

108TH CONGRESS
1ST SESSION

S. 741

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, and Mr. HARKIN) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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,*

3 **SECTION 1. SHORT TITLE.**

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

6 **SEC. 2. FINDINGS.**

7 Congress makes the following findings:

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

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

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

10 (4) Because the populations for which such new
11 animal drugs are intended may be small and condi-
12 tions of animal management may vary widely, it is
13 often difficult to design and conduct studies to es-
14 tablish drug safety and effectiveness under tradi-
15 tional new animal drug approval processes.

16 (5) It is in the public interest and in the inter-
17 est of animal welfare to provide for special proce-
18 dures to allow the lawful use and marketing of cer-
19 tain new animal drugs for minor species and minor
20 uses that take into account these special cir-
21 cumstances and that ensure that such drugs do not
22 endanger animal or public health.

23 (6) Exclusive marketing rights and tax credits
24 for clinical testing expenses have helped encourage
25 the development of “orphan” drugs for human use,

1 and comparable incentives should encourage the de-
2 velopment of new animal drugs for minor species
3 and minor uses.

4 **SEC. 3. AMENDMENTS TO THE FEDERAL FOOD, DRUG, AND**
5 **COSMETIC ACT.**

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

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

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

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

17 (b) THREE-YEAR EXCLUSIVITY FOR MINOR USE AND
18 MINOR SPECIES APPROVALS.—Section 512(c)(2)(F) (ii),
19 (iii), and (v) of the Federal Food, Drug, and Cosmetic
20 Act is amended by striking “(other than bioequivalence or
21 residue studies)” and inserting “(other than bioequiva-
22 lence studies or residue depletion studies, except residue
23 depletion studies for minor uses or minor species)” every
24 place it appears.

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

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

15 (d) MINOR USE AND MINOR SPECIES NEW ANIMAL
 16 DRUGS.—Chapter V of the Federal Food, Drug, and Cos-
 17 metic Act (21 U.S.C. 351 et seq.) is amended by adding
 18 at the end the following:

19 **“Subchapter F—New Animal Drugs for Minor**
 20 **Use and Minor Species**

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

23 “(a)(1) Except as provided in paragraph (3) of this
 24 section, any person may file with the Secretary an applica-
 25 tion for conditional approval of a new animal drug in-

1 tended for a minor use or a minor species. Such an appli-
2 cation may not be a supplement to an application ap-
3 proved under section 512. Such application must comply
4 in all respects with the provisions of section 512 of this
5 Act except sections 512(a)(4), 512(b)(2), 512(c)(1),
6 512(c)(2), 512(c)(3), 512(d)(1), 512(e), 512(h), and
7 512(n) unless otherwise stated in this section, and any ad-
8 ditional provisions of this section.

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

12 “(A) all information necessary to meet the re-
13 quirements of section 512(b)(1) except section
14 512(b)(1)(A);

15 “(B) full reports of investigations which have
16 been made to show whether or not such drug is safe
17 and there is a reasonable expectation of effectiveness
18 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 in-
22 formation available;

23 “(E) information regarding the quantity of
24 drug expected to be distributed on an annual basis
25 to meet 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
4 under 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 person has previously filed an applica-
8 tion for conditional approval under paragraph (1)
9 for the same drug in the same dosage form for the
10 same intended use whether or not subsequently con-
11 ditionally approved by the Secretary under sub-
12 section (b), or

13 “(B) the person obtained the application, or
14 data or other information contained therein, directly
15 or indirectly from the person who filed for condi-
16 tional approval under paragraph (1) for the same
17 drug in the same dosage form for the same intended
18 use whether or not subsequently conditionally ap-
19 proved by the Secretary under subsection (b).

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

24 “(1) issue an order, effective for one year, con-
25 ditionally approving the application if the Secretary

1 finds that none of the grounds for denying condi-
2 tional approval, specified in subsection (c) of this
3 section applies, or

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

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

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

11 “(2) the information submitted to the Secretary
12 as part of the application and any other information
13 before the Secretary with respect to such drug, is in-
14 sufficient to show that there is a reasonable expecta-
15 tion that the drug will have the effect it purports or
16 is represented to have under the conditions of use
17 prescribed, recommended, or suggested in the pro-
18 posed labeling thereof; or

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

1 the Secretary shall issue an order refusing to conditionally
2 approve the application. If, after such notice and oppor-
3 tunity for an informal hearing, the Secretary finds that
4 paragraphs (1) through (3) do not apply, the Secretary
5 shall issue an order conditionally approving the application
6 effective for one year. Any order issued under this sub-
7 section refusing to conditionally approve an application
8 shall state the findings upon which it is based.

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

17 “(1) No later than 90 days from the end of the
18 1-year period for which the original or renewed con-
19 ditional approval is effective, the applicant may sub-
20 mit a request to renew a conditional approval for an
21 additional 1-year term.

22 “(2) A conditional approval shall be deemed re-
23 newed at the end of the 1-year period, or at the end
24 of a 90-day extension that the Secretary may, at the
25 Secretary’s discretion, grant by letter in order to

1 complete review of the renewal request, unless the
2 Secretary determines before the expiration of the 1-
3 year period or the 90-day extension that—

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

6 “(B) the request fails to contain sufficient
7 information to show that—

8 “(i) the applicant is making sufficient
9 progress toward meeting approval require-
10 ments under section 512(d)(1)(E), and is
11 likely to be able to fulfill those require-
12 ments and obtain an approval under sec-
13 tion 512 before the expiration of the 5-year
14 maximum term of the conditional approval;

15 “(ii) the quantity of the drug that has
16 been distributed is consistent with the con-
17 ditionally approved intended use and condi-
18 tions of use, unless there is adequate ex-
19 planation that ensures that the drug is
20 only used for its intended purpose; or

21 “(iii) the same drug in the same dos-
22 age form for the same intended use has
23 not received approval under section 512, or
24 if such a drug has been approved, that the
25 holder of the approved application is un-

1 able to assure the availability of sufficient
2 quantities of the drug to meet the needs
3 for which the drug is intended; or

4 “(C) any of the provisions of section
5 512(e)(1) (A) through (B) or (D) through (F)
6 are applicable.

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

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

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

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

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

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

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

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

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

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

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

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

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

24 “(2) give the applicant an opportunity for a
25 hearing before the Secretary under section 512(d)

1 on the question whether such application can be ap-
2 proved.

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

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

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

21 “(a) The Secretary shall establish an index of unap-
22 proved minor species new animal drugs that may be law-
23 fully marketed for use in minor species. The index shall
24 be limited to—

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

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

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

16 “(B) there is no significant likelihood that
17 harmful residues will be present in the animal
18 or edible products from the animal presented as
19 food for food-producing animals as a result of
20 treatment at the early life stage; and

21 “(C) there are no concerns about the use
22 of the drug at later life stages because a toler-
23 ance and regulatory method to test for the drug
24 at later life stages are available or there is no
25 practical use for the drug in later life stages.

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

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

8 “(A) information regarding the need for the
9 new animal drug, the species for which the new ani-
10 mal drug is intended, the proposed intended use and
11 conditions of use, and anticipated annual distribu-
12 tion;

13 “(B) information to support the conclusion that
14 the proposed use meets the conditions of subsection
15 (a)(1) or (a)(2) of this section;

16 “(C) information regarding the components and
17 composition of the new animal drug;

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

21 “(E) an environmental assessment or informa-
22 tion to support a categorical exclusion from the re-
23 quirement to prepare an environmental assessment;

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

1 drug does not present a threat to the safety of indi-
2 viduals exposed to the new animal drug through its
3 manufacture 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) of this section, or 180 days for a request
10 submitted based on subsection (a)(2) of this section, the
11 Secretary shall grant or deny the request, and notify the
12 person who requested such determination of the Sec-
13 retary’s decision. The Secretary shall grant the request if
14 the Secretary finds that—

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

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

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

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

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

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

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

16 “(C) a proposed index entry;

17 “(D) facsimile labeling;

18 “(E) anticipated annual distribution of the new
19 animal drug;

20 “(F) a written commitment to manufacture the
21 new animal drug and animal feeds bearing or con-
22 taining such new animal drug according to current
23 good manufacturing practices;

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

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

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

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

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

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

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

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

23 “(E) include a recommendation regarding
24 whether the new animal drug should be limited to

1 use under the professional supervision of a licensed
2 veterinarian.

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

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

9 “(B) operates external to FDA; and

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

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

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

1 minor species in question. If the Secretary denies the re-
2 quest, the Secretary shall thereafter provide due notice
3 and the opportunity for an informal conference. The deci-
4 sion of the Secretary following an informal conference
5 shall constitute final agency action subject to judicial re-
6 view.

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

10 “(A) the name and address of the person who
11 holds the index listing;

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

15 “(C) product labeling; and

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

10 “(a) DESIGNATION.—

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

18 “(2) The Secretary may declare a new animal
19 drug a ‘designated new animal drug’ for an intended
20 use if—

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

23 “(B) the same drug in the same dosage
24 form for the same intended use is not approved

1 under section 512 or 571 or designated under
2 this section at the time the request is made.

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

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

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

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

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

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 proc-
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 “(c) EXCLUSIVITY FOR DESIGNATED NEW ANIMAL
13 DRUGS.—

14 “(1) Except as provided in subsection (c)(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 “(u) 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 (c), (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.

○