)(1)(E), and is
20 likely to be able to fulfill those require-
21 ments and obtain an approval under sec-
22 tion 512 before the expiration of the 5-year
23 maximum term of the conditional approval;

24 “(ii) the quantity of the drug that has
25 been distributed is consistent with the con-

1 ditionally approved intended use and condi-
2 tions of use, unless there is adequate ex-
3 planation that ensures that the drug is
4 only used for its intended purpose; or

5 “~~(iii)~~ the same drug in the same dos-
6 age form for the same intended use has
7 not received approval under section 512, or
8 if such a drug has been approved, that the
9 holder of the approved application is un-
10 able to assure the availability of sufficient
11 quantities of the drug to meet the needs
12 for which the drug is intended; or

13 “~~(C)~~ any of the provisions of section
14 512(e)(1) ~~(A) through (B) or (D) through (F)~~
15 are applicable.

16 “~~(3)~~ If the Secretary determines before the end
17 of the 1-year period or the 90-day extension, if
18 granted, that a conditional approval should not be
19 renewed, the Secretary shall issue an order refusing
20 to renew the conditional approval, and such condi-
21 tional approval shall be deemed withdrawn and no
22 longer in effect. The Secretary shall thereafter pro-
23 vide an opportunity for an informal hearing to the
24 applicant on the issue whether the conditional ap-
25 proval shall be reinstated.

1 “(e)(1) The Secretary shall issue an order with-
2 drawing conditional approval of an application filed pursu-
3 ant to subsection (a) if the Secretary finds that another
4 person has received approval under section 512 for the
5 same drug in the same dosage form for the same intended
6 use and that person is able to assure the availability of
7 sufficient quantities of the drug to meet the needs for
8 which the drug is intended.

9 “(2) The Secretary shall, after due notice and oppor-
10 tunity for an informal hearing to the applicant, issue an
11 order withdrawing conditional approval of an application
12 filed pursuant to subsection (a) if the Secretary finds
13 that—

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

17 “(B) on the basis of new information before the
18 Secretary with respect to such drug, evaluated to-
19 gether with the evidence available to the Secretary
20 when the application was conditionally approved,
21 that there is not a reasonable expectation that such
22 drug will have the effect it purports or is rep-
23 resented to have under the conditions of use pre-
24 scribed, recommended, or suggested in the labeling
25 thereof.

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

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

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

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

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

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

21 “(h) 180 days prior to the termination date estab-
22 lished under subsection (d)(1) of this section, an applicant
23 shall have submitted all the information necessary to sup-
24 port a complete new animal drug application in accordance
25 with section 512(b)(1) or the conditional approval issued

1 under this section is no longer in effect. Following review
2 of this information, the Secretary shall either—

3 “(1) issue an order approving the application
4 under section 512(e) if the Secretary finds that none
5 of the grounds for denying approval specified in sec-
6 tion 512(d)(1) applies; or

7 “(2) give the applicant an opportunity for a
8 hearing before the Secretary under section 512(d)
9 on the question whether such application can be ap-
10 proved.

11 Upon issuance of an order approving the application,
12 product labeling and administrative records of approval
13 shall be modified accordingly. If the Secretary has not
14 issued an order under section 512(e) approving such appli-
15 cation prior to the termination date established under sub-
16 section (d)(1) of this section, the conditional approval
17 issued under this section is no longer in effect unless the
18 Secretary grants an extension of an additional 180-day pe-
19 riod so that the Secretary can complete review of the ap-
20 plication. The decision to grant an extension is committed
21 to the discretion of the Secretary and not subject to judi-
22 cial review.

23 “(i) The decision of the Secretary under subsection
24 (e), (d), or (c) of this section refusing or withdrawing con-

ditional approval of an application shall constitute final agency action subject to judicial review.

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

“(a) The Secretary shall establish an index of unapproved minor species new animal drugs that may be lawfully marketed for use in minor species. The index shall be limited to—

“(1) 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

“(2) new animal drugs intended for use in an early life stage of a food-producing minor species where human food safety can be demonstrated in accordance with the standard of section 512(d) by showing that—

“(A) there is no significant likelihood that harmful residues will be present in the animal or edible products from the animal presented as food for humans as a result of treatment at the early life stage;

“(B) there is no significant likelihood that harmful residues will be present in the animal

1 or edible products from the animal presented as
2 food for food-producing animals as a result of
3 treatment at the early life stage; and

4 “(C) there are no concerns about the use
5 of the drug at later life stages because a toler-
6 ance and regulatory method to test for the drug
7 at later life stages are available or there is no
8 practical use for the drug in later life stages.

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

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

16 “(A) information regarding the need for the
17 new animal drug; the species for which the new ani-
18 mal drug is intended; the proposed intended use and
19 conditions of use; and anticipated annual distribu-
20 tion;

21 “(B) information to support the conclusion that
22 the proposed use meets the conditions of subsection
23 (a)(1) or (a)(2) of this section;

24 “(C) information regarding the components and
25 composition of the new animal drug;

1 ~~“(D) a description of the methods used in, and~~
2 ~~the facilities and controls used for, the manufacture,~~
3 ~~processing, and packing of such new animal drug;~~

4 ~~“(E) an environmental assessment or informa-~~
5 ~~tion to support a categorical exclusion from the re-~~
6 ~~quirement to prepare an environmental assessment;~~

7 ~~“(F) information sufficient to support the con-~~
8 ~~clusion that the proposed use of the new animal~~
9 ~~drug does not present a threat to the safety of indi-~~
10 ~~viduals exposed to the new animal drug through its~~
11 ~~manufacture or use; and~~

12 ~~“(G) such other information as the Secretary~~
13 ~~may deem necessary to make this eligibility deter-~~
14 ~~mination.~~

15 ~~“(2) Within 90 days after the submission of a request~~
16 ~~for a determination of eligibility for indexing based on sub-~~
17 ~~section (a)(1) of this section, or 180 days for a request~~
18 ~~submitted based on subsection (a)(2) of this section, the~~
19 ~~Secretary shall grant or deny the request, and notify the~~
20 ~~person who requested such determination of the Sec-~~
21 ~~retary’s decision. The Secretary shall grant the request if~~
22 ~~the Secretary finds that—~~

23 ~~“(A) the same drug in the same dosage form~~
24 ~~for the same intended use is not approved or condi-~~
25 ~~tionally approved;~~

1 “(B) the proposed use does not raise concerns
2 related to safety; and

3 “(C) the person requesting the determination
4 has established appropriate specifications for the
5 manufacture and control of the new animal drug
6 and has demonstrated an understanding of the re-
7 quirements of current good manufacturing practices.

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

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

19 “(A) a copy of the Secretary’s determination of
20 eligibility issued under subsection (b);

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

23 “(C) a proposed index entry;

24 “(D) facsimile labeling;

1 “(E) anticipated annual distribution of the new
2 animal drug;

3 “(F) a written commitment to manufacture the
4 new animal drug and animal feeds bearing or con-
5 taining such new animal drug according to current
6 good manufacturing practices;

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

10 “(H) upon specific request of the Secretary, in-
11 formation submitted to the expert panel described in
12 paragraph (3); and

13 “(I) any additional requirements that the Sec-
14 retary may prescribe by general regulation or spe-
15 cific order.

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

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

18 “(B) include an evaluation of all available tar-
19 get animal safety and effectiveness information, in-
20 cluding anecdotal information;

21 “(C) state the expert panel’s opinion regarding
22 whether the benefits of using the new animal drug
23 for the proposed use in a minor species outweigh its
24 risks, taking into account the harm being caused by

1 the absence of an approved or conditionally approved
2 new animal drug for the minor species in question;

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

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

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

11 “(A) is composed of experts qualified by sci-
12 entific training and experience to evaluate the target
13 animal safety and effectiveness of the new animal
14 drug under consideration;

15 “(B) operates external to FDA; and

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

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

21 “(4) Within 180 days after the receipt of a request
22 for listing a new animal drug in the index, the Secretary
23 shall grant or deny the request. The Secretary shall grant
24 the request if the request for indexing continues to meet
25 the eligibility criteria in subsection (a) and the Secretary

1 finds, on the basis of the report of the qualified expert
2 panel and other information available to the Secretary,
3 that the benefits of using the new animal drug for the
4 proposed use in a minor species outweigh its risks, taking
5 into account the harm caused by the absence of an ap-
6 proved or conditionally-approved new animal drug for the
7 minor species in question. If the Secretary denies the re-
8 quest, the Secretary shall thereafter provide due notice
9 and the opportunity for an informal conference. The deci-
10 sion of the Secretary following an informal conference
11 shall constitute final agency action subject to judicial re-
12 view.

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

16 “(A) the name and address of the person who
17 holds the index listing;

18 “(B) the name of the drug and the intended
19 use and conditions of use for which it is being in-
20 dexed;

21 “(C) product labeling; and

22 “(D) conditions and any limitations that the
23 Secretary deems necessary regarding use of the
24 drug.

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

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

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

9 “(A) the expert panel failed to meet the re-
10 requirements as set forth by the Secretary by regula-
11 tion;

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

18 “(C) the conditions of subsection (e)(2) of this
19 section are no longer satisfied;

20 “(D) the manufacture of the new animal drug
21 is not in accordance with current good manufac-
22 turing practices;

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

1 ~~“(F) the conditions and limitations of use asso-~~
2 ~~ciated with the index listing have not been followed;~~
3 ~~or~~

4 ~~“(G) the request for indexing contains any un-~~
5 ~~true statement of material fact,~~

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

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

14 ~~“(A) suspend the listing of such drug imme-~~
15 ~~diately;~~

16 ~~“(B) give the person listed in the index prompt~~
17 ~~notice of the Secretary’s action; and~~

18 ~~“(C) afford that person the opportunity for an~~
19 ~~informal conference.~~

20 ~~The decision of the Secretary following an informal con-~~
21 ~~ference shall constitute final agency action subject to judi-~~
22 ~~cial review.~~

23 ~~“(g) For purposes of indexing new animal drugs~~
24 ~~under this section, to the extent consistent with the public~~
25 ~~health, the Secretary shall promulgate regulations for ex-~~

1 emptying from the operation of section 512 minor species
2 new animal drugs and animal feeds bearing or containing
3 new animal drugs intended solely for investigational use
4 by experts qualified by scientific training and experience
5 to investigate the safety and effectiveness of minor species
6 animal drugs. Such regulations may, at the discretion of
7 the Secretary, among other conditions relating to the pro-
8 tection of the public health, provide for conditioning such
9 exemption upon the establishment and maintenance of
10 such records, and the making of such reports to the Sec-
11 retary, by the manufacturer or the sponsor of the inves-
12 tigation of such article, of data (including but not limited
13 to analytical reports by investigators) obtained as a result
14 of such investigational use of such article, as the Secretary
15 finds will enable the Secretary to evaluate the safety and
16 effectiveness of such article in the event of the filing of
17 a request for an index listing pursuant to this section.

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

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

24 “(2) except in the case of new animal drugs in-
25 dexed for use in an early life stage of a food-pro-

1 ducing animal, ‘This product is not to be used in
2 animals intended for use as food for humans or
3 other animals.’; and

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

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

24 “(2) Every person required under this subsection to
25 maintain records, and every person in charge or custody

1 thereof, shall, upon request of an officer or employee des-
2 ignated by the Secretary, permit such officer or employee
3 at all reasonable times to have access to and copy and
4 verify such records.

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

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

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

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

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

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

1 “(A) for the purpose of, or as part of a plan,
2 scheme, or device for, obtaining the right to make,
3 use, or market, or making, using, or marketing, out-
4 side the United States, the drug identified in the re-
5 quest for indexing; and

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

11 **“SEC. 573. DESIGNATED NEW ANIMAL DRUGS FOR MINOR**
12 **USE OR MINOR SPECIES.**

13 “(a) DESIGNATION.—

14 “(1) The manufacturer or the sponsor of a new
15 animal drug for a minor use or use in a minor spe-
16 cies may request that the Secretary declare that
17 drug a ‘designated new animal drug’. A request for
18 designation of a new animal drug shall be made be-
19 fore the submission of an application under section
20 512(b) or section 571 for the new animal drug.

21 “(2) The Secretary may declare a new animal
22 drug a ‘designated new animal drug’ for an intended
23 use if—

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

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

5 “(3) Regarding the termination of a designa-
6 tion—

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

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

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

1 ~~“(D) the designation shall terminate upon~~
 2 ~~the expiration of any applicable exclusivity pe-~~
 3 ~~riod under subsection (e).~~

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

7 ~~“(b) GRANTS AND CONTRACTS FOR DEVELOPMENT~~
 8 ~~OF DESIGNATED NEW ANIMAL DRUGS.—~~

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

16 ~~“(2) For purposes of paragraph (1) of this sec-~~
 17 ~~tion—~~

18 ~~“(A) The term ‘qualified safety and effec-~~
 19 ~~tiveness testing’ means testing—~~

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

1 “(ii) which is carried out under an in-
2 vestigational exemption under section
3 512(j).

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

12 “(e) EXCLUSIVITY FOR DESIGNATED NEW ANIMAL
13 DRUGS.—

14 “(1) Except as provided in subsection (e)(2), if
15 the Secretary—

16 “(A) approves or conditionally approves an
17 application for a designated new animal drug,
18 and no active ingredient (including any salt or
19 ester of the active ingredient) of that des-
20 ignated new animal drug has been approved or
21 conditionally approved previously, the Secretary
22 may not approve or conditionally approve an-
23 other application submitted for a new animal
24 drug with the same active ingredient and in-
25 tended use as the designated new animal drug

1 for another applicant before the expiration of
2 ten years from the date of the approval or con-
3 ditional approval of the application.

4 “(B) approves or conditionally approves an
5 application for a designated new animal drug,
6 and an active ingredient (including an ester or
7 salt of the active ingredient) of that designated
8 new animal drug has been approved or condi-
9 tionally approved previously, the Secretary may
10 not approve or conditionally approve another
11 application submitted for a new animal drug
12 with the same active ingredient and intended
13 use as the designated new animal drug for an-
14 other applicant before the expiration of seven
15 years from the date of approval or conditional
16 approval of the application.

17 “(2) If an application filed pursuant to section
18 ~~512~~ or section ~~571~~ is approved for a designated new
19 animal drug, the Secretary may, during the 10-year
20 or 7-year exclusivity period beginning on the date of
21 the application approval or conditional approval, ap-
22 prove or conditionally approve another application
23 under section ~~512~~ or section ~~571~~ for such drug for
24 such minor use or minor species for another appli-
25 cant if—

1 “(A) the Secretary finds, after providing
2 the holder of such an approved application no-
3 tice and opportunity for the submission of
4 views, that in the granted exclusivity period the
5 holder of the approved application cannot as-
6 sure the availability of sufficient quantities of
7 the drug to meet the needs for which the drug
8 was designated; or

9 “(B) such holder provides written consent
10 to the Secretary for the approval or conditional
11 approval of other applications before the expira-
12 tion of such exclusivity period.”.

13 (e) CONFORMING AMENDMENTS.—

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

17 (2) Section 201(v) of the Federal Food, Drug,
18 and Cosmetic Act is amended by inserting the fol-
19 lowing after paragraph (2): “Provided that any drug
20 intended for minor use or use in a minor species
21 that is not the subject of a final regulation published
22 by the Secretary through notice and comment rule-
23 making finding that the criteria of paragraphs (1)
24 and (2) have not been met (or that the exception to

1 the criterion in paragraph (1) has been met) is a
2 new animal drug.”.

3 (3) Section 301(e) of the Federal Food, Drug,
4 and Cosmetic Act is amended by striking
5 “512(a)(4)(C), 512(j), (l) or (m)” and inserting
6 “512(a)(4)(C), 512 (j), (l) or (m), 572(i).”

7 (4) Section 301(j) of the Federal Food, Drug,
8 and Cosmetic Act is amended by deleting “520” and
9 inserting “520, 571, 572, 573.”

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

13 “(a) If it is a new animal drug—

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

20 “(2) that is indexed under section 572 and its
21 labeling does not conform with the index listing
22 under section 572(e) or 572(h), or that has not been
23 indexed under section 572 and its label bears the
24 statement set forth in section 572(h).”.

1 (6) Section 503(f) of the Federal Food, Drug,
2 and Cosmetic Act is amended by—

3 (A) in paragraph (1)(A)(ii) by striking
4 “512” and inserting “512, a conditionally-ap-
5 proved application under section 571, or an
6 index listing under section 572”; and

7 (B) in paragraph (3) by striking “section
8 512” and inserting “section 512, 571, or 572”.

9 (7) Section 504(a)(1) of the Federal Food,
10 Drug, and Cosmetic Act is amended by striking
11 “512(b)” and inserting “512(b), a conditionally-ap-
12 proved application filed pursuant to section 571, or
13 an index listing pursuant to section 572”.

14 (8) Sections 504(a)(2)(B) and 504(b) of the
15 Federal Food, Drug, and Cosmetic Act are amended
16 by striking “512(i)” each place it appears and in-
17 serting “512(i), or the index listing pursuant to sec-
18 tion 572(e)”.

19 (9) Section 512(a) of the Federal Food, Drug,
20 and Cosmetic Act is amended by striking paragraphs
21 (1) and (2) and inserting the following:

22 “(1) A new animal drug shall, with respect to any
23 particular use or intended use of such drug, be deemed
24 unsafe for purposes of section 501(a)(5) and section
25 402(a)(2)(C)(ii) unless—

1 “(A) there is in effect an approval of an appli-
2 cation filed pursuant to subsection (b) with respect
3 to such use or intended use of such drug, and such
4 drug, its labeling, and such use conform to such ap-
5 proved application;

6 “(B) there is in effect a conditional approval of
7 an application filed pursuant to section 571 with re-
8 spect to such use or intended use of such drug, and
9 such drug, its labeling, and such use conform to
10 such conditionally approved application; or

11 “(C) there is in effect an index listing pursuant
12 to section 572 with respect to such use or intended
13 use of such drug in a minor species, and such drug,
14 its labeling, and such use conform to such index list-
15 ing.

16 A new animal drug shall also be deemed unsafe for such
17 purposes in the event of removal from the establishment
18 of a manufacturer, packer, or distributor of such drug for
19 use in the manufacture of animal feed in any State unless
20 at the time of such removal such manufacturer, packer,
21 or distributor has an unrevoked written statement from
22 the consignee of such drug, or notice from the Secretary,
23 to the effect that, with respect to the use of such drug
24 in animal feed, such consignee (i) holds a license issued
25 under subsection (m) and has in its possession current ap-

1 proved labeling for such drug in animal feed; or (ii) will,
2 if the consignee is not a user of the drug, ship such drug
3 only to a holder of a license issued under subsection (m).

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

8 “(A) there is in effect—

9 “(i) an approval of an application filed
10 pursuant to subsection (b) with respect to such
11 drug, as used in such animal feed, and such
12 animal feed and its labeling, distribution, hold-
13 ing, and use conform to such approved applica-
14 tion;

15 “(ii) a conditional approval of an applica-
16 tion filed pursuant to section 571 with respect
17 to such drug, as used in such animal feed, and
18 such animal feed and its labeling, distribution,
19 holding, and use conform to such conditionally
20 approved application; or

21 “(iii) an index listing pursuant to section
22 572 with respect to such drug, as used in such
23 animal feed, and such animal feed and its label-
24 ing, distribution, holding, and use conform to
25 such index listing; and

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

5 (10) Section 512(b)(3) of the Federal Food,
6 Drug, and Cosmetic Act is amended by striking
7 “under paragraph (1) or a request for an investiga-
8 tional exemption under subsection (j)” and inserting
9 “under paragraph (1), section 571, or a request for
10 an investigational exemption under subsection (j)”.

11 (11) Section 512(d)(4) of the Federal Food,
12 Drug, and Cosmetic Act is amended by striking
13 “have previously been separately approved” and in-
14 serting “have previously been separately approved
15 pursuant to an application submitted under section
16 512(b)(1)”.

17 (12) Section 512(f) of the Federal Food, Drug,
18 and Cosmetic Act is amended by striking “sub-
19 section (d), (e), or (m)” and inserting “subsection
20 (d), (e), or (m), or section 571 (e), (d), or (e)”.

21 (13) Section 512(g) of the Federal Food, Drug,
22 and Cosmetic Act is amended by striking “this sec-
23 tion” and inserting “this section, or section 571”.

24 (14) Section 512(i) of the Federal Food, Drug,
25 and Cosmetic Act is amended by striking “sub-

1 section (b)” and inserting “subsection (b) or section
2 571” and by inserting “or upon failure to renew a
3 conditional approval under section 571” after “or
4 upon its suspension”.

5 (15) Section 512(l)(1) of the Federal Food,
6 Drug, and Cosmetic Act is amended by striking
7 “subsection (b)” and inserting “subsection (b) or
8 section 571”.

9 (16) Section 512(m)(1)(C) of the Federal Food,
10 Drug, and Cosmetic Act is amended by striking “ap-
11 plicable regulations published pursuant to subsection
12 (i)” and inserting “applicable regulations published
13 pursuant to subsection (i) or for indexed new animal
14 drugs in accordance with the index listing published
15 pursuant to section 572(e)(2) and the labeling re-
16 quirements set forth in section 572(h)”.

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

21 (18) Section 512(p)(1) of the Federal Food,
22 Drug, and Cosmetic Act is amended by striking
23 “subsection (b)(1)” and inserting “subsection (b)(1)
24 or section 571(a)”.

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

5 (20) Section 108(b)(3) of Public Law 90-399 is
6 amended by striking “section 201(w) as added by
7 this Act” and inserting “section 201(v) as added by
8 the Minor Use and Minor Species Animal Health
9 Act of 2003”.

10 (f) REGULATIONS.—The Secretary of Health and
11 Human Services shall implement sections 571 and 573 of
12 the Federal Food, Drug, and Cosmetic Act and subse-
13 quently publish implementing regulations. Not later than
14 12 months after the date of enactment of this Act, the
15 Secretary shall issue proposed regulations to implement
16 section 573 of the Federal Food, Drug, and Cosmetic Act
17 (as added by this Act), and not later than 24 months after
18 the date of enactment of this Act, the Secretary shall issue
19 final regulations implementing section 573 of the Federal
20 Food, Drug, and Cosmetic Act. Not later than 18 months
21 after the date of enactment of this Act, the Secretary shall
22 issue proposed regulations to implement section 572 of the
23 Federal Food, Drug, and Cosmetic Act (as added by this
24 Act), and not later than 36 months after the date of enact-
25 ment of this Act, the Secretary shall issue final regulations

1 implementing section 572 of the Federal Food, Drug, and
2 Cosmetic Act. Not later than 30 months after the date
3 of enactment of this Act, the Secretary shall issue pro-
4 posed regulations to implement section 571 of the Federal
5 Food, Drug, and Cosmetic Act (as added by this Act), and
6 not later than 42 months after the date of enactment of
7 this Act, the Secretary shall issue final regulations imple-
8 menting section 571 of the Federal Food, Drug, and Cos-
9 metic Act. These timeframes shall be extended by 12
10 months for each fiscal year, in which the funds authorized
11 to be appropriated under subsection (i) are not in fact ap-
12 propriated.

13 (g) OFFICE.—The Secretary of Health and Human
14 Services shall establish within the Center for Veterinary
15 Medicine (of the Food and Drug Administration), an Of-
16 fice of Minor Use and Minor Species Animal Drug Devel-
17 opment that reports directly to the Director of the Center
18 for Veterinary Medicine. This office shall be responsible
19 for overseeing the development and legal marketing of new
20 animal drugs for minor uses and minor species. There is
21 authorized to be appropriated to carry out this subsection
22 \$1,200,000 for fiscal year 2003 and such sums as may
23 be necessary for each fiscal year thereafter.

24 (h) AUTHORIZATION OF APPROPRIATIONS.—There is
25 authorized to be appropriated to carry out section 573(b)

1 of the Federal Food, Drug, and Cosmetic Act (as added
2 by this Act) \$1,000,000 for the fiscal year following publi-
3 cation of final implementing regulations, \$2,000,000 for
4 the subsequent fiscal year, and such sums as may be nec-
5 essary for each fiscal year thereafter.

6 **TITLE I—MINOR USE AND MINOR**
7 **SPECIES HEALTH**

8 **SECTION 101. SHORT TITLE.**

9 *This title may be cited as the “Minor Use and Minor*
10 *Species Animal Health Act of 2003”.*

11 **SEC. 102. MINOR USE AND MINOR SPECIES ANIMAL**
12 **HEALTH.**

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

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

16 *(2) There is a severe shortage of approved new*
17 *animal drugs for treating animal diseases and condi-*
18 *tions that occur infrequently or in limited geographic*
19 *areas.*

20 *(3) Because of the small market shares, low-prof-*
21 *it margins involved, and capital investment required,*
22 *it is generally not economically feasible for new ani-*
23 *mal drug applicants to pursue approvals for these*
24 *species, diseases, and conditions.*

1 (4) *Because the populations for which such new*
2 *animal drugs are intended may be small and condi-*
3 *tions of animal management may vary widely, it is*
4 *often difficult to design and conduct studies to estab-*
5 *lish drug safety and effectiveness under traditional*
6 *new animal drug approval processes.*

7 (5) *It is in the public interest and in the interest*
8 *of animal welfare to provide for special procedures to*
9 *allow the lawful use and marketing of certain new*
10 *animal drugs for minor species and minor uses that*
11 *take into account these special circumstances and that*
12 *ensure that such drugs do not endanger animal or*
13 *public health.*

14 (6) *Exclusive marketing rights for clinical test-*
15 *ing expenses have helped encourage the development of*
16 *“orphan” drugs for human use, and comparable in-*
17 *centives should encourage the development of new ani-*
18 *mal drugs for minor species and minor uses.*

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

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

1 “(nn) *The term ‘major species’ means cattle, horses,*
 2 *swine, chickens, turkeys, dogs, and cats, except that the Sec-*
 3 *retary may add species to this definition by regulation.*

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

6 “(pp) *The term ‘minor use’ means the intended use*
 7 *of a drug in a major species for an indication that occurs*
 8 *infrequently and in only a small number of animals or in*
 9 *limited geographical areas and in only a small number of*
 10 *animals annually.”*

11 (2) *THREE-YEAR EXCLUSIVITY FOR MINOR USE*
 12 *AND MINOR SPECIES APPROVALS.—Section*
 13 *512(c)(2)(F) (ii), (iii), and (v) of the Federal Food,*
 14 *Drug, and Cosmetic Act is amended by striking*
 15 *“(other than bioequivalence or residue studies)” and*
 16 *inserting “(other than bioequivalence studies or res-*
 17 *idue depletion studies, except residue depletion studies*
 18 *for minor uses or minor species)” every place it ap-*
 19 *pears.*

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

24 “(5) *In reviewing an application that proposes*
 25 *a change to add an intended use for a minor use or*

1 *erwise stated in this section, and any additional provisions*
2 *of this section. New animal drugs are subject to application*
3 *of the same safety standards that would be applied to such*
4 *drugs under section 512(d) (including, for antimicrobial*
5 *new animal drugs, with respect to antimicrobial resist-*
6 *ance).*

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

10 “(A) *all information necessary to meet the re-*
11 *quirements of section 512(b)(1) except section*
12 *512(b)(1)(A);*

13 “(B) *full reports of investigations which have*
14 *been made to show whether or not such drug is safe*
15 *under section 512(d) (including, for an antimicrobial*
16 *new animal drug, with respect to antimicrobial re-*
17 *sistance) and there is a reasonable expectation of ef-*
18 *fectiveness for use;*

19 “(C) *data for establishing a conditional dose;*

20 “(D) *projections of expected need and the jus-*
21 *tification for that expectation based on the best infor-*
22 *mation available;*

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

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

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

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

10 “(B) the person has previously filed an applica-
11 tion for conditional approval under paragraph (1) for
12 the same drug in the same dosage form for the same
13 intended use whether or not subsequently condi-
14 tionally approved by the Secretary under subsection
15 (b), or

16 “(C) the person obtained the application, or data
17 or other information contained therein, directly or in-
18 directly from the person who filed for conditional ap-
19 proval under paragraph (1) for the same drug in the
20 same dosage form for the same intended use whether
21 or not subsequently conditionally approved by the
22 Secretary under subsection (b).

23 “(b) Within 180 days after the filing of an application
24 pursuant to subsection (a), or such additional period as

1 *may be agreed upon by the Secretary and the applicant,*
2 *the Secretary shall either—*

3 “(1) *issue an order, effective for one year, condi-*
4 *tionally approving the application if the Secretary*
5 *finds that none of the grounds for denying conditional*
6 *approval, specified in subsection (c) of this section*
7 *applies and publish a Federal Register notice of the*
8 *conditional approval, or*

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

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

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

16 “(2) *the information submitted to the Secretary*
17 *as part of the application and any other information*
18 *before the Secretary with respect to such drug, is in-*
19 *sufficient to show that there is a reasonable expecta-*
20 *tion that the drug will have the effect it purports or*
21 *is represented to have under the conditions of use pre-*
22 *scribed, recommended, or suggested in the proposed*
23 *labeling thereof; or*

24 “(3) *another person has received approval under*
25 *section 512 for the same drug in the same dosage form*

1 *for the same intended use, and that person is able to*
2 *assure the availability of sufficient quantities of the*
3 *drug to meet the needs for which the drug is intended;*
4 *the Secretary shall issue an order refusing to conditionally*
5 *approve the application. If, after such notice and oppor-*
6 *tunity for an informal hearing, the Secretary finds that*
7 *paragraphs (1) through (3) do not apply, the Secretary*
8 *shall issue an order conditionally approving the applica-*
9 *tion effective for one year and publish a Federal Register*
10 *notice of the conditional approval. Any order issued under*
11 *this subsection refusing to conditionally approve an appli-*
12 *cation shall state the findings upon which it is based.*

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

20 *“(1) No later than 90 days from the end of the*
21 *1-year period for which the original or renewed con-*
22 *ditional approval is effective, the applicant may sub-*
23 *mit a request to renew a conditional approval for an*
24 *additional 1-year term.*

1 “(2) *A conditional approval shall be deemed re-*
2 *newed at the end of the 1-year period, or at the end*
3 *of a 90-day extension that the Secretary may, at the*
4 *Secretary’s discretion, grant by letter in order to com-*
5 *plete review of the renewal request, unless the Sec-*
6 *retary determines before the expiration of the 1-year*
7 *period or the 90-day extension that—*

8 “(A) *the applicant failed to submit a timely*
9 *renewal request;*

10 “(B) *the request fails to contain sufficient*
11 *information to show that—*

12 “(i) *the applicant is making sufficient*
13 *progress toward meeting approval require-*
14 *ments under section 512(d)(1)(E), and is*
15 *likely to be able to fulfill those requirements*
16 *and obtain an approval under section 512*
17 *before the expiration of the 5-year max-*
18 *imum term of the conditional approval;*

19 “(ii) *the quantity of the drug that has*
20 *been distributed is consistent with the con-*
21 *ditionally approved intended use and condi-*
22 *tions of use, unless there is adequate expla-*
23 *nation that ensures that the drug is only*
24 *used for its intended purpose; or*

1 “(iii) the same drug in the same dos-
2 age form for the same intended use has not
3 received approval under section 512, or if
4 such a drug has been approved, that the
5 holder of the approved application is unable
6 to assure the availability of sufficient quan-
7 tities of the drug to meet the needs for which
8 the drug is intended; or

9 “(C) any of the provisions of section
10 512(e)(1) (A) through (B) or (D) through (F) are
11 applicable.

12 “(3) If the Secretary determines before the end of
13 the 1-year period or the 90-day extension, if granted,
14 that a conditional approval should not be renewed,
15 the Secretary shall issue an order refusing to renew
16 the conditional approval, and such conditional ap-
17 proval shall be deemed withdrawn and no longer in
18 effect. The Secretary shall thereafter provide an op-
19 portunity for an informal hearing to the applicant on
20 the issue whether the conditional approval shall be re-
21 instated.

22 “(e)(1) The Secretary shall issue an order withdrawing
23 conditional approval of an application filed pursuant to
24 subsection (a) if the Secretary finds that another person has
25 received approval under section 512 for the same drug in

1 *the same dosage form for the same intended use and that*
2 *person is able to assure the availability of sufficient quan-*
3 *tities of the drug to meet the needs for which the drug is*
4 *intended.*

5 “(2) *The Secretary shall, after due notice and oppor-*
6 *tunity for an informal hearing to the applicant, issue an*
7 *order withdrawing conditional approval of an application*
8 *filed pursuant to subsection (a) if the Secretary finds that—*

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

11 “(B) *on the basis of new information before the*
12 *Secretary with respect to such drug, evaluated to-*
13 *gether with the evidence available to the Secretary*
14 *when the application was conditionally approved,*
15 *that there is not a reasonable expectation that such*
16 *drug will have the effect it purports or is represented*
17 *to have under the conditions of use prescribed, rec-*
18 *ommended, or suggested in the labeling thereof.*

19 “(3) *The Secretary may also, after due notice and op-*
20 *portunity for an informal hearing to the applicant, issue*
21 *an order withdrawing conditional approval of an applica-*
22 *tion filed pursuant to subsection (a) if the Secretary finds*
23 *that any of the provisions of section 512(e)(2) are applica-*
24 *ble.*

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

3 “(A) *bear the statement, ‘conditionally approved*
4 *by FDA pending a full demonstration of effectiveness*
5 *under application number’; and*

6 “(B) *contain such other information as pre-*
7 *scribed by the Secretary.*

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

12 “(g) *A conditionally approved new animal drug appli-*
13 *cation may not be amended or supplemented to add indica-*
14 *tions for use.*

15 “(h) *180 days prior to the termination date established*
16 *under subsection (d) of this section, an applicant shall have*
17 *submitted all the information necessary to support a com-*
18 *plete new animal drug application in accordance with sec-*
19 *tion 512(b)(1) or the conditional approval issued under this*
20 *section is no longer in effect. Following review of this infor-*
21 *mation, the Secretary shall either—*

22 “(1) *issue an order approving the application*
23 *under section 512(c) if the Secretary finds that none*
24 *of the grounds for denying approval specified in sec-*
25 *tion 512(d)(1) applies, or*

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

5 Upon issuance of an order approving the application, prod-
6 uct labeling and administrative records of approval shall
7 be modified accordingly. If the Secretary has not issued an
8 order under section 512(e) approving such application
9 prior to the termination date established under subsection
10 (d) of this section, the conditional approval issued under
11 this section is no longer in effect unless the Secretary grants
12 an extension of an additional 180-day period so that the
13 Secretary can complete review of the application. The deci-
14 sion to grant an extension is committed to the discretion
15 of the Secretary and not subject to judicial review.

16 “(i) The decision of the Secretary under subsection (c),
17 (d), or (e) of this section refusing or withdrawing condi-
18 tional approval of an application shall constitute final
19 agency action subject to judicial review.

20 “(j) In this section and section 572, the term
21 ‘transgenic animal’ means an animal whose genome con-
22 tains a nucleotide sequence that has been intentionally
23 modified *in vitro*, and the progeny of such an animal; Pro-
24 vided that the term ‘transgenic animal’ does not include

1 *an animal of which the nucleotide sequence of the genome*
2 *has been modified solely by selective breeding.*

3 **“SEC. 572. INDEX OF LEGALLY MARKETED UNAPPROVED**
4 **NEW ANIMAL DRUGS FOR MINOR SPECIES.**

5 *“(a)(1) The Secretary shall establish an index limited*
6 *to—*

7 *“(A) new animal drugs intended for use in a*
8 *minor species for which there is a reasonable cer-*
9 *tainty that the animal or edible products from the*
10 *animal will not be consumed by humans or food-pro-*
11 *ducing animals; and*

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

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

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

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

5 “(A) information regarding the need for the new
6 animal drug, the species for which the new animal
7 drug is intended, the proposed intended use and con-
8 ditions of use, and anticipated annual distribution;

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

12 “(C) information regarding the components and
13 composition of the new animal drug;

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

17 “(E) an environmental assessment that meets the
18 requirements of the National Environmental Policy
19 Act of 1969, as amended, and as defined in 21 CFR
20 Part 25, as it appears on the date of enactment of
21 this provision and amended thereafter or information
22 to support a categorical exclusion from the require-
23 ment to prepare an environmental assessment;

24 “(F) information sufficient to support the con-
25 clusion that the proposed use of the new animal drug

1 *is safe under section 512(d) with respect to individ-*
2 *uals exposed to the new animal drug through its man-*
3 *ufacture or use; and*

4 *“(G) such other information as the Secretary*
5 *may deem necessary to make this eligibility deter-*
6 *mination.*

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

15 *“(A) the same drug in the same dosage form for*
16 *the same intended use is not approved or condi-*
17 *tionally approved;*

18 *“(B) the proposed use of the drug meets the con-*
19 *ditions of subparagraph (A) or (B) of subsection*
20 *(a)(1), as appropriate;*

21 *“(C) the person requesting the determination has*
22 *established appropriate specifications for the manu-*
23 *facture and control of the new animal drug and has*
24 *demonstrated an understanding of the requirements of*
25 *current good manufacturing practices;*

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

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

6 *If the Secretary denies the request, the Secretary shall there-*
7 *after provide due notice and an opportunity for an infor-*
8 *mal conference. A decision of the Secretary to deny an eligi-*
9 *bility request following an informal conference shall con-*
10 *stitute final agency action subject to judicial review.*

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

17 “(A) *a copy of the Secretary’s determination of*
18 *eligibility issued under subsection (c);*

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

21 “(C) *a proposed index entry;*

22 “(D) *facsimile labeling;*

23 “(E) *anticipated annual distribution of the new*
24 *animal drug;*

1 “(F) a written commitment to manufacture the
2 new animal drug and animal feeds bearing or con-
3 taining such new animal drug according to current
4 good manufacturing practices;

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

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

11 “(I) any additional requirements that the Sec-
12 retary may prescribe by general regulation or specific
13 order.

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

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

16 “(B) include an evaluation of all available target
17 animal safety and effectiveness information, including
18 anecdotal information;

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

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

3 “(E) include a recommendation regarding
4 whether the new animal drug should be limited to use
5 under the professional supervision of a licensed veteri-
6 narian.

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

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

13 “(B) operates external to FDA; and

14 “(C) is not subject to the Federal Advisory Com-
15 mittee Act, 5 U.S.C. App. 2.

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

19 “(4) Within 180 days after the receipt of a request for
20 listing a new animal drug in the index, the Secretary shall
21 grant or deny the request. The Secretary shall grant the
22 request if the request for indexing continues to meet the eli-
23 gibility criteria in subsection (a) and the Secretary finds,
24 on the basis of the report of the qualified expert panel and
25 other information available to the Secretary, that the bene-

1 *fits of using the new animal drug for the proposed use in*
2 *a minor species outweigh its risks to the target animal, tak-*
3 *ing into account the harm caused by the absence of an ap-*
4 *proved or conditionally-approved new animal drug for the*
5 *minor species in question. If the Secretary denies the re-*
6 *quest, the Secretary shall thereafter provide due notice and*
7 *the opportunity for an informal conference. The decision*
8 *of the Secretary following an informal conference shall con-*
9 *stitute final agency action subject to judicial review.*

10 “(e)(1) *The index established under subsection (a) shall*
11 *include the following information for each listed 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 use*
15 *and conditions of use for which it is being indexed;*

16 “(C) *product labeling; and*

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

19 “(2) *The Secretary shall publish the index, and revise*
20 *it periodically.*

21 “(3) *The Secretary may establish by regulation a proc-*
22 *ess for reporting changes in the conditions of manufac-*
23 *turing 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 require-*
5 *ments as set forth by the Secretary by regulation;*

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

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

14 “(D) *the manufacture of the new animal drug is*
15 *not in accordance with current good manufacturing*
16 *practices;*

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

20 “(F) *the conditions and limitations of use associ-*
21 *ated with the index listing have not been followed; or*

22 “(G) *the request for indexing contains any un-*
23 *true statement of material fact,*

24 *the Secretary shall remove the new animal drug from the*
25 *index. The decision of the Secretary following an informal*

1 *conference shall constitute final agency action subject to ju-*
2 *dicial review.*

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

7 “(A) *suspend the listing of such drug imme-*
8 *diately;*

9 “(B) *give the person listed in the index prompt*
10 *notice of the Secretary’s action; and*

11 “(C) *afford that person the opportunity for an*
12 *informal conference.*

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

16 “(g) *For purposes of indexing new animal drugs under*
17 *this section, to the extent consistent with the public health,*
18 *the Secretary shall promulgate regulations for exempting*
19 *from the operation of section 512 minor species new animal*
20 *drugs and animal feeds bearing or containing new animal*
21 *drugs intended solely for investigational use by experts*
22 *qualified by scientific training and experience to investigate*
23 *the safety and effectiveness of minor species animal drugs.*
24 *Such regulations may, at the discretion of the Secretary,*
25 *among other conditions relating to the protection of the pub-*

1 *lic health, provide for conditioning such exemption upon*
2 *the establishment and maintenance of such records, and the*
3 *making of such reports to the Secretary, by the manufac-*
4 *turer or the sponsor of the investigation of such article, of*
5 *data (including but not limited to analytical reports by in-*
6 *vestigators) obtained as a result of such investigational use*
7 *of such article, as the Secretary finds will enable the Sec-*
8 *retary to evaluate the safety and effectiveness of such article*
9 *in the event of the filing of a request for an index listing*
10 *pursuant to this section.*

11 “(h) *The labeling of a new animal drug that is the*
12 *subject of an index listing shall state, prominently and con-*
13 *spicuously—*

14 “(1) *‘NOT APPROVED BY FDA.—Legally marketed*
15 *as an FDA indexed product. Extra-label use is pro-*
16 *hibited.’;*

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

22 “(3) *such other information as may be prescribed*
23 *by the Secretary in the index listing.*

24 “(i)(1) *In the case of any new animal drug for which*
25 *an index listing pursuant to subsection (a) is in effect, the*

1 *person who has an index listing shall establish and main-*
2 *tain such records, and make such reports to the Secretary,*
3 *of data relating to experience, and other data or informa-*
4 *tion, received or otherwise obtained by such person with re-*
5 *spect to such drug, or with respect to animal feeds bearing*
6 *or containing such drug, as the Secretary may by general*
7 *regulation, or by order with respect to such listing, prescribe*
8 *on the basis of a finding that such records and reports are*
9 *necessary in order to enable the Secretary to determine, or*
10 *facilitate a determination, whether there is or may be*
11 *ground for invoking subsection (f). Such regulation or order*
12 *shall provide, where the Secretary deems it to be appro-*
13 *priate, for the examination, upon request, by the persons*
14 *to whom such regulation or order is applicable, of similar*
15 *information received or otherwise obtained by the Secretary.*

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

22 “(j)(1) *Safety and effectiveness data and information*
23 *which has been submitted in support of a request for a new*
24 *animal drug to be indexed under this section and which*
25 *has not been previously disclosed to the public shall be made*

1 *available to the public, upon request, unless extraordinary*
2 *circumstances are shown—*

3 “(A) *if no work is being or will be undertaken*
4 *to have the drug indexed in accordance with the re-*
5 *quest,*

6 “(B) *if the Secretary has determined that such*
7 *drug cannot be indexed and all legal appeals have*
8 *been exhausted,*

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

11 “(D) *if the Secretary has determined that such*
12 *drug is not a new animal drug.*

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

18 “(A) *for the purpose of, or as part of a plan,*
19 *scheme, or device for, obtaining the right to make, use,*
20 *or market, or making, using, or marketing, outside*
21 *the United States, the drug identified in the request*
22 *for indexing; and*

23 “(B) *without obtaining from any person to*
24 *whom the data and information are disclosed an*
25 *identical verified statement, a copy of which is to be*

1 *provided by such person to the Secretary, which meets*
2 *the requirements of this paragraph.*

3 **“SEC. 573. DESIGNATED NEW ANIMAL DRUGS FOR MINOR**
4 **USE OR MINOR SPECIES.**

5 “(a) *DESIGNATION.*—

6 “(1) *The manufacturer or the sponsor of a new*
7 *animal drug for a minor use or use in a minor spe-*
8 *cies may request that the Secretary declare that drug*
9 *a ‘designated new animal drug’. A request for des-*
10 *ignation of a new animal drug shall be made before*
11 *the submission of an application under section 512(b)*
12 *or section 571 for the new animal drug.*

13 “(2) *The Secretary may declare a new animal*
14 *drug a ‘designated new animal drug’ if—*

15 “(A) *it is intended for a minor use or use*
16 *in a minor species; and*

17 “(B) *the same drug in the same dosage form*
18 *for the same intended use is not approved under*
19 *section 512 or 571 or designated under this sec-*
20 *tion at the time the request is made.*

21 “(3) *Regarding the termination of a designa-*
22 *tion—*

23 “(A) *the sponsor of a new animal drug shall*
24 *notify the Secretary of any decision to dis-*
25 *continue active pursuit of approval under section*

1 512 or 571 of an application for a designated
2 new animal drug. The Secretary shall terminate
3 the designation upon such notification;

4 “(B) the Secretary may also terminate des-
5 ignation if the Secretary independently deter-
6 mines that the sponsor is not actively pursuing
7 approval under section 512 or 571 with due dili-
8 gence;

9 “(C) the sponsor of an approved designated
10 new animal drug shall notify the Secretary of
11 any discontinuance of the manufacture of such
12 new animal drug at least one year before dis-
13 continuance. The Secretary shall terminate the
14 designation upon such notification; and

15 “(D) the designation shall terminate upon
16 the expiration of any applicable exclusivity pe-
17 riod under subsection (c).

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

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

23 “(1) The Secretary may make grants to and
24 enter into contracts with public and private entities
25 and individuals to assist in defraying the costs of

1 *qualified safety and effectiveness testing expenses and*
2 *manufacturing expenses incurred in connection with*
3 *the development of designated new animal drugs.*

4 “(2) *For purposes of paragraph (1) of this sec-*
5 *tion—*

6 “(A) *The term ‘qualified safety and effec-*
7 *tiveness testing’ means testing—*

8 “(i) *which occurs after the date such*
9 *new animal drug is designated under this*
10 *section and before the date on which an ap-*
11 *plication with respect to such drug is sub-*
12 *mitted under section 512; and*

13 “(ii) *which is carried out under an in-*
14 *vestigational exemption under section*
15 *512(j).*

16 “(B) *The term ‘manufacturing expenses’*
17 *means expenses incurred in developing processes*
18 *and procedures associated with manufacture of*
19 *the designated new animal drug which occur*
20 *after the new animal drug is designated under*
21 *this section and before the date on which an ap-*
22 *plication with respect to such new animal drug*
23 *is submitted under section 512 or 571.*

24 “(c) *EXCLUSIVITY FOR DESIGNATED NEW ANIMAL*
25 *DRUGS.—*

1 “(1) *Except as provided in subsection (c)(2), if*
2 *the Secretary approves or conditionally approves an*
3 *application for a designated new animal drug, the*
4 *Secretary may not approve or conditionally approve*
5 *another application submitted for such new animal*
6 *drug with the same intended use as the designated*
7 *new animal drug for another applicant before the ex-*
8 *piration of seven years from the date of approval or*
9 *conditional approval of the application.*

10 “(2) *If an application filed pursuant to section*
11 *512 or section 571 is approved for a designated new*
12 *animal drug, the Secretary may, during the 7-year*
13 *exclusivity period beginning on the date of the appli-*
14 *cation approval or conditional approval, approve or*
15 *conditionally approve another application under sec-*
16 *tion 512 or section 571 for such drug for such minor*
17 *use or minor species for another applicant if—*

18 “(A) *the Secretary finds, after providing the*
19 *holder of such an approved application notice*
20 *and opportunity for the submission of views,*
21 *that in the granted exclusivity period the holder*
22 *of the approved application cannot assure the*
23 *availability of sufficient quantities of the drug to*
24 *meet the needs for which the drug was des-*
25 *ignated; or*

1 “(B) such holder provides written consent to
2 the Secretary for the approval or conditional ap-
3 proval of other applications before the expiration
4 of such exclusivity period.”.

5 (5) CONFORMING AMENDMENTS.—

6 (A) Section 201(u) of the Federal Food,
7 Drug, and Cosmetic Act is amended by striking
8 “512” and inserting “512, 571”.

9 (B) Section 201(v) of the Federal Food,
10 Drug, and Cosmetic Act is amended by inserting
11 the following after paragraph (2): “Provided that
12 any drug intended for minor use or use in a
13 minor species that is not the subject of a final
14 regulation published by the Secretary through
15 notice and comment rulemaking finding that the
16 criteria of paragraphs (1) and (2) have not been
17 met (or that the exception to the criterion in
18 paragraph (1) has been met) is a new animal
19 drug.”.

20 (C) Section 301(e) of the Federal Food,
21 Drug, and Cosmetic Act is amended by striking
22 “512(a)(4)(C), 512(j), (l) or (m)” and inserting
23 “512(a)(4)(C), 512 (j), (l) or (m), 572(i).”

1 (D) Section 301(j) of the Federal Food,
2 Drug, and Cosmetic Act is amended by striking
3 “520” and inserting “520, 571, 572, 573.”

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

7 “(w) If it is a new animal drug—

8 “(1) that is conditionally approved under section
9 571 and its labeling does not conform with the ap-
10 proved application or section 571(f), or that is not
11 conditionally approved under section 571 and its
12 label bears the statement set forth in section
13 571(f)(1)(A); or

14 “(2) that is indexed under section 572 and its
15 labeling does not conform with the index listing under
16 section 572(e) or 572(h), or that has not been indexed
17 under section 572 and its label bears the statement set
18 forth in section 572(h).”.

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

21 (i) in paragraph (1)(A)(ii) by striking
22 “512” and inserting “512, a conditionally-
23 approved application under section 571, or
24 an index listing under section 572”; and

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

4 (G) Section 504(a)(1) of the Federal Food,
5 Drug, and Cosmetic Act is amended by striking
6 “512(b)” and inserting “512(b), a conditionally-
7 approved application filed pursuant to section
8 571, or an index listing pursuant to section
9 572”.

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

15 (I) Section 512(a) of the Federal Food,
16 Drug, and Cosmetic Act is amended by striking
17 paragraphs (1) and (2) and inserting the fol-
18 lowing:

19 “(1) A new animal drug shall, with respect to any par-
20 ticular use or intended use of such drug, be deemed unsafe
21 for purposes of section 501(a)(5) and section
22 402(a)(2)(C)(ii) unless—

23 “(A) there is in effect an approval of an applica-
24 tion filed pursuant to subsection (b) with respect to
25 such use or intended use of such drug, and such drug,

1 *its labeling, and such use conform to such approved*
2 *application;*

3 *“(B) there is in effect a conditional approval of*
4 *an application filed pursuant to section 571 with re-*
5 *spect to such use or intended use of such drug, and*
6 *such drug, its labeling, and such use conform to such*
7 *conditionally approved application; or*

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

12 *A new animal drug shall also be deemed unsafe for such*
13 *purposes in the event of removal from the establishment of*
14 *a manufacturer, packer, or distributor of such drug for use*
15 *in the manufacture of animal feed in any State unless at*
16 *the time of such removal such manufacturer, packer, or dis-*
17 *tributor has an unrevoked written statement from the con-*
18 *signee of such drug, or notice from the Secretary, to the*
19 *effect that, with respect to the use of such drug in animal*
20 *feed, such consignee (i) holds a license issued under sub-*
21 *section (m) and has in its possession current approved la-*
22 *beling for such drug in animal feed; or (ii) will, if the con-*
23 *signee is not a user of the drug, ship such drug only to*
24 *a holder of a license issued under subsection (m).*

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

5 “(A) *there is in effect—*

6 “(i) *an approval of an application filed*
7 *pursuant to subsection (b) with respect to such*
8 *drug, as used in such animal feed, and such ani-*
9 *mal feed and its labeling, distribution, holding,*
10 *and use conform to such approved application;*

11 “(ii) *a conditional approval of an applica-*
12 *tion filed pursuant to section 571 with respect to*
13 *such drug, as used in such animal feed, and such*
14 *animal feed and its labeling, distribution, hold-*
15 *ing, and use conform to such conditionally ap-*
16 *proved application; or*

17 “(iii) *an index listing pursuant to section*
18 *572 with respect to such drug, as used in such*
19 *animal feed, and such animal feed and its label-*
20 *ing, distribution, holding, and use conform to*
21 *such index listing; and*

22 “(B) *such animal feed is manufactured at a site*
23 *for which there is in effect a license issued pursuant*
24 *to subsection (m)(1) to manufacture such animal*
25 *feed.”.*

1 *(J) Section 512(b)(3) of the Federal Food,*
2 *Drug, and Cosmetic Act is amended by striking*
3 *“under paragraph (1) or a request for an inves-*
4 *tigational exemption under subsection (j)” and*
5 *inserting “under paragraph (1), section 571, or*
6 *a request for an investigational exemption under*
7 *subsection (j)”.*

8 *(K) Section 512(d)(4) of the Federal Food,*
9 *Drug, and Cosmetic Act is amended by striking*
10 *“have previously been separately approved” and*
11 *inserting “have previously been separately ap-*
12 *proved pursuant to an application submitted*
13 *under section 512(b)(1)”.*

14 *(L) Section 512(f) of the Federal Food,*
15 *Drug, and Cosmetic Act is amended by striking*
16 *“subsection (d), (e), or (m)” and inserting “sub-*
17 *section (d), (e), or (m), or section 571 (c), (d),*
18 *or (e)”.*

19 *(M) Section 512(g) of the Federal Food,*
20 *Drug, and Cosmetic Act is amended by striking*
21 *“this section” and inserting “this section, or sec-*
22 *tion 571”.*

23 *(N) Section 512(i) of the Federal Food,*
24 *Drug, and Cosmetic Act is amended by striking*
25 *“subsection (b)” and inserting “subsection (b) or*

1 *section 571” and by inserting “or upon failure*
2 *to renew a conditional approval under section*
3 *571” after “or upon its suspension”.*

4 *(O) Section 512(l)(1) of the Federal Food,*
5 *Drug, and Cosmetic Act is amended by striking*
6 *“subsection (b)” and inserting “subsection (b) or*
7 *section 571”.*

8 *(P) Section 512(m)(1)(C) of the Federal*
9 *Food, Drug, and Cosmetic Act is amended by*
10 *striking “applicable regulations published pursu-*
11 *ant to subsection (i)” and inserting “applicable*
12 *regulations published pursuant to subsection (i)*
13 *or for indexed new animal drugs in accordance*
14 *with the index listing published pursuant to sec-*
15 *tion 572(e)(2) and the labeling requirements set*
16 *forth in section 572(h)”.*

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

21 *(R) Section 512(p)(1) of the Federal Food,*
22 *Drug, and Cosmetic Act is amended by striking*
23 *“subsection (b)(1)” and inserting “subsection*
24 *(b)(1) or section 571(a)”.*

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

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

8 (6) REGULATIONS.—On the date of enactment of
9 this Act, the Secretary of Health and Human Services
10 shall implement sections 571 and 573 of the Federal
11 Food, Drug, and Cosmetic Act and subsequently pub-
12 lish implementing regulations. Not later than 12
13 months after the date of enactment of this Act, the
14 Secretary shall issue proposed regulations to imple-
15 ment section 573 of the Federal Food, Drug, and Cos-
16 metic Act (as added by this Act), and not later than
17 24 months after the date of enactment of this Act, the
18 Secretary shall issue final regulations implementing
19 section 573 of the Federal Food, Drug, and Cosmetic
20 Act. Not later than 18 months after the date of enact-
21 ment of this Act, the Secretary shall issue proposed
22 regulations to implement section 572 of the Federal
23 Food, Drug, and Cosmetic Act (as added by this Act),
24 and not later than 36 months after the date of enact-
25 ment of this Act, the Secretary shall issue final regu-

1 *lations implementing section 572 of the Federal Food,*
2 *Drug, and Cosmetic Act. Not later than 30 months*
3 *after the date of enactment of this Act, the Secretary*
4 *shall issue proposed regulations to implement section*
5 *571 of the Federal Food, Drug, and Cosmetic Act (as*
6 *added by this Act), and not later than 42 months*
7 *after the date of enactment of this Act, the Secretary*
8 *shall issue final regulations implementing section 571*
9 *of the Federal Food, Drug, and Cosmetic Act. These*
10 *timeframes shall be extended by 12 months for each*
11 *fiscal year, in which the funds authorized to be ap-*
12 *propriated under subsection (i) are not in fact appro-*
13 *propriated.*

14 (7) *OFFICE.—The Secretary of Health and*
15 *Human Services shall establish within the Center for*
16 *Veterinary Medicine (of the Food and Drug Adminis-*
17 *tration), an Office of Minor Use and Minor Species*
18 *Animal Drug Development that reports directly to the*
19 *Director of the Center for Veterinary Medicine. This*
20 *office shall be responsible for overseeing the develop-*
21 *ment and legal marketing of new animal drugs for*
22 *minor uses and minor species. There is authorized to*
23 *be appropriated to carry out this subsection*
24 *\$1,200,000 for fiscal year 2004 and such sums as*
25 *may be necessary for each fiscal year thereafter.*

1 (8) *AUTHORIZATION OF APPROPRIATIONS.—*
 2 *There is authorized to be appropriated to carry out*
 3 *section 573(b) of the Federal Food, Drug, and Cos-*
 4 *metic Act (as added by this section) \$1,000,000 for*
 5 *the fiscal year following publication of final imple-*
 6 *menting regulations, \$2,000,000 for the subsequent*
 7 *fiscal year, and such sums as may be necessary for*
 8 *each fiscal year thereafter.*

9 **TITLE II—FOOD ALLERGEN LA-**
 10 **BELING AND CONSUMER PRO-**
 11 **TECTION**

12 **SEC. 201. SHORT TITLE.**

13 *This title may be cited as the “Food Allergen Labeling*
 14 *and Consumer Protection Act of 2003”.*

15 **SEC. 202. FINDINGS.**

16 *Congress finds that—*

17 (1) *it is estimated that—*

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

21 (B) *each year, roughly 30,000 individuals*
 22 *require emergency room treatment and 150 indi-*
 23 *viduals die because of allergic reactions to food;*

24 (2)(A) *eight major foods or food groups—milk,*
 25 *eggs, fish, Crustacean shellfish, tree nuts, peanuts,*

1 *wheat, and soybeans—account for 90 percent of food*
2 *allergies;*

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

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

7 *(3)(A) in a review of the foods of randomly se-*
8 *lected manufacturers of baked goods, ice cream, and*
9 *candy in Minnesota and Wisconsin in 1999, the Food*
10 *and Drug Administration found that 25 percent of*
11 *sampled foods failed to list peanuts or eggs as ingre-*
12 *dients on the food labels; and*

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

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

20 *(5)(A) ingredients in foods must be listed by*
21 *their “common or usual name”;*

22 *(B) in some cases, the common or usual name of*
23 *an ingredient may be unfamiliar to consumers, and*
24 *many consumers may not realize the ingredient is de-*
25 *rived from, or contains, a major food allergen; and*

1 (C) *in other cases, the ingredients may be de-*
2 *clared as a class, including spices, flavorings, and*
3 *certain colorings, or are exempt from the ingredient*
4 *labeling requirements, such as incidental additives;*
5 *and*

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

9 (B) *the current recommended treatment is avoid-*
10 *ance of glutens in foods that are associated with celiac*
11 *disease; and*

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

15 **SEC. 203. FOOD LABELING; REQUIREMENT OF INFORMA-**
16 **TION REGARDING ALLERGENIC SUBSTANCES.**

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

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

23 “(A) *the word ‘Contains’, followed by the name*
24 *of the food source from which the major food allergen*
25 *is derived, is printed immediately after or is adjacent*

1 *to the list of ingredients (in a type size no smaller*
2 *than the type size used in the list of ingredients) re-*
3 *quired under subsections (g) and (i); or*

4 *“(B) the common or usual name of the major*
5 *food allergen in the list of ingredients required under*
6 *subsections (g) and (i) is followed in parentheses by*
7 *the name of the food source from which the major food*
8 *allergen is derived, except that the name of the food*
9 *source is not required when—*

10 *“(i) the common or usual name of the in-*
11 *gredient uses the name of the food source from*
12 *which the major food allergen is derived; or*

13 *“(ii) the name of the food source from which*
14 *the major food allergen is derived appears else-*
15 *where in the ingredient list, unless the name of*
16 *the food source that appears elsewhere in the in-*
17 *gredient list appears as part of the name of a*
18 *food ingredient that is not a major food allergen*
19 *under section 201(qq)(2)(A) or (B).*

20 *“(2) As used in this subsection, the term ‘name of the*
21 *food source from which the major food allergen is derived’*
22 *means the name described in section 201(qq)(1); provided*
23 *that in the case of a tree nut, fish, or Crustacean shellfish,*
24 *the term ‘name of the food source from which the major*

1 *food allergen is derived' means the name of the specific type*
2 *of nut or species of fish or Crustacean shellfish.*

3 “(3) *The information required under this subsection*
4 *may appear in labeling in lieu of appearing on the label*
5 *only if the Secretary finds that such other labeling is suffi-*
6 *cient to protect the public health. A finding by the Secretary*
7 *under this paragraph (including any change in an earlier*
8 *finding under this paragraph) is effective upon publication*
9 *in the Federal Register as a notice.*

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

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

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

1 “(B) *The Secretary shall approve or deny such petition*
2 *within 180 days of receipt of the petition or the petition*
3 *shall be deemed denied, unless an extension of time is mutu-*
4 *ally agreed upon by the Secretary and the petitioner.*

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

11 “(D) *A determination regarding a petition under this*
12 *paragraph shall constitute final agency action.*

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

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

22 “(i) *scientific evidence (including the analytical*
23 *method used) that demonstrates that the food ingre-*
24 *redient (as derived by the method specified in the noti-*

1 *fication, where applicable) does not contain allergenic*
2 *protein; or*

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

7 *“(B) The food ingredient may be introduced or deliv-*
8 *ered for introduction into interstate commerce as a food in-*
9 *redient that is not a major food allergen 90 days after*
10 *the date of receipt of the notification by the Secretary, un-*
11 *less the Secretary determines within the 90-day period that*
12 *the notification does not meet the requirements of this para-*
13 *graph, or there is insufficient scientific evidence to deter-*
14 *mine that the food ingredient does not contain allergenic*
15 *protein or does not cause an allergenic response that poses*
16 *a risk to human health.*

17 *“(C) The Secretary shall promptly post to a public site*
18 *all notifications received under this subparagraph within*
19 *14 days of receipt and promptly post any objections thereto*
20 *by the Secretary.*

21 *“(x) Notwithstanding subsection (g), (i), or (k), or any*
22 *other law, a spice, flavoring, coloring, or incidental additive*
23 *that is, or that bears or contains, a food allergen (other than*
24 *a major food allergen), as determined by the Secretary by*

1 *regulation, shall be disclosed in a manner specified by the*
2 *Secretary by regulation.”.*

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

9 **(c) CONFORMING AMENDMENTS.**—

10 **(1)** *Section 201 of the Federal Food, Drug, and*
11 *Cosmetic Act (21 U.S.C. 321) (as amended by section*
12 *102(b)) is amended by adding at the end the fol-*
13 *lowing:*

14 **“(qq)** *The term ‘major food allergen’ means any of the*
15 *following:*

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

20 **“(2)** *A food ingredient that contains protein de-*
21 *derived from a food specified in paragraph (1), except*
22 *the following:*

23 **“(A)** *Any highly refined oil derived from a*
24 *food specified in paragraph (1) and any ingre-*
25 *redient derived from such highly refined oil.*

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

3 (2) Section 403A(a)(2) of the Federal Food,
4 Drug, and Cosmetic Act (21 U.S.C. 343–1(a)(2)) is
5 amended by striking “or 403(i)(2)” and inserting
6 “403(i)(2), 403(w), or 403(x)”.

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

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

11 Not later than 18 months after the date of enactment
12 of this Act, the Secretary of Health and Human Services
13 (in this section referred to as the “Secretary”) shall submit
14 to the Committee on Health, Education, Labor, and Pen-
15 sions of the Senate and the Committee on Energy and Com-
16 merce of the House of Representatives a report that—

17 (1)(A) analyzes—

18 (i) the ways in which foods, during manu-
19 facturing and processing, are unintentionally
20 contaminated with major food allergens, includ-
21 ing contamination caused by the use by manu-
22 facturers of the same production line to produce
23 both products for which major food allergens are
24 intentional ingredients and products for which

1 *major food allergens are not intentional ingredi-*
2 *ents; and*

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

6 *(B) estimates how common the practices de-*
7 *scribed in subparagraph (A) are in the food industry,*
8 *with breakdowns by food type as appropriate;*

9 *(2) advises whether good manufacturing prac-*
10 *tices or other methods can be used to reduce or elimi-*
11 *nate cross-contact of foods with the major food aller-*
12 *gens;*

13 *(3) describes—*

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

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

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

22 *(4) describes how consumers with food allergies*
23 *or the caretakers of consumers would prefer that in-*
24 *formation about the risk of cross-contact be commu-*

1 *nicated on food labels as determined by using appro-*
2 *priate survey mechanisms;*

3 *(5) states the number of inspections of food man-*
4 *ufacturing and processing facilities conducted in the*
5 *previous 2 years and describes—*

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

11 *(B) the nature of the violations found; and*

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

15 *(6) assesses the extent to which the Secretary and*
16 *the food industry have effectively addressed cross-con-*
17 *tact issues.*

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

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

24 *(1) to ensure that the entities operating the fa-*
25 *cilities comply with practices to reduce or eliminate*

1 *cross-contact of a food with residues of major food al-*
2 *lergens that are not intentional ingredients of the*
3 *food; and*

4 *(2) to ensure that major food allergens are prop-*
5 *erly labeled on foods.*

6 **SEC. 206. GLUTEN LABELING.**

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

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

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

24 *(1) the prevalence of food allergies;*

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

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

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

8 **SEC. 208. FOOD ALLERGIES RESEARCH.**

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

15 (b) *RECOMMENDATIONS.—Not later than 1 year after*
16 *the date of enactment of this Act, the panel shall make rec-*
17 *ommendations to the Secretary for enhancing and coordi-*
18 *nating research activities concerning food allergies, which*
19 *the Secretary shall make public.*

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

21 *The Secretary of Health and Human Services shall,*
22 *in the Conference for Food Protection, as part of its efforts*
23 *to encourage cooperative activities between the States under*
24 *section 311 of the Public Health Service Act (42 U.S.C.*
25 *243), pursue revision of the Food Code to provide guidelines*

1 *for preparing allergen-free foods in food establishments, in-*
2 *cluding in restaurants, grocery store delicatessens and bak-*
3 *eries, and elementary and secondary school cafeterias. The*
4 *Secretary shall consider guidelines and recommendations*
5 *developed by public and private entities for public and pri-*
6 *vate food establishments for preparing allergen-free foods in*
7 *pursuing this revision.*

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

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

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108TH CONGRESS
2D SESSION

S. 741

[Report No. 108-226]

A BILL

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

FEBRUARY 18, 2004

Reported under authority of the order of the Senate of February 12, 2004, with an amendment