

108TH CONGRESS  
1ST SESSION

# H. R. 2079

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

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## IN THE HOUSE OF REPRESENTATIVES

MAY 13, 2003

Mr. PICKERING (for himself, Mr. JOHN, Mr. BERRY, Mr. THOMPSON of Mississippi, Mr. TOWNS, Mr. ALEXANDER, Mr. ROSS, Mr. GREENWOOD, Ms. BORDALLO, Mr. OTTER, Mr. UPTON, Mr. LIPINSKI, Mr. BOSWELL, Mr. GOODE, Mr. BONNER, Mr. ADERHOLT, Mr. BACHUS, Mr. DAVIS of Alabama, Mr. BONILLA, Mr. EVERETT, Mr. PUTNAM, Mr. EDWARDS, and Mr. SIMPSON) introduced the following bill; which was referred to the Committee on Energy and Commerce

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## 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(c)(1),  
13 512(c)(2), 512(c)(3), 512(d)(1), 512(e), 512(h), and  
14 512(n) unless otherwise stated in this section, and any ad-  
15 ditional provisions of this section.

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.

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

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

○