

107TH CONGRESS
1ST SESSION

S. 1346

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

AUGUST 2, 2001

Mr. SESSIONS (for himself, Mr. BINGAMAN, Mr. ALLARD, and Ms. COLLINS) introduced the following bill; which was read twice and referred to the Committee on Finance

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 2001”.

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 sponsors 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 final residue depletion studies, except final
23 residue depletion studies for minor uses or minor species)”
24 every 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**
 20 **For Minor 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 512(b)(2), 512(c)(1), 512(c)(2), 512(c)(3),
6 512(d)(1), 512(e), 512(h), and 512(n) unless otherwise
7 stated in this section, and any additional provisions of this
8 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 512(b)(1)(A);

14 “(B) full reports of investigations which have
15 been made to show whether or not such drug is safe
16 and there is a reasonable expectation of effectiveness
17 for use;

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

19 “(D) projections of expected need and the jus-
20 tification for that expectation based on the best in-
21 formation available;

22 “(E) information regarding the quantity of
23 drug expected to be distributed on an annual basis
24 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 without adequate justification—

7 “(A) the person has previously filed an applica-
8 tion for conditional approval under paragraph (1)
9 for the same drug, conditions of use, and dosage
10 form whether or not subsequently conditionally ap-
11 proved by the Secretary under subsection (b), or

12 “(B) the person obtained the application, or
13 data or other information contained therein, directly
14 or indirectly from the person who filed for condi-
15 tional approval under paragraph (1) for the same
16 drug and conditions of use whether or not subse-
17 quently conditionally approved by the Secretary
18 under subsection (b).

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

23 “(1) issue an order, effective for one year, con-
24 ditionally approving the application if the Secretary
25 finds that none of the grounds for denying condi-

1 tional approval, specified in subsection (c) of this
2 section applies, or

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

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

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

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 a drug with the same active
21 ingredient or ingredients, the same conditions of use,
22 and the same dosage form and that person is able
23 to assure the availability of sufficient quantities of
24 the drug to meet the needs for which the drug is in-
25 tended;

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 subparagraphs (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 subsections (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) If the renewal request is submitted no
23 later than 90-days from the end of the 1-year pe-
24 riod, a conditional approval shall be deemed renewed
25 at the end of the 1-year period, or at the end of an

1 additional 90-day extension when deemed necessary
2 to complete review of an application, unless the Sec-
3 retary makes a written determination before the ex-
4 piration of the 1-year period or the 90-day extension
5 that—

6 “(A) 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 in-
17 tended use, unless there is adequate expla-
18 nation that ensures that the drug is only
19 used for its intended purpose; or

20 “(iii) no other drug with the same ac-
21 tive ingredient or ingredients, for the same
22 conditions of use, and dosage form has re-
23 ceived approval under section 512, or if
24 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 “(B) 1 or more of the conditions of sub-
5 section 512(e)(1)(A) through (B) and (D)
6 through (F) are met.

7 “(3) If the Secretary makes a timely written
8 determination that a conditional approval should not
9 be renewed, or the applicant fails to submit a timely
10 renewal request, the Secretary shall issue an order
11 refusing to renew the conditional approval, and such
12 conditional approval shall be deemed withdrawn and
13 no longer in effect. The Secretary shall thereafter
14 provide an opportunity for an informal hearing to
15 the applicant on the issue whether the conditional
16 approval 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 a drug
21 with the same active ingredient or ingredients, the same
22 conditions of use, and dosage form, and that person is able
23 to assure the availability of sufficient quantities of the
24 drug to meet the needs for 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
7 512(e)(1)(A) through (B) or (D) through (F) are
8 applicable; 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, a sponsor
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. Upon receipt of
19 this information, the Secretary shall either—

20 “(1) issue an order approving the application if
21 the Secretary finds that none of the grounds for de-
22 nying approval specified in 512(d)(1) applies, or

23 “(2) give the sponsor an opportunity for a hear-
24 ing before the Secretary under 512(d) on the ques-
25 tion whether such application can be approved. Upon

1 issuance of an order approving the application, prod-
 2 uct labeling and administrative records of approval
 3 shall be modified accordingly. If the Secretary has
 4 not issued an order under section 512(c) approving
 5 such application prior to the termination date estab-
 6 lished under subsection (d)(1) of this section, the
 7 conditional approval issued under this section is no
 8 longer in effect unless the Secretary grants an ex-
 9 tension of an additional 180-day period so that the
 10 Secretary can complete review of the application.
 11 The decision to grant an extension is committed to
 12 Agency discretion and not subject to judicial review.
 13 “(i) The decision of the Secretary under subsections
 14 (c), (d), or (e) of this section, refusing or withdrawing con-
 15 ditional approval of an application shall constitute final
 16 agency action subject to judicial review.

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

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

23 “(1) new animal drugs intended for use in a
 24 minor species for which there is a reasonable cer-

1 tainty that the animal or edible products from the
2 animal will not be consumed by humans, and

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

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

12 “(B) there is no significant likelihood that
13 harmful residues will be present in the animal
14 presented as food for food-producing animals as
15 a result of treatment at the early life stage; and

16 “(C) there are no concerns about the use
17 of the drug at later life stages because a toler-
18 ance and regulatory method to test for the drug
19 at later life stages are available or there is no
20 practical use for the drug in later life stages.

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

24 “(c)(1) Any person may submit a request to the Sec-
25 retary for a determination whether a new animal drug

1 may be eligible for inclusion in the index. Such a request
2 shall include—

3 “(A) information regarding the need for the
4 new animal drug, the species for which the new ani-
5 mal drug is intended, the proposed intended use and
6 conditions of use, and anticipated annual distribu-
7 tion;

8 “(B) information to support the conclusion that
9 the proposed use meets the conditions of subsections
10 (a)(1) or (a)(2) of this section;

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

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

16 “(E) an environmental assessment or informa-
17 tion to support a categorical exclusion from the re-
18 quirement to prepare an environmental assessment;

19 “(F) information sufficient to support the con-
20 clusion that the proposed use of the new animal
21 drug does not present a threat to the safety of indi-
22 viduals exposed to the new animal drug through its
23 manufacture or use; and

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

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

12 “(A) no new animal drug, including the same
13 active ingredient or any salt or ester thereof is ap-
14 proved or conditionally approved in the same dosage
15 form for the same intended use;

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

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

23 If the Secretary denies the request, the Secretary shall
24 thereafter provide due notice and an opportunity for an
25 informal conference. The decision of the Secretary fol-

1 lowing an informal conference shall constitute final agency
2 action subject to judicial review.

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

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

11 “(B) a written report that meets the require-
12 ments in subparagraph (d)(2) of this section;

13 “(C) a proposed index entry;

14 “(D) facsimile labeling;

15 “(E) anticipated annual distribution of the new
16 animal drug;

17 “(F) a written commitment to manufacture the
18 new animal drug according to current good manu-
19 facturing practices;

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

23 “(H) upon specific request of the Secretary, in-
24 formation submitted to the expert panel described in
25 subparagraph (3); and

1 “(I) any additional requirements that the Sec-
 2 retary may prescribe by general regulation or spe-
 3 cific order.

4 “(2) The report required in subparagraph (1) shall:

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

6 “(B) include an evaluation of all available tar-
 7 get animal safety and effectiveness information, in-
 8 cluding anecdotal information;

9 “(C) State the expert panel’s opinion regarding
 10 whether the benefits of using the new animal drug
 11 for the proposed use in a minor species outweigh its
 12 risks, taking into account the harm being caused by
 13 the absence of an approved or conditionally-approved
 14 new animal drug for the minor species in question;

15 “(D) include information upon which labeling
 16 can be written; and

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

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

23 “(A) is composed of experts qualified by sci-
 24 entific training and experience to evaluate the target

1 animal safety and effectiveness of the new animal
2 drug under consideration;

3 “(B) operates external to FDA; and

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

6 The Secretary shall define the criteria for selection of a
7 qualified expert panel and the procedures for the operation
8 of the panel by regulation.

9 “(4) Within 180 days after the receipt of a request
10 for listing a new animal drug in the index, the Secretary
11 shall grant or deny the request. The Secretary shall grant
12 the request if the request for indexing continues to meet
13 the eligibility criteria in subsection (a) and the Secretary
14 finds, on the basis of the report of the qualified expert
15 panel and other information available to the Secretary,
16 that the benefits of using the new animal drug for the
17 proposed use in a minor species outweigh its risks, taking
18 into account the harm caused by the absence of an ap-
19 proved or conditionally-approved new animal drug for the
20 minor species in question. If the Secretary denies the re-
21 quest, the Secretary shall thereafter provide due notice
22 and the opportunity for an informal conference. The deci-
23 sion of the Secretary following an informal conference
24 shall constitute final agency action subject to judicial re-
25 view.

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

4 “(A) the name and address of the person who
5 holds the index listing;

6 “(B) the name of the drug and the intended
7 use and conditions of use for which it is being in-
8 dexed;

9 “(C) product labeling; and

10 “(D) conditions and any limitations that the
11 Secretary deems necessary regarding use of the
12 drug.

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

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

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

21 “(A) the expert panel failed to meet the re-
22 quirements as set forth by the Secretary by regula-
23 tion;

24 “(B) on the basis of new information before the
25 Secretary, evaluated together with the evidence

1 available to the Secretary when the new animal drug
2 was listed in the index, the benefits of using the new
3 animal drug for the indexed use do not outweigh its
4 risks;

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

7 “(D) the manufacture of the new animal drug
8 is not in accordance with current good manufac-
9 turing practices;

10 “(E) the labeling, distribution, or promotion of
11 the new animal drug is not in accordance with the
12 index entry;

13 “(F) the conditions and limitations of use asso-
14 ciated with the index listing have not been followed;
15 or

16 “(G) the request for indexing contains any un-
17 true statement of material fact;

18 the Secretary shall remove the new animal drug from the
19 index. The decision of the Secretary following an informal
20 conference shall constitute final agency action subject to
21 judicial review.

22 “(2) If the Secretary finds that there is a reasonable
23 probability that the use of the drug would adversely affect
24 the health of humans or other animals, the Secretary may:

1 “(A) suspend the listing of such drug imme-
2 diately;

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

5 “(C) afford that person the opportunity for an
6 informal conference.

7 The decision of the Secretary following an informal con-
8 ference shall constitute final agency action subject to judi-
9 cial review.

10 “(g) For purposes of indexing new animal drugs
11 under this section, to the extent consistent with the public
12 health, the Secretary shall promulgate regulations for ex-
13 empting from the operation of section 512 minor species
14 new animal drugs and animal feeds bearing or containing
15 new animal drugs intended solely for investigational use
16 by experts qualified by scientific training and experience
17 to investigate the safety and effectiveness of minor species
18 animal drugs. Such regulations may, at the discretion of
19 the Secretary, among other conditions relating to the pro-
20 tection of the public health, provide for conditioning such
21 exemption upon the establishment and maintenance of
22 such records, and the making of such reports to the Sec-
23 retary, by the manufacturer or the sponsor of the inves-
24 tigation of such article, of data (including but not limited
25 to analytical reports by investigators) obtained as a result

1 of such investigational use of such article, as the Secretary
2 finds will enable the Secretary to evaluate the safety and
3 effectiveness of such article in the event of the filing of
4 a request for an index listing pursuant to this section.

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

8 “(1) NOT APPROVED BY FDA.—Legally mar-
9 keted as an FDA indexed product. Extra-label use
10 is prohibited.”;

11 “(2) except in the case of new animal drugs in-
12 dexed for use in an early life stage of a food pro-
13 ducing animal, “This product is not to be used in
14 animals intended for use as food for humans or
15 other animals.”; and

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

18 “(i)(1) In the case of any new animal drug for which
19 an index listing pursuant to subsection (a) is in effect,
20 the person who has an index listing shall establish and
21 maintain such records, and make such reports to the Sec-
22 retary, of data relating to experience, and other data or
23 information, received or otherwise obtained by such person
24 with respect to such drug, or with respect to animal feeds
25 bearing or containing such drug, as the Secretary may by

1 general regulation, or by order with respect to such listing,
2 prescribe on the basis of a finding that such records and
3 reports are necessary in order to enable the Secretary to
4 determine, or facilitate a determination, whether there is
5 or may be ground for invoking subsection (f). Such regula-
6 tion or order shall provide, where the Secretary deems it
7 to be appropriate, for the examination, upon request, by
8 the persons to whom such regulation or order is applica-
9 ble, of similar information received or otherwise obtained
10 by the Secretary.

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

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

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

1 “(B) if the Secretary has determined that such
2 drug cannot be indexed and all legal appeals have
3 been exhausted,

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

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

8 “(2) Any request for data and information pursuant
9 to paragraph (1) shall include a verified statement by the
10 person making the request that any data or information
11 received under such paragraph shall not be disclosed by
12 such person to any other person—

13 “(A) for the purpose of, or as part of a plan,
14 scheme, or device for, obtaining the right to make,
15 use, or market, or making, using, or marketing, out-
16 side the United States, the drug identified in the re-
17 quest for indexing; and

18 “(B) without obtaining from any person to
19 whom the data and information are disclosed an
20 identical verified statement, a copy of which is to be
21 provided by such person to the Secretary, which
22 meets the requirements of this paragraph.

23 **“SEC. 573. DESIGNATED NEW ANIMAL DRUGS FOR MINOR**
24 **USE OR MINOR SPECIES.**

25 “(a) DESIGNATION.—

1 “(1) The manufacturer or the sponsor of a new
2 animal drug for a minor use or use in a minor spe-
3 cies may request that the Secretary declare that
4 drug a ‘designated new animal drug’. A request for
5 designation of a new animal drug shall be made be-
6 fore the submission of an application under section
7 512(b) or section 571 for the new animal drug.

8 “(2) The Secretary may declare a new animal
9 drug a ‘designated new animal drug’ for an intended
10 use if—

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

13 “(B) a new animal drug containing the
14 same active ingredient, including any salt or
15 ester of the active ingredient, for the same in-
16 tended use, in the same species, and in the
17 same dosage form is not approved under section
18 512 or section 571 or designated for the in-
19 tended use at the time the request is made.

20 “(3) Regarding the termination of a
21 designation—

22 “(A) the sponsor of a new animal drug
23 shall notify the Secretary of any decision to dis-
24 continue active pursuit of approval under sec-
25 tions 512 or 571 of an application for a des-

1 ignated new animal drug. The Secretary shall
2 terminate the designation upon such notifica-
3 tion;

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

9 “(C) the sponsor of an approved des-
10 ignated new animal drug shall notify the Sec-
11 retary of any discontinuance of the manufac-
12 ture of such new animal drug at least one year
13 before discontinuance. The Secretary shall ter-
14 minate the designation upon such notification;
15 and

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

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

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

24 “(1) The Secretary may make grants to and
25 enter into contracts with public and private entities

1 and individuals to assist in defraying the costs of
2 qualified safety and effectiveness testing expenses
3 and manufacturing expenses incurred in connection
4 with the development of designated new animal
5 drugs.

6 “(2) For purposes of subsection (1) of this
7 section—

8 “(A) The term “qualified safety and effec-
9 tiveness testing” means testing—

10 “(i) which occurs after the date such
11 new animal drug is designated under this
12 section and before the date on which an
13 application with respect to such drug is
14 submitted under section 512 or 571; and

15 “(ii) which is carried out under an in-
16 vestigational exemption under section
17 512(j).

18 “(B) The term “manufacturing expenses”
19 means expenses incurred in developing proc-
20 esses and procedures associated with manufac-
21 ture of the designated new animal drug which
22 occur after the new animal drug is designated
23 under this section and before the date on which
24 an application with respect to such new animal

1 drug is submitted under section 512 or section
2 571.

3 “(3) There is authorized to be appropriated to
4 carry out this subsection \$1,000,000 for the fiscal
5 year following publication of final implementing reg-
6 ulations, \$2,000,000 for the subsequent fiscal year
7 and such sums as may be necessary for each fiscal
8 year thereafter.

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

11 “(1) Except as provided in subsection (c)(2), if
12 the Secretary—

13 “(A) approves or conditionally approves an
14 application for a designated new animal drug,
15 and no active ingredient (including any salt or
16 ester of the active ingredient) of that des-
17 ignated new animal drug has been approved or
18 conditionally approved previously, the Secretary
19 may not approve or conditionally approve an-
20 other application submitted for a new animal
21 drug with the same active ingredient and in-
22 tended use as the designated new animal drug
23 for another applicant before the expiration of
24 ten years from the date of the approval or con-
25 ditional approval of the application.

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

14 “(2) If an application filed pursuant to section
15 512 or section 571 is approved for a designated new
16 animal drug, the Secretary may, during the 10-year
17 or 7-year exclusivity period beginning on the date of
18 the application approval or conditional approval, ap-
19 prove or conditionally approve another application
20 under section 512 or section 571 for such drug for
21 such minor use or minor species for another appli-
22 cant if—

23 “(A) the Secretary finds, after providing
24 the holder of such an approved application no-
25 tice and opportunity for the submission of

1 views, that in the granted exclusivity period the
2 holder of the approved application cannot as-
3 sure the availability of sufficient quantities of
4 the drug to meet the needs for which the drug
5 was designated; or

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

10 (e) CONFORMING AMENDMENTS.—

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

14 (2) Section 201(v) of the Federal Food, Drug,
15 and Cosmetic Act is amended by inserting the fol-
16 lowing after paragraph (2): “Provided that any drug
17 intended for minor use or use in a minor species
18 that is not the subject of a final regulation published
19 by the Secretary through notice and comment rule-
20 making finding that the criteria of paragraphs (1)
21 and (2) or of section 108 of Public Law 90–399
22 have been met is a new animal drug.”

23 (3) Section 301(e) of the Federal Food, Drug,
24 and Cosmetic Act is amended by striking

1 “512(a)(4)(C), 512(j), (l) or (m)” and inserting
 2 “512(a)(4)(C), 512(j), (l) or (m), 572(i).”

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

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

9 “(u) If it is a new animal drug—

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

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

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

23 (A) in paragraph (1)(A)(ii) by striking
 24 “512” and inserting “512, a conditionally-ap-

1 proved application under section 571, or an
2 index listing under section 572”; and

3 (B) in paragraph (3) by striking “section
4 512” and inserting “sections 512, 571, or
5 572”.

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

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

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

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

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

1 drug, its labeling, and such use conform to such ap-
2 proved application;

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

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

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

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

5 “(A) there is in effect—

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

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

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

23 “(B) such animal feed is manufactured at a site
24 for which there is in effect a license issued pursuant

1 to subsection (m)(1) to manufacture such animal
2 feed.”.

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

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

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

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

22 (14) Section 512(i) of the Federal Food, Drug,
23 and Cosmetic Act is amended by striking “sub-
24 section (b)” and inserting “subsection (b) or section
25 571” and by inserting “or upon failure to renew a

1 conditional approval under section 571” after “or
2 upon its suspension”.

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

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

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

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

23 (19) Section 512(p)(2) of the Federal Food,
24 Drug, and Cosmetic Act is amended by striking

1 “subsection (b)(1)” and inserting “subsection (b)(1)
 2 or section 571(a)”.

3 **SEC. 4. INTERNAL REVENUE CODE AMENDMENTS.**

4 (a) The Internal Revenue Code of 1986 is amended
 5 by adding the following new section after section 45C:

6 **“SEC. 45D. SAFETY AND EFFECTIVENESS TESTING EX-**
 7 **PENSES FOR DESIGNATED NEW ANIMAL**
 8 **DRUGS FOR MINOR USES AND MINOR SPE-**
 9 **CIES.**

10 “(a) For purposes of section 38, the credit deter-
 11 mined under this section for the taxable year is an amount
 12 equal to 50 percent of the qualified safety and effective-
 13 ness testing expenses for the designated new animal drug
 14 for the taxable year.

15 “(b) For purposes of this section—

16 “(1) Qualified safety and effectiveness testing
 17 expenses—

18 “(A) Except as otherwise provided in this
 19 paragraph, the term ‘qualified safety and effec-
 20 tiveness testing expenses’ means the amounts
 21 which are paid or incurred by the taxpayer dur-
 22 ing the taxable year which would be described
 23 in subsection (b) of section 41 if such sub-
 24 section were applied with the modifications set
 25 forth in subparagraph (B).

1 “(B) For purposes of subparagraph (A),
2 subsection (b) of section 41 shall be applied—

3 “(i) by substituting ‘safety and effec-
4 tiveness testing’ for ‘qualified research’
5 each place it appears in paragraphs (2)
6 and (3) of such subsection; and

7 “(ii) by substituting ‘100 percent’ for
8 ‘65 percent’ in paragraph (3)(A) of such
9 subsection.

10 “(C) The term ‘qualified safety and effec-
11 tiveness testing expenses’ shall not include any
12 amount to the extent such amount is funded by
13 any grant, contract, or otherwise by another
14 person (or any governmental entity).

15 “(D) For purposes of this paragraph—

16 “(i) section 41 shall be deemed to re-
17 main in effect for periods after June 30,
18 2001; and

19 “(ii) the ‘trade or business of the tax-
20 payer’ requirement of section 41(b)(1)
21 shall be deemed to be satisfied in the case
22 of a taxpayer that owns animals that are
23 the subject of safety and effectiveness test-
24 ing.

1 “(2)(A) The term ‘safety and effectiveness test-
2 ing’ means any safety and effectiveness testing—

3 “(i) which is carried out under an exemp-
4 tion for a new animal drug being tested for
5 minor use or a minor species under section
6 512(j) of the Federal Food, Drug, and Cos-
7 metic Act (or regulations issued under such sec-
8 tion);

9 “(ii) which occurs—

10 “(I) after the date such new animal
11 drug request is filed for designation under
12 section 573 of such Act, and

13 “(II) before the date on which an ap-
14 plication with respect to such drug is ap-
15 proved under section 512(c) of such Act;
16 and

17 “(iii) which is conducted by or on behalf
18 of—

19 “(I) the taxpayer who applied for the
20 designation under section 573; or

21 “(II) the owner of the animals that
22 are the subject of safety and effectiveness
23 testing.

24 “(B) Safety and effectiveness testing shall be
25 taken into account under subparagraph (A) only to

1 the extent such testing is related to the use of a
2 new animal drug for the minor use or minor species
3 for which it was designated under section 573 of the
4 Federal Food, Drug, and Cosmetic Act.

5 “(c)(1) Except as provided in paragraph (2), any
6 qualified safety and effectiveness testing expenses for a
7 taxable year to which an election under this section applies
8 shall not be taken into account for purposes of deter-
9 mining the credit allowable under section 41 for such tax-
10 able year.

11 “(2) Any qualified safety and effectiveness testing ex-
12 penses for any taxable year which are qualified research
13 expenses (within the meaning of section 41(b)) shall be
14 taken into account in determining base period research ex-
15 penses for purposes of applying section 41 to subsequent
16 taxable years.

17 “(d)(1) For purposes of this section, the term ‘minor
18 use’ is defined in section 201(mm) of the Federal Food,
19 Drug, and Cosmetic Act and ‘minor species’ is defined in
20 section 201(ll). Determinations under the preceding sen-
21 tence with respect to any new animal drug shall be made
22 on the basis of the facts and circumstances as of the date
23 such new animal drug is designated under section 573 of
24 the Federal Food, Drug, and Cosmetic Act.

1 “(2) No credit shall be allowed under this section
 2 with respect to any safety and effectiveness testing con-
 3 ducted by a corporation to which an election under section
 4 936 applies.

5 “(3) Rules similar to the rules of paragraphs (1) and
 6 (2) of section 41(f) shall apply for purposes of this section.

7 “(4) This section shall apply to any taxpayer for any
 8 taxable year only if such taxpayer elects (at such time and
 9 in such manner as the Secretary may by regulations pre-
 10 scribe) to have this section apply for such taxable year.”.

11 (b) CONFORMING AMENDMENTS.—

12 (1) Section 38(b) of the Internal Revenue Code
 13 is amended—

14 (A) By deleting “plus” at end of para-
 15 graph (11);

16 (B) By deleting the period at the end of
 17 paragraph (12) and replacing it with the fol-
 18 lowing: “, plus”; and

19 (C) By adding the following new para-
 20 graph at the end: “the minor use and minor
 21 species new animal drug credit determined
 22 under section 45D(a)”.

23 (2) Section 280C(b) of the Internal Revenue
 24 Code is amended—

1 (A) in paragraph (1), by deleting “section
 2 45C(b)” and substituting the following: “section
 3 45C(b) or 45D(b)”; and

4 (B) in paragraphs (1) and (2), by deleting
 5 “section 45C” wherever it appears and sub-
 6 stituting the following: “section 45C or 45D”.

7 (c) REGULATIONS.—The Secretary of the Treasury
 8 shall publish proposed regulations to implement amend-
 9 ments to the Internal Revenue Code made by this Act
 10 within 6 months of the date of enactment, and final regu-
 11 lations within 24 months of the date of enactment.

12 **SEC. 5. REGULATIONS.**

13 Not later than 18 months after the date of enactment
 14 of this Act, the Secretary of Health and Human Services
 15 shall issue proposed regulations to implement section 572
 16 of the Federal Food, Drug, and Cosmetic Act (as added
 17 by this Act), and not later than 36 months after the date
 18 of enactment of this Act, the Secretary shall issue final
 19 regulations implementing such amendments. Not later
 20 than 12 months after the date of enactment of this Act,
 21 the Secretary of Health and Human Services shall issue
 22 proposed regulations to implement section 573 of the Fed-
 23 eral Food, Drug, and Cosmetic Act (as added by this Act),
 24 and not later than 24 months after the date of enactment
 25 of this Act, the Secretary shall issue final regulations im-

1 plementing such amendments; provided that these time-
2 frames shall be extended by 12 months for each fiscal year
3 in which the funds authorized to be appropriated by this
4 Act are not in fact appropriated. The Secretary shall im-
5 plement section 571 of the Federal Food, Drug, and Cos-
6 metic Act (as added by this Act) on the date of enactment
7 of this Act and subsequently publish any needed imple-
8 menting regulations.

9 **SEC. 6. OFFICE OF MINOR USE AND MINOR SPECIES ANI-**
10 **MAL DRUG DEVELOPMENT.**

11 The Secretary of Health and Human Services shall
12 establish within the Center of Veterinary Medicine (of the
13 Food and Drug Administration), an Office of Minor Use
14 and Minor Species Animal Drug Development that reports
15 directly to the Director of the Center for Veterinary Medi-
16 cine. This office shall be responsible for overseeing the de-
17 velopment and legal marketing of new animal drugs for
18 minor uses and minor species. There is authorized to be
19 appropriated to carry out this subsection \$1,200,000 for
20 fiscal year 2002 and such sums as may be necessary for
21 each fiscal year thereafter.

○