

107TH CONGRESS
1ST SESSION

H. R. 1956

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

IN THE HOUSE OF REPRESENTATIVES

MAY 23, 2001

Mr. PICKERING (for himself, Mr. COMBEST, Mr. SIMPSON, Mr. OTTER, Mrs. THURMAN, and Mr. HAYES) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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:

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

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

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

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

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

1 (6) Exclusive marketing rights and tax credits
 2 for clinical testing expenses have helped encourage
 3 the development of ‘orphan’ drugs for human use,
 4 and comparable incentives should encourage the de-
 5 velopment of new animal drugs for minor species
 6 and minor uses.

7 **SEC. 3. AMENDMENTS TO THE FEDERAL FOOD, DRUG, AND**
 8 **COSMETIC ACT.**

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

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

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

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

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

1 residue depletion studies for minor uses or minor species)”
2 every place it appears.

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

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

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

1 **“Subchapter F—New Animal Drugs**
2 **For Minor 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 512(b)(2), 512(c)(1), 512(c)(2), 512(c)(3),
13 512(d)(1), 512(e), 512(h), and 512(n) unless otherwise
14 stated in this section, and any additional provisions of this
15 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 512(b)(1)(A);

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

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

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

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

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

11 “(3) A person may not file an application under para-
12 graph (1) if without adequate justification—

13 “(A) the person has previously filed an applica-
14 tion for conditional approval under paragraph (1)
15 for the same drug, conditions of use, and dosage
16 form whether or not subsequently conditionally ap-
17 proved by the Secretary under subsection (b), or

18 “(B) the person obtained the application, or
19 data or other information contained therein, directly
20 or indirectly from the person who filed for condi-
21 tional approval under paragraph (1) for the same
22 drug and conditions of use whether or not subse-
23 quently conditionally approved by the Secretary
24 under subsection (b).

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

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

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

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

15 “(1) any of the provisions of section
16 512(d)(1)(A) through (D) or (F) through (I) are ap-
17 plicable;

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

1 “(3) another person has received approval
2 under section 512 for a drug with the same active
3 ingredient or ingredients, the same conditions of use,
4 and the same dosage form and that person is able
5 to assure the availability of sufficient quantities of
6 the drug to meet the needs for which the drug is in-
7 tended;

8 the Secretary shall issue an order refusing to conditionally
9 approve the application.

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

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

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

6 “(2) If the renewal request is submitted no
7 later than 90-days from the end of the 1-year pe-
8 riod, a conditional approval shall be deemed renewed
9 at the end of the 1-year period, or at the end of an
10 additional 90-day extension when deemed necessary
11 to complete review of an application, unless the Sec-
12 retary makes a written determination before the ex-
13 piration of the 1-year period or the 90-day extension
14 that—

15 “(A) 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 in-

1 tended use, unless there is adequate expla-
2 nation that ensures that the drug is only
3 used for its intended purpose; or

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

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

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

6 “(2) give the sponsor an opportunity for a hear-
7 ing before the Secretary under 512(d) on the ques-
8 tion whether such application can be approved. Upon
9 issuance of an order approving the application, prod-
10 uct labeling and administrative records of approval
11 shall be modified accordingly. If the Secretary has
12 not issued an order under section 512(c) approving
13 such application prior to the termination date estab-
14 lished under subsection (d)(1) of this section, the
15 conditional approval issued under this section is no
16 longer in effect unless the Secretary grants an ex-
17 tension of an additional 180-day period so that the
18 Secretary can complete review of the application.
19 The decision to grant an extension is committed to
20 Agency discretion and not subject to judicial review.
21 “(i) The decision of the Secretary under subsections
22 (c), (d), or (e) of this section, refusing or withdrawing con-
23 ditional approval of an application shall constitute final
24 agency action subject to judicial review.

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

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

7 “(1) new animal drugs intended for use in a
8 minor species for which there is a reasonable cer-
9 tainty that the animal or edible products from the
10 animal will not be consumed by humans, and

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

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

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

24 “(C) there are no concerns about the use
25 of the drug at later life stages because a toler-
26 ance and regulatory method to test for the drug

1 at later life stages are available or there is no
2 practical use for the drug in later life stages.

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

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

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

15 “(B) information to support the conclusion that
16 the proposed use meets the conditions of subsections
17 (a)(1) or (a)(2) of this section;

18 “(C) information regarding the components and
19 composition of the new animal drug;

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

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

1 “(F) information sufficient to support the con-
2 clusion that the proposed use of the new animal
3 drug does not present a threat to the safety of indi-
4 viduals exposed to the new animal drug through its
5 manufacture or use; and

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

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

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

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

23 “(C) the person requesting the determination
24 has established appropriate specifications for the
25 manufacture and control of the new animal drug

1 and has demonstrated an understanding of the re-
2 quirements of current good manufacturing practices.
3 If the Secretary denies the request, the Secretary shall
4 thereafter provide due notice and an opportunity for an
5 informal conference. The decision of the Secretary fol-
6 lowing an informal conference shall constitute final agency
7 action subject to judicial review.

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

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

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

18 “(C) a proposed index entry;

19 “(D) facsimile labeling;

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

22 “(F) a written commitment to manufacture the
23 new animal drug according to current good manu-
24 facturing practices;

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

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

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

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

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

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

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

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

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

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

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

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

9 “(B) operates external to FDA; and

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

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

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

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

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

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

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

15 “(C) product labeling; and

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

10 “(a) DESIGNATION.—

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

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

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

23 “(B) a new animal drug containing the
 24 same active ingredient, including any salt or
 25 ester of the active ingredient, for the same in-

1 tended use, in the same species, and in the
2 same dosage form is not approved under section
3 512 or section 571 or designated for the in-
4 tended use at the time the request is made.

5 “(3) Regarding the termination of a
6 designation—

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 tions 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 sections 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 subsection (1) of this
17 section—

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 or 571; 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 section
12 571.

13 “(3) There is authorized to be appropriated to
14 carry out this subsection \$1,000,000 for the fiscal
15 year following publication of final implementing reg-
16 ulations, \$2,000,000 for the subsequent fiscal year
17 and such sums as may be necessary for each fiscal
18 year thereafter.

19 “(c) EXCLUSIVITY FOR DESIGNATED NEW ANIMAL
20 DRUGS.—

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

23 “(A) approves or conditionally approves an
24 application for a designated new animal drug,
25 and no active ingredient (including any salt or

1 ester of the active ingredient) of that des-
2 ignated new animal drug has been approved or
3 conditionally approved previously, the Secretary
4 may not approve or conditionally approve an-
5 other application submitted for a new animal
6 drug with the same active ingredient and in-
7 tended use as the designated new animal drug
8 for another applicant before the expiration of
9 ten years from the date of the approval or con-
10 ditional approval of the application.

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

24 “(2) If an application filed pursuant to section
25 512 or section 571 is approved for a designated new

1 animal drug, the Secretary may, during the 10-year
2 or 7-year exclusivity period beginning on the date of
3 the application approval or conditional approval, ap-
4 prove or conditionally approve another application
5 under section 512 or section 571 for such drug for
6 such minor use or minor species for another appli-
7 cant if—

8 “(A) the Secretary finds, after providing
9 the holder of such an approved application no-
10 tice and opportunity for the submission of
11 views, that in the granted exclusivity period the
12 holder of the approved application cannot as-
13 sure the availability of sufficient quantities of
14 the drug to meet the needs for which the drug
15 was designated; or

16 “(B) such holder provides written consent
17 to the Secretary for the approval or conditional
18 approval of other applications before the expira-
19 tion of such exclusivity period.”.

20 (e) CONFORMING AMENDMENTS.—

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

24 (2) Section 201(v) of the Federal Food, Drug,
25 and Cosmetic Act is amended by inserting the fol-

1 lowing after paragraph (2): “Provided that any drug
2 intended for minor use or use in a minor species
3 that is not the subject of a final regulation published
4 by the Secretary through notice and comment rule-
5 making finding that the criteria of paragraphs (1)
6 and (2) or of section 108 of Public Law 90–399
7 have been met is a new animal drug.”

8 (3) Section 301(e) of the Federal Food, Drug,
9 and Cosmetic Act is amended by striking
10 “512(a)(4)(C), 512(j), (l) or (m)” and inserting
11 “512(a)(4)(C), 512(j), (l) or (m), 572(i).”

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

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

18 “(u) If it is a new animal drug—

19 “(1) that is conditionally approved under sec-
20 tion 571 and its labeling does not conform with the
21 approved application or section 571(f), or that is not
22 conditionally approved under section 571 and its
23 label bears the statement set forth in section
24 571(f)(1)(A); or

1 “(2) that is indexed under section 572 and its
2 labeling does not conform with the index listing
3 under section 572(e) or 572(h), or that has not been
4 indexed under section 572 and its label bears the
5 statement set forth in section 572(h).”

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

8 (A) in paragraph (1)(A)(ii) by striking
9 “512” and inserting “512, a conditionally-ap-
10 proved application under section 571, or an
11 index listing under section 572”; and

12 (B) in paragraph (3) by striking “section
13 512” and inserting “sections 512, 571, or
14 572”.

15 (7) Section 504(a)(1) of the Federal Food,
16 Drug, and Cosmetic Act is amended by striking
17 “512(b)” and inserting “512(b), a conditionally-ap-
18 proved application filed pursuant to section 571, or
19 an index listing pursuant to section 572”.

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

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

4 “(1) A new animal drug shall, with respect to any
5 particular use or intended use of such drug, be deemed
6 unsafe for purposes of section 501(a)(5) and section
7 402(a)(2)(C)(ii) unless—

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

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

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

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

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

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

15 “(A) there is in effect—

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

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

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

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

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

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

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

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

1 section (d), (e), or (m)” and inserting “subsection
2 (d), (e), or (m), or section 571(c), (d), or (e)”.

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

6 (14) Section 512(i) of the Federal Food, Drug,
7 and Cosmetic Act is amended by striking “sub-
8 section (b)” and inserting “subsection (b) or section
9 571” and by inserting “or upon failure to renew a
10 conditional approval under section 571” after “or
11 upon its suspension”.

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

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

24 (17) Section 512(m)(3) of the Federal Food,
25 Drug, and Cosmetic Act is amended by inserting “or

1 an index listing pursuant to section 572(e)” after
 2 “subsection (i)”.

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

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

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

12 The Internal Revenue Code of 1986 is amended by
 13 adding the following new section after section 45C:

14 **“SEC. 45D. SAFETY AND EFFECTIVENESS TESTING EX-**
 15 **PENSES FOR DESIGNATED NEW ANIMAL**
 16 **DRUGS FOR MINOR USES AND MINOR SPE-**
 17 **CIES.**

18 “(a) For purposes of section 38, the credit deter-
 19 mined under this section for the taxable year is an amount
 20 equal to 50 percent of the qualified safety and effective-
 21 ness testing expenses for the designated new animal drug
 22 for the taxable year.

23 “(b) For purposes of this section—

24 “(1) Qualified safety and effectiveness testing
 25 expenses—

1 “(A) Except as otherwise provided in this
2 paragraph, the term ‘qualified safety and effec-
3 tiveness testing expenses’ means the amounts
4 which are paid or incurred by the taxpayer dur-
5 ing the taxable year which would be described
6 in subsection (b) of section 41 if such sub-
7 section were applied with the modifications set
8 forth in subparagraph (B).

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

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

15 “(ii) by substituting ‘100 percent’ for
16 ‘65 percent’ in paragraph (3)(A) of such
17 subsection.

18 “(C) The term ‘qualified safety and effec-
19 tiveness testing expenses’ shall not include any
20 amount to the extent such amount is funded by
21 any grant, contract, or otherwise by another
22 person (or any governmental entity).

23 “(D) For purposes of this paragraph—

1 “(i) section 41 shall be deemed to re-
2 main in effect for periods after June 30,
3 2001; and

4 “(ii) the ‘trade or business of the tax-
5 payer’ requirement of section 41(b)(1)
6 shall be deemed to be satisfied in the case
7 of a taxpayer that owns animals that are
8 the subject of safety and effectiveness test-
9 ing.

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

12 “(i) which is carried out under an exemp-
13 tion for a new animal drug being tested for
14 minor use or a minor species under section
15 512(j) of the Federal Food, Drug, and Cos-
16 metic Act (or regulations issued under such sec-
17 tion);

18 “(ii) which occurs—

19 “(I) after the date such new animal
20 drug request is filed for designation under
21 section 573 of such Act, and

22 “(II) before the date on which an ap-
23 plication with respect to such drug is ap-
24 proved under section 512(c) of such Act;
25 and

1 “(iii) which is conducted by or on behalf
2 of—

3 “(I) the taxpayer who applied for the
4 designation under section 573; or

5 “(II) the owner of the animals that
6 are the subject of safety and effectiveness
7 testing.

8 “(B) Safety and effectiveness testing shall be
9 taken into account under subparagraph (A) only to
10 the extent such testing is related to the use of a new
11 animal drug for the minor use or minor species for
12 which it was designated under section 573 of the
13 Federal Food, Drug, and Cosmetic Act.

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

20 “(2) Any qualified safety and effectiveness testing ex-
21 penses for any taxable year which are qualified research
22 expenses (within the meaning of section 41(b)) shall be
23 taken into account in determining base period research ex-
24 penses for purposes of applying section 41 to subsequent
25 taxable years.

1 “(d)(1) For purposes of this section, the term ‘minor
 2 use’ is defined in section 201(mm) of the Federal Food,
 3 Drug, and Cosmetic Act and ‘minor species’ is defined in
 4 section 201(ll). Determinations under the preceding sen-
 5 tence with respect to any new animal drug shall be made
 6 on the basis of the facts and circumstances as of the date
 7 such new animal drug is designated under section 573 of
 8 the Federal Food, Drug, and Cosmetic Act.

9 “(2) No credit shall be allowed under this section
 10 with respect to any safety and effectiveness testing con-
 11 ducted by a corporation to which an election under section
 12 936 applies.

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

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

19 (b) CONFORMING AMENDMENTS.—

20 (1) Section 38(b) of the Internal Revenue Code
 21 is amended—

22 (A) by deleting “plus” at end of paragraph
 23 (11);

1 (B) by deleting the period at the end of
 2 paragraph (12) and replacing it with the fol-
 3 lowing: “, plus”; and

4 (C) by adding the following new paragraph
 5 at the end: “the minor use and minor species
 6 new animal drug credit determined under sec-
 7 tion 45D(a)”.

8 (2) Section 280C(b) of the Internal Revenue
 9 Code is amended—

10 (A) in paragraph (1), by deleting “section
 11 45C(b)” and substituting the following: “section
 12 45C(b) or 45D(b)”;

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

16 (c) REGULATIONS.—The Secretary of the Treasury
 17 shall publish proposed regulations to implement amend-
 18 ments to the Internal Revenue Code made by this Act
 19 within 6 months of the date of enactment, and final regu-
 20 lations within 24 months of the date of enactment.

21 **SEC. 5. REGULATIONS.**

22 Not later than 18 months after the date of enactment
 23 of this Act, the Secretary of Health and Human Services
 24 shall issue proposed regulations to implement section 572
 25 of the Federal Food, Drug, and Cosmetic Act (as added

1 by this Act), and not later than 36 months after the date
2 of enactment of this Act, the Secretary shall issue final
3 regulations implementing such amendments. Not later
4 than 12 months after the date of enactment of this Act,
5 the Secretary of Health and Human Services shall issue
6 proposed regulations to implement section 573 of the Fed-
7 eral Food, Drug, and Cosmetic Act (as added by this Act),
8 and not later than 24 months after the date of enactment
9 of this Act, the Secretary shall issue final regulations im-
10 plementing such amendments; provided that these time-
11 frames shall be extended by 12 months for each fiscal year
12 in which the funds authorized to be appropriated by this
13 Act are not in fact appropriated. The Secretary shall im-
14 plement section 571 of the Federal Food, Drug, and Cos-
15 metic Act (as added by this Act) on the date of enactment
16 of this Act and subsequently publish any needed imple-
17 menting regulations.

18 **SEC. 6. OFFICE OF MINOR USE AND MINOR SPECIES ANI-**
19 **MAL DRUG DEVELOPMENT.**

20 The Secretary of Health and Human Services shall
21 establish within the Center of Veterinary Medicine (of the
22 Food and Drug Administration), an Office of Minor Use
23 and Minor Species Animal Drug Development that reports
24 directly to the Director of the Center for Veterinary Medi-
25 cine. This office shall be responsible for overseeing the de-

1 velopment and legal marketing of new animal drugs for
2 minor uses and minor species. There is authorized to be
3 appropriated to carry out this subsection \$1,200,000 for
4 fiscal year 2002 and such sums as may be necessary for
5 each fiscal year thereafter.

○