

106TH CONGRESS
2D SESSION

S. 3169

To amend the Federal Food, Drug, and Cosmetic Act and the Internal Revenue Code of 1986 with respect to drugs for minor animal species, and for other purposes.

IN THE SENATE OF THE UNITED STATES

OCTOBER 5 (legislative day, SEPTEMBER 22), 2000

Mr. SESSIONS (for himself, Mr. BINGAMAN, Mr. ALLARD, Mr. JOHNSON, Mr. CRAPO, and Mrs. LINCOLN) 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 and the Internal Revenue Code of 1986 with respect to drugs for minor animal species, 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 Animal Species
5 Health and Welfare Act of 2000”.

6 **SEC. 2. FINDINGS.**

7 The Congress finds as follows:

8 (1) There is a severe shortage of approved ani-
9 mal drugs for use in minor species.

1 (2) There is a severe shortage of approved
2 drugs for treating animal diseases and conditions
3 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 animal drug manufacturers to pursue approvals for
9 these species, diseases, and conditions.

10 (4) Because the populations for which such
11 drugs are intended are small and conditions of ani-
12 mal management may vary widely, it is often dif-
13 ficult or impossible to design and conduct studies to
14 establish drug safety and effectiveness under tradi-
15 tional 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 sanction the lawful use and marketing of
19 animal drugs for minor species and minor uses that
20 take into account these special circumstances and
21 that ensure that such drugs do not endanger the
22 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 will help encourage the
2 development and sanctioning for lawful marketing of
3 animal drugs for minor species and minor uses.

4 **SEC. 3. AMENDMENTS AFFECTING THE FOOD AND DRUG**
5 **ADMINISTRATION.**

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 ‘minor species’ means animals other
10 than cattle, horses, swine, chickens, turkeys, dogs, and
11 cats, except that the Secretary may amend this definition
12 by regulation.

13 “(ll) The term ‘minor use’ means the use of a drug—

14 “(1) in a minor species, or

15 “(2) in an animal species other than a minor
16 species for a disease or condition that occurs infre-
17 quently or in limited geographic areas, except that
18 the Secretary may amend this definition by regula-
19 tion.

20 “(mm) The term ‘species with no human food safety
21 concern’ means an animal species, or life stage of an ani-
22 mal species, that is not customarily used for food for hu-
23 mans and does not endanger the public health.”.

24 (b) MINOR USE ANIMAL DRUGS.—Chapter V of the
25 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351

1 et seq.) is amended by adding at the end the following
2 new subchapter:

3 “SUBCHAPTER F—ANIMAL DRUGS FOR MINOR
4 USES

5 “DESIGNATION OF DRUGS FOR MINOR USES

6 “SEC. 571. (a) Prior to the submission of an applica-
7 tion for approval of a new animal drug under section
8 512(b), a manufacturer or sponsor of such drug may re-
9 quest that the Secretary designate such drug as a drug
10 for a minor use. The Secretary shall designate such drug
11 as a drug for minor use if the Secretary finds that such
12 drug is or will be investigated for a minor use and the
13 application for such drug is approved under section 512.
14 A request for a designation of a drug under this subsection
15 shall contain the consent of the applicant to notice being
16 given by the Secretary under subsection (c) respecting the
17 designation of the drug.

18 “(b) The designation of a drug as a drug for a minor
19 use under subsection (a) shall be subject to the condition
20 that—

21 “(1) if an application was approved for the
22 drug under section 512(c), the manufacturer of the
23 drug will notify the Secretary of any discontinuance
24 of the production of the drug at least 1 year before
25 discontinuance; and

1 “(2) if an application has not been approved for
2 the drug under section 512(c) and if preclinical in-
3 vestigations or investigations under section 512(j)
4 are being conducted with the drug, the manufacturer
5 or sponsor of the drug will notify the Secretary of
6 any decision to discontinue active pursuit of ap-
7 proval of an application under section 512(b).

8 “(c) Notice respecting the designation of a drug
9 under subsection (a) shall be made available to the public.

10 “PROTECTION FOR DRUGS FOR MINOR USES

11 “SEC. 572. (a) Except as provided in subsection (b):

12 “(1) If the Secretary approves an application
13 filed pursuant to section 512 for a drug designated
14 under section 571 for a minor use, no active ingre-
15 dient (including any salt or ester of the active ingre-
16 dient) of which has been approved in any other ap-
17 plication under section 512, the Secretary may not
18 approve or conditionally approve another application
19 submitted under section 512 or section 573 for such
20 drug for such minor use for a person who is not the
21 holder of such approved application until the expira-
22 tion of 10 years from the date of the approval of the
23 application.

24 “(2) If the Secretary approves an application
25 filed pursuant to section 512 for a drug designated
26 under section 571 for a minor use, which includes

1 an active ingredient (including an ester or salt of
2 the active ingredient) that has been approved in any
3 other application under section 512, the Secretary
4 may not approve or conditionally approve another
5 application submitted under section 512 or section
6 573 for such drug for such minor use for a person
7 who is not the holder of such approved application
8 until the expiration of 7 years from the date of ap-
9 proval of the application.

10 “(b) If an application filed pursuant to section 512
11 is approved for a drug designated under section 571, the
12 Secretary may, during the 10-year or 7-year period begin-
13 ning on the date of the application approval, approve or
14 conditionally approve another application under section
15 512 or section 573 for such drug for such minor use for
16 a person who is not the holder of such approved applica-
17 tion if—

18 “(1) the Secretary finds, after providing the
19 holder notice and opportunity for the submission of
20 views, that in such period the holder of the approved
21 application cannot assure the availability of suffi-
22 cient quantities of the drug to meet the needs for
23 which the drug was designated; or

24 “(2) such holder provides the Secretary in writ-
25 ing the consent of such holder for the approval or

1 conditional approval of other applications before the
2 expiration of such 10-year or 7-year period.

3 “CONDITIONAL APPROVAL FOR MINOR USE NEW ANIMAL
4 DRUGS

5 “SEC. 573. (a)(1) Except as provided in paragraph
6 (2), any person may file with the Secretary an application
7 for conditional approval of a new animal drug for a minor
8 use. Such person shall submit to the Secretary as part
9 of an application—

10 “(A) reports of investigations which have been
11 made to show whether or not such drug is safe for
12 use;

13 “(B) information to show that there is a rea-
14 sonable expectation that the drug is effective for its
15 intended use, such as data from a pilot investigation,
16 data from an investigation in a related species, data
17 from a single investigation, data from an investiga-
18 tion using surrogate endpoints, data based on phar-
19 macokinetic extrapolations, data from a short-term
20 investigation, or data from the investigation of close-
21 ly-related diseases;

22 “(C) the quantity of drug expected to be manu-
23 factured and distributed on an annual basis;

24 “(D) a commitment that the applicant will con-
25 duct additional investigations to support approval of

1 an application under section 512 within the time
2 frame set forth in subsection (d)(1)(A);

3 “(E) reasonable data for establishing a condi-
4 tional dose; and

5 “(F) the information required by section
6 512(b)(1)(B)–(H).

7 “(2) A person may not file an application under para-
8 graph (1) if the person has filed a previous application
9 under paragraph (1) for the same drug and conditions for
10 use that was conditionally approved by the Secretary
11 under subsection (b).

12 “(b)(1) Within 180 days after the filing of an applica-
13 tion pursuant to subsection (a), or such additional period
14 as may be agreed upon by the Secretary and the applicant,
15 the Secretary shall either (A) issue an order conditionally
16 approving the application if the Secretary then finds that
17 none of the grounds for denying conditional approval spec-
18 ified in subsection (c) applies, or (B) give the applicant
19 notice of an opportunity for an expedited informal hearing
20 on the question whether such application is conditionally
21 approvable.

22 “(2) A drug manufactured in a pilot or other small
23 facility may be used to demonstrate the safety and effec-
24 tiveness of the drug and to obtain conditional approval for
25 the drug prior to manufacture of the drug in a larger facil-

1 ity, unless the Secretary makes a determination that a full
2 scale production facility is necessary to ensure the safety
3 or effectiveness of the drug.

4 “(c)(1) If the Secretary finds, after due notice to the
5 applicant and giving the applicant an opportunity for an
6 expedited informal hearing, that—

7 “(A) the investigations, reports of which are re-
8 quired to be submitted to the Secretary pursuant to
9 subsection (a), do not include adequate tests by all
10 methods reasonably applicable to show whether or
11 not such drug is safe for use under the conditions
12 prescribed, recommended, or suggested in the pro-
13 posed labeling;

14 “(B) the results of such tests show that such
15 drug is unsafe for use under such conditions or do
16 not show that such drug is safe for use under such
17 conditions;

18 “(C) the methods used in, and the facilities and
19 controls used for, the manufacture, processing, and
20 packing of such drug are inadequate to preserve its
21 identity, strength, quality, and purity;

22 “(D) upon the basis of the information sub-
23 mitted to the Secretary as part of the application, or
24 upon the basis of any other information before the
25 Secretary with respect to such drug, the Secretary

1 has insufficient information to determine whether
2 such drug is safe for use under such conditions;

3 “(E) evaluated on the basis of the information
4 submitted to the Secretary as part of the application
5 and any other information before the Secretary with
6 respect to such drug, there is insufficient informa-
7 tion to show that there is a reasonable expectation
8 that the drug will have the effect it purports or is
9 represented to have under the conditions of use pre-
10 scribed, recommended, or suggested in the proposed
11 labeling;

12 “(F) upon the basis of information submitted to
13 the Secretary as part of the application or any other
14 information before the Secretary with respect to
15 such drug, any use prescribed, recommended, or
16 suggested in labeling proposed for such drug will re-
17 sult in a residue of such drug in excess of a toler-
18 ance found by the Secretary to be safe for such
19 drug;

20 “(G) based on a fair evaluation of all material
21 facts, such labeling is false or misleading in any par-
22 ticular;

23 “(H) such drug induces cancer when ingested
24 by humans or animal or, after tests which are appro-
25 priate for the evaluation of the safety of such drug,

1 induces cancer in humans or animal, unless the Sec-
2 retary finds that, under the conditions for use speci-
3 fied in proposed labeling and reasonably certain to
4 be followed in practice—

5 “(i) such drug will not adversely affect the
6 animals for which it is intended; and

7 “(ii) no residue of such drug will be found
8 (by methods of examination prescribed or ap-
9 proved by the Secretary by regulations, which
10 regulations shall not be subject to subsections
11 (c)) in any edible portion of such animals after
12 slaughter or in any food yielded by or derived
13 from the living animals; or

14 “(I) another person has received approval under
15 section 512 for a drug with the same active ingre-
16 dient or ingredients and the same conditions of use,
17 and that person is able to assure the availability of
18 sufficient quantities of the drug to meet the needs
19 for which the drug is intended;

20 the Secretary shall issue an order refusing to conditionally
21 approve the application. If, after such notice and oppor-
22 tunity for hearing, the Secretary finds that subparagraphs
23 (A) through (I) do not apply, the Secretary shall issue an
24 order conditionally approving the application.

1 “(2) In determining whether such drug is safe for use
2 under the conditions prescribed, recommended, or sug-
3 gested in the proposed labeling thereof, the Secretary shall
4 consider, among other relevant factors, (A) the probable
5 consumption of such drug and of any substance formed
6 in or on food because of the use of such drug, (B) the
7 cumulative effect on man or animal of such drug, taking
8 into account any chemically or pharmacologically related
9 substance, (C) safety factors which in the opinion of ex-
10 perts, qualified by scientific training and experience to
11 evaluate the safety of such drugs, are appropriate for the
12 use of animal experimentation data, and (D) whether the
13 conditions of use prescribed, recommended, or suggested
14 in the proposed labeling are reasonably certain to be fol-
15 lowed in practice. Any order issued under this subsection
16 refusing to approve an application shall state the findings
17 upon which it is based.

18 “(d)(1) A conditional approval granted by the Sec-
19 retary under this section shall be effective for a 1-year
20 period. The Secretary shall, upon request, renew a condi-
21 tional approval for up to 4 additional 1-year terms, unless
22 the Secretary by order makes a finding that—

23 “(A) the applicant is not making appropriate
24 progress toward meeting approval requirements
25 under section 512, and is unlikely to be able to ful-

1 fill such requirements and obtain such approval
2 under such section before the 5 year maximum term
3 of the conditional approval expires;

4 “(B) excessive quantities of the drug have been
5 produced, without adequate explanation; or

6 “(C) another drug with the same active ingre-
7 dient or ingredients for the same conditions of use
8 has received approval under section 512, and the
9 holder of the approved application is able to assure
10 the availability of sufficient quantities of the drug to
11 meet the needs for which the drug is intended.

12 “(2) If the Secretary does not renew a conditional
13 approval, the Secretary shall provide due notice and an
14 opportunity for an expedited informal hearing to the appli-
15 cant.

16 “(e)(1) The Secretary shall, after due notice and op-
17 portunity for an expedited informal hearing to the appli-
18 cant, issue an order withdrawing conditional approval of
19 an application filed pursuant to subsection (a) if the Sec-
20 retary finds—

21 “(A) that experience or scientific data show
22 that such drug is unsafe for use under the condi-
23 tions of use upon the basis of which the application
24 was conditionally approved;

1 “(B) that new evidence not contained in such
2 application or not available to the Secretary until
3 after such application was conditionally approved, or
4 tests by new methods, or tests by methods not
5 deemed reasonably applicable when such application
6 was conditionally approved, evaluated together with
7 the evidence available to the Secretary when the ap-
8 plication was conditionally approved, shows that
9 such drug is not shown to be safe for use under the
10 conditions of use upon the basis of which the appli-
11 cation was conditionally approved;

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

20 “(D) that the application contains any untrue
21 statement of a material fact; or

22 “(E) that the applicant has made any changes
23 from the standpoint of safety or effectiveness beyond
24 the variations provided for in the application unless
25 the applicant has supplemented the application by

1 filing with the Secretary adequate information re-
2 specting all such changes and unless there is in ef-
3 fect a conditional approval of the supplemental ap-
4 plication, which supplemental application shall be
5 treated in the same manner as the original applica-
6 tion.

7 If the Secretary finds that there is an imminent hazard
8 to the health of man or of the animals for which such
9 drug is intended, the Secretary may suspend the condi-
10 tional approval of such application immediately, and give
11 the applicant prompt notice of the Secretary's action and
12 afford the applicant the opportunity for an expedited in-
13 formal hearing. Authority to suspend the conditional ap-
14 proval of an application shall not be delegated below the
15 Commissioner of Food and Drugs.

16 “(2) The Secretary may also, after due notice and
17 opportunity for an expedited informal hearing to the appli-
18 cant, issue an order withdrawing the conditional approval
19 of an application with respect to any new animal drug
20 under this section if the Secretary finds—

21 “(A) that the applicant has failed to establish
22 a system for maintaining required records, or has
23 repeatedly or deliberately failed to maintain such
24 records or to make required reports in accordance
25 with a regulation or order under subsection (h), or

1 the applicant has refused to permit access to, or
2 copying or verification of, such records as required
3 by paragraph (2) of such subsection;

4 “(B) that on the basis of new information be-
5 fore the Secretary, evaluated together with the evi-
6 dence before the Secretary when the application was
7 conditionally approved, the methods used in, or the
8 facilities and controls used for, the manufacture,
9 processing, and packing of such drug are inadequate
10 to assure and preserve its identity, strength, quality,
11 and purity and were not made adequate within a
12 reasonable time after receipt of written notice from
13 the Secretary specifying the matter complained of;
14 or

15 “(C) that on the basis of new information be-
16 fore the Secretary, evaluated together with the evi-
17 dence before the Secretary when the application was
18 conditionally approved, the labeling of such drug,
19 based on a fair evaluation of all material facts, is
20 false or misleading in any particular and was not
21 corrected within a reasonable time after receipt of
22 written notice from the Secretary specifying the
23 matter complained of.

24 “(3) Any order under this subsection shall state the
25 findings upon which it is based.

1 “(f) The decision of the Secretary under subsections
2 (c), (d), or (e) shall constitute a final agency decision for
3 purposes of judicial review.

4 “(g)(1) When an application filed pursuant to sub-
5 section (a) is conditionally approved, the Secretary shall
6 by notice publish in the Federal Register the name and
7 address of the applicant and the conditions and indications
8 of use of the new animal drug covered by such application,
9 including any tolerance and withdrawal period or other use
10 restriction and, if such new animal drug is intended for
11 use in animal feed, appropriate purposes and conditions
12 of use (including special labeling requirements and any re-
13 quirement that an animal feed bearing or containing the
14 new animal drug be limited to use under the professional
15 supervision of a licensed veterinarian) applicable to any
16 animal feed for use in which such drug is conditionally
17 approved, the expiration date of the conditional approval,
18 and such other information, upon the basis of which such
19 application was conditionally approved, as the Secretary
20 deems necessary to assure the safe and effective use of
21 such drug.

22 “(2) Upon withdrawal of conditional approval of such
23 new animal drug application or upon its suspension, the
24 Secretary shall publish a notice in the Federal Register.

1 “(h)(1) In the case of any new animal drug for which
2 a conditional approval of an application filed pursuant to
3 subsection (a) is in effect, the applicant 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 appli-
7 cant with respect to such drug, or with respect to animal
8 feeds bearing or containing such drug, as the Secretary
9 may by general regulation, or by order with respect to
10 such application, prescribe on the basis of a finding that
11 such records and reports are necessary in order to enable
12 the Secretary to determine, or facilitate a determination,
13 whether there is or may be ground for refusing to renew
14 the conditional approval under subsection (d) or for invok-
15 ing subsection (e). Such regulation or order shall provide,
16 where the Secretary deems it to be appropriate, for the
17 examination, upon request, by the persons to whom such
18 regulation or order is applicable, of similar information re-
19 ceived or otherwise obtained by the Secretary.

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

1 “(i)(1) The label and labeling of a drug with a condi-
2 tional approval under this section shall state that fact
3 prominently and conspicuously.

4 “(2) Conditions of use that are the subject of a condi-
5 tional approval under this section shall not be combined
6 in product labeling with any conditions of use approved
7 under section 512.

8 “(j)(1) Safety and effectiveness data and information
9 which has been submitted in an application filed under
10 subsection (a) for a drug and which has not previously
11 been disclosed to the public shall be made available to the
12 public, upon request, unless extraordinary circumstances
13 are shown—

14 “(A) if no work is being or will be undertaken
15 to have the application conditionally approved,

16 “(B) if the Secretary has determined that the
17 application is not conditionally approvable and all
18 legal appeals have been exhausted,

19 “(C) if conditional approval of the application
20 under subsection (c) is withdrawn and all legal ap-
21 peals have been exhausted, or

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

24 “(2) Any request for data and information pursuant
25 to paragraph (1) shall include a verified statement by the

1 person making the request that any data or information
2 received under such paragraph shall not be disclosed by
3 such person to any other person—

4 “(A) for the purpose of, or as part of a plan,
5 scheme, or device for, obtaining the right to make,
6 use, or market, or making, using, or marketing, out-
7 side the United States, the drug identified in the ap-
8 plication filed under subsection (a), and

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

14 “(k) To the extent consistent with the public health,
15 the Secretary shall promulgate regulations for exempting
16 from the operation of this section new animal drugs, and
17 animal feeds bearing or containing new animal drugs, in-
18 tended solely for investigational use by experts qualified
19 by scientific training and experience to investigate the
20 safety and effectiveness of animal drugs. Such regulations
21 may, in the discretion of the Secretary, among other con-
22 ditions relating to the protection of the public health, pro-
23 vide for conditioning such exemption upon the establish-
24 ment and maintenance of such records, and the making
25 of such reports to the Secretary, by the manufacturer or

1 the sponsor of the investigation of such article, of data
2 (including but not limited to analytical reports by inves-
3 tigators) obtained as a result of such investigational use
4 of such article, as the Secretary finds will enable the Sec-
5 retary to evaluate the safety and effectiveness of such arti-
6 cle in the event of the filing of an application pursuant
7 to this section. Such regulations, among other things, shall
8 set forth the conditions (if any) upon which animals treat-
9 ed with such articles, and any products of such animals
10 (before or after slaughter), may be marketed for food use.

11 “INDEX OF LEGALLY MARKETED UNAPPROVED MINOR
12 USE ANIMAL DRUGS FOR MINOR SPECIES WITH NO
13 HUMAN FOOD SAFETY CONCERN

14 “SEC. 574. (a)(1) The Secretary shall establish an
15 index of unapproved minor use new animal drugs that may
16 be lawfully marketed for use in minor species with no
17 human food safety concern.

18 “(2) Such index is intended to benefit primarily zoo
19 and wildlife species, aquarium and bait fish, reptiles and
20 amphibians, caged birds, and small pet mammals as well
21 as some commercially produced species such as cricket,
22 earthworms and possibly nonfood life stages of some minor
23 species used for human food such as oysters and shellfish.

24 “(3) Such index shall conform to the requirements
25 in subsection (d).

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

5 “(A) information regarding the proposed spe-
6 cies, conditions of use, and anticipated annual pro-
7 duction;

8 “(B) information regarding product formulation
9 and manufacturing; and

10 “(C) information sufficient for the Secretary to
11 determine that there does not appear to be human
12 food safety, environmental safety, occupational safe-
13 ty, or bioavailability concerns with the proposed use
14 of the drug.

15 “(2) Within 90 days after the submission of a request
16 for a preliminary determination under paragraph (1), the
17 Secretary shall grant or deny the request, and notify the
18 submitter of the Secretary’s conclusion. The Secretary
19 shall grant the request if it appears that—

20 “(A) the request addresses the need for a minor
21 use animal drug for which there is no approved or
22 conditionally approved drug, and

23 “(B) the proposed drug use does not appear to
24 raise human food safety, environmental safety, occu-
25 pational safety, or bioavailability concerns.

1 “(3) If the Secretary denies the request, the Sec-
2 retary shall provide due notice and an opportunity for an
3 expedited informal hearing.

4 “(4) If the Secretary does not grant or deny the re-
5 quest within 90 days, the Secretary shall provide the Com-
6 mittee on Commerce of the House of Representatives and
7 the Committee on Health, Education, Labor, and Pen-
8 sions of the Senate with the reasons action on the request
9 did not occur within such 90 days.

10 “(5) The decision of the Secretary under this sub-
11 section shall constitute a final agency decision for pur-
12 poses of judicial review.

13 “(c)(1) With respect to a drug for which the Sec-
14 retary has made a preliminary determination of eligibility
15 under subsection (b), the submitter of that request may
16 request that the Secretary add the drug to the index estab-
17 lished by subsection (a). Such a request shall include—

18 “(A) a copy of the Secretary’s preliminary de-
19 termination of eligibility issued under subsection (b);

20 “(B) a qualified expert panel report that meets
21 the requirements in paragraph (2);

22 “(C) a proposed index entry;

23 “(D) proposed labeling;

24 “(E) anticipated annual production of the drug;

25 and

1 “(F) a commitment to manufacture, label, and
2 distribute the drug in accordance with the index
3 entry and any additional requirements that the Sec-
4 retary may prescribe by general regulation or spe-
5 cific order.

6 “(2) For purposes of paragraph (1), a ‘qualified ex-
7 pert panel report’ is a written report that—

8 “(A) is authored by a panel of individuals quali-
9 fied by scientific training and experience to evaluate
10 the safety and effectiveness of animal drugs for the
11 intended uses and species in question and operating
12 external to the Food and Drug Administration;

13 “(B) addresses all available target animal safe-
14 ty and effectiveness information, including anecdotal
15 information where necessary;

16 “(C) addresses proposed labeling;

17 “(D) addresses whether the drug should be lim-
18 ited to use under the professional supervision of a li-
19 censed veterinarian; and

20 “(E) addresses whether, in the expert panel’s
21 opinion, the benefits of using the drug outweigh its
22 risks, taking into account the harm being caused by
23 the absence of an approved or conditionally approved
24 new animal drug for the minor use in question.

1 “(3) Within 180 days after the receipt of a request
2 for listing a drug in the index, the Secretary shall grant
3 or deny the request. The Secretary shall grant the request
4 if the Secretary finds, on the basis of the expert panel
5 report and other information available to the Secretary,
6 that the benefits of using the drug outweigh its risks, tak-
7 ing into account the harm caused by the absence of an
8 approved or conditionally approved new animal drug for
9 the minor use in question. If the Secretary denies the re-
10 quest, the Secretary shall provide due notice and the op-
11 portunity for an expedited informal hearing. If the Sec-
12 retary does not grant or deny the request within 180 days,
13 the Secretary shall provide the Committee on Commerce
14 of the House of Representatives and the Committee on
15 Health, Education, Labor, and Pensions of the Senate
16 with the reasons action on the request did not occur within
17 such 180 days. The decision of the Secretary under this
18 paragraph shall constitute a final agency decision for pur-
19 poses of judicial review.

20 “(d)(1) The index established by subsection (a) shall
21 include the following information for each listed drug:

22 “(A) The name and address of the sponsor of
23 the index listing.

24 “(B) The name of the drug, its dosage form,
25 and its strength.

1 “(C) Labeling.

2 “(D) Production limits or other conditions the
3 Secretary deems necessary to prevent misuse of the
4 drug.

5 “(E) Requirements that the Secretary deems
6 necessary for the safe and effective use of the drug.

7 “(2) The Secretary shall publish the index, and revise
8 it monthly.

9 “(e)(1) If the Secretary finds, after due notice to the
10 sponsor and an opportunity for an expedited informal
11 hearing, that—

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

17 “(B) the conditions and limitations of use in
18 the index listing have not been followed,

19 the Secretary shall remove the drug from the index. The
20 decision of the Secretary shall constitute final agency deci-
21 sion for purposes of judicial review.

22 “(2) If the Secretary finds that there is an imminent
23 hazard to the health of man or of the animals for which
24 such drug is intended, the Secretary may suspend the list-
25 ing of such drug immediately, and give the sponsor prompt

1 notice of the Secretary's action and afford the sponsor the
2 opportunity for an expedited informal hearing. Authority
3 to suspend the listing of a drug shall not be delegated
4 below the Commissioner of Food and Drugs.

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

22 “(2) Every person required under this subsection to
23 maintain records, and every person in charge or custody
24 thereof, shall, upon request of an officer or employee des-
25 ignated by the Secretary, permit such officer or employee

1 at all reasonable times to have access to and copy and
2 verify such records.

3 “(g) The labeling of a drug that is the subject of an
4 index listing shall state, prominently and conspicuously,
5 that the drug is legally marketed but not approved.

6 “(h) The Secretary shall promulgate regulations to
7 implement this section. Such regulations shall address,
8 among other subjects, the composition of the expert panel,
9 sponsorship of the expert panel under the auspices of a
10 recognized professional organization, conflict of interest
11 criteria for panel members, and the use of advisory com-
12 mittees convened by the Food and Drug Administration.

13 “(i) To the extent consistent with the public health,
14 the Secretary shall promulgate regulations for exempting
15 from the operation of this section new animal drugs in-
16 tended solely for investigational use by experts qualified
17 by scientific training and experience to investigate the
18 safety and effectiveness of animal drugs. Such regulations
19 may, in the discretion of the Secretary, among other con-
20 ditions relating to the protection of the public health, pro-
21 vide for conditioning such exemption upon the establish-
22 ment and maintenance of such records, and the making
23 of such reports to the Secretary, by the manufacturer or
24 the sponsor of the investigation of such article, of data
25 (including but not limited to analytical reports by inves-

1 tigators) obtained as a result of such investigational use
2 of such article, as the Secretary finds will enable the Sec-
3 retary to evaluate the safety and effectiveness of such arti-
4 cle in the event of the filing of a request for an index list-
5 ing pursuant to this section. Such regulations, among
6 other things, shall set forth the conditions (if any) upon
7 which animals treated with such articles, and any products
8 of such animals (before or after slaughter), may be mar-
9 keted for food use.

10 “GRANTS AND CONTRACTS FOR DEVELOPMENT OF
11 ANIMAL DRUGS FOR MINOR USES

12 “SEC. 575. (a) The Secretary may make grants to
13 and enter into contracts with public and private entities
14 and individuals to assist in defraying the costs of qualified
15 testing expenses and manufacturing expenses incurred in
16 connection with the development of drugs for minor uses.

17 “(b) For purposes of subsection (a) of this section:

18 “(1) The term ‘qualified testing’ means—

19 “(A) clinical testing—

20 “(i) which is carried out under an ex-
21 emption for a drug for minor uses under
22 section 512(j), 573(k), or 574(i); and

23 “(ii) which occurs after the date such
24 drug is designated under section 571 and
25 before the date on which an application

1 with respect to such drug is submitted
2 under section 512; and

3 “(B) preclinical testing involving a drug
4 for minor use which occurs after the date such
5 drug is designated under section 571 and before
6 the date on which an application with respect to
7 such drug is submitted under section 512.

8 “(2) The term ‘manufacturing expenses’ means
9 expenses incurred in developing processes and proce-
10 dures intended to meet current good manufacturing
11 practice requirements which occur after such drug is
12 designated under section 571 and before the date on
13 which an application with respect to such drug is
14 submitted under section 512.

15 “(c) For grants and contracts under subsection (a),
16 there are authorized to be appropriated \$1,000,000 for fis-
17 cal year 2001, \$1,500,000 for fiscal year 2002, and
18 \$2,000,000 for fiscal year 2003.”.

19 (c) THREE-YEAR EXCLUSIVITY FOR MINOR USE AP-
20 PROVALS.—Section 512(c)(2)(F)(ii), (iii), and (v) of the
21 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
22 360b(c)(2)(F)(ii), (iii), and (v)) is amended by striking
23 “(other than bioequivalence or residue studies)” and in-
24 serting “(other than bioequivalence studies or, except in

1 the case of a new animal drug for minor uses, residue
2 studies)”.
3

4 (d) SCOPE OF REVIEW FOR MINOR USE APPLICA-
5 TIONS.—Section 512(d) of the Federal Food, Drug, and
6 Cosmetic Act (21 U.S.C. 360b(d)) is amended by adding
7 at the end the following:

8 “(5) In reviewing a supplement to an approved appli-
9 cation that seeks a minor use approval, the Secretary shall
10 not reconsider information in the approved application to
11 determine whether it meets current standards for ap-
12 proval.”.

13 (e) PRESUMPTION OF NEW ANIMAL DRUG STA-
14 TUS.—Section 709 of the Federal Food, Drug, and Cos-
15 metic Act (21 U.S.C. 379a) is amended by designating
16 the existing text as subsection (a), and by adding after
17 such new subsection the following:

18 “(b) In any action to enforce the requirements of this
19 Act respecting a drug for minor use that is not the subject
20 of an approval under section 512, a conditional approval
21 under section 573, or an index listing under section 574,
22 it shall be presumed that the drug is a new animal drug.”.

23 (f) CONFORMING AMENDMENTS.—

24 (1) Section 512(a)(1) of the Federal Food,
Drug, and Cosmetic Act (21 U.S.C. 360b(a)(1)) is

1 amended by striking subparagraphs (A) and (B) and
2 inserting the following:

3 “(A) there is in effect an approval of an
4 application filed pursuant to subsection (b) with
5 respect to such use or intended use of such
6 drug, and such drug, its labeling, and such use
7 conform to such approved application;

8 “(B) there is in effect a conditional ap-
9 proval of an application filed pursuant to sec-
10 tion 573 with respect to such use or intended
11 use of such drug, and such drug, its labeling,
12 and such use conform to such conditionally ap-
13 proved application; or

14 “(C) there is in effect an index listing pur-
15 suant to section 574 with respect to such use
16 or intended use of such drug, and such drug, its
17 labeling, and such use conform to such index
18 listing.”.

19 (2) Section 512(a)(4) of the Federal Food,
20 Drug, and Cosmetic Act (21 U.S.C. 360b(a)(4)) is
21 amended by adding after “if an approval of an appli-
22 cation filed under subsection (b)” the following: “or
23 a conditional approval of an application filed under
24 section 573”.

1 (3) Section 503(f) of the Federal Food, Drug,
2 and Cosmetic Act (21 U.S.C. 353(f)) is amended as
3 follows:

4 (A) In paragraph (1)(A)(ii) by striking
5 “512” and inserting the following: “512, a con-
6 ditionally approved application under subsection
7 (b) of section 573, or an index listing under
8 subsection (a) of section 574.”.

9 (B) In paragraph (3) by striking “section
10 512” and inserting the following: “sections 512,
11 573, or 574.”.

12 (4) Section 504(a)(1) of the Federal Food,
13 Drug, and Cosmetic Act (21 U.S.C. 354(a)(1)) is
14 amended by striking “512(b)” and inserting
15 “512(b), a conditionally approved application filed
16 pursuant to section 573, or an index listing pursu-
17 ant to section 574.”.

18 (5) Section 504(a)(2)(B) and (b) of the Federal
19 Food, Drug, and Cosmetic Act (21 U.S.C.
20 354(a)(2)(B), and 354(b)) are amended by striking
21 “512(i)” and inserting “512(i) or section 573(g), or
22 the index listing pursuant to section 574.”.

23 (6) Section 403(a) of the Food and Drug Ad-
24 ministration Modernization Act of 1997 (21 U.S.C.
25 371(a)) is amended by adding at the end “For pur-

1 poses of this section, an approved article includes a
2 new animal drug that is the subject of a conditional
3 approval or an index listing under sections 573 and
4 574 of the Federal Food, Drug, and Cosmetic Act,
5 respectively.”.

6 (g) REGULATIONS.—The Secretary of Health and
7 Human Services shall promulgate proposed regulations to
8 implement amendments to the Federal Food, Drug, and
9 Cosmetic Act made by this Act within 6 months of the
10 date of enactment of this Act, and final regulations within
11 24 months of the date of enactment of this Act.

12 (h) OFFICE OF MINOR USE ANIMAL DRUG DEVELOP-
13 OPMENT.—

14 (1) The Secretary of Health and Human Serv-
15 ices shall establish within the Center of Veterinary
16 Medicine of the Food and Drug Administration an
17 Office of Minor Use Animal Drug Development (re-
18 ferred to in this subsection as the “Office”). The
19 Secretary of Health and Human Services shall select
20 an individual to serve as the Director of such Office.
21 The Director of such Office shall report directly to
22 the Director of the Center for Veterinary Medicine.
23 The Office shall be responsible for designating minor
24 use animal drugs under section 571 of the Federal
25 Food, Drug, and Cosmetic Act, for administering

1 grants and contracts for the development of animal
 2 drugs for minor uses under section 575 of the Fed-
 3 eral Food, Drug, and Cosmetic Act, and for serving
 4 as liaison with any party interested in minor use
 5 animal drug development.

6 (2) For the Office described under paragraph
 7 (1), there are authorized to be appropriated
 8 \$1,200,000 for each of the fiscal years 2001 through
 9 2003.

10 **SEC. 4. CREDIT FOR CLINICAL TESTING EXPENSES FOR**
 11 **CERTAIN ANIMAL DRUGS FOR MINOR USES.**

12 (a) IN GENERAL.—Subpart D of part IV of sub-
 13 chapter A of chapter 1 of the Internal Revenue Code of
 14 1986 is amended by inserting after section 45C the fol-
 15 lowing new section:

16 **“SEC. 45D. CLINICAL TESTING EXPENSES FOR CERTAIN**
 17 **ANIMAL DRUGS FOR MINOR USES.**

18 “(a) GENERAL RULE.—For purposes of section 38,
 19 the minor use animal drug credit determined under this
 20 section for the taxable year is an amount equal to 50 per-
 21 cent of the qualified animal clinical testing expenses for
 22 the taxable year.

23 “(b) QUALIFIED ANIMAL CLINICAL TESTING EX-
 24 PENSES.—For purposes of this section—

1 “(1) QUALIFIED ANIMAL CLINICAL TESTING EX-
2 PENSES.—

3 “(A) IN GENERAL.—Except as otherwise
4 provided in this paragraph, the term ‘qualified
5 animal clinical testing expenses’ means the
6 amounts which are paid or incurred by the tax-
7 payer during the taxable year which would be
8 described in subsection (b) of section 41 if such
9 subsection were applied with the modifications
10 set forth in subparagraph (B).

11 “(B) MODIFICATIONS.—For purposes of
12 subparagraph (A), subsection (b) of section 41
13 shall be applied—

14 “(i) by substituting ‘animal clinical
15 testing’ for ‘qualified research’ each place
16 it appears in paragraphs (2) and (3) of
17 such subsection, and

18 “(ii) by substituting ‘100 percent’ for
19 ‘65 percent’ in paragraph (3)(A) of such
20 subsection.

21 “(C) EXCLUSION FOR AMOUNTS FUNDED
22 BY GRANTS, ETC.—The term ‘qualified animal
23 clinical testing expenses’ shall not include any
24 amount to the extent such amount is funded by

1 any grant, contract, or otherwise by another
2 person (or any governmental entity).

3 “(D) SPECIAL RULE.—For purposes of
4 this paragraph:

5 “(i) section 41 shall be deemed to re-
6 main in effect for periods after June 30,
7 2000; and

8 “(ii) the trade or business require-
9 ment of section 41(b)(1) shall be deemed
10 to be satisfied in the case of a taxpayer
11 that owns animals and that conducts clin-
12 ical testing on such animals.

13 “(2) ANIMAL CLINICAL TESTING.—

14 “(A) IN GENERAL.—The term ‘animal clin-
15 ical testing’ means any clinical testing—

16 “(i) which is carried out under an ex-
17 emption for a drug being tested for minor
18 use under section 512(j), 573(k), or 574(i)
19 of the Federal Food, Drug, and Cosmetic
20 Act (or regulations issued under such sec-
21 tions),

22 “(ii) which occurs—

23 “(I) after the date such drug is
24 designated under section 571 of such
25 Act, and

1 “(II) before the date on which an
2 application with respect to such drug
3 is approved under section 512(c) of
4 such Act, and

5 “(iii) which is conducted by or on be-
6 half of—

7 “(I) the taxpayer to whom the
8 designation under such section 571
9 applies, or

10 “(II) the owner of the animals
11 that are the subject of clinical testing.

12 “(B) TESTING MUST BE FOR MINOR
13 USE.—Animal clinical testing shall be taken
14 into account under subparagraph (A) only to
15 the extent such testing is related to the use of
16 a drug for the minor use for which it was des-
17 ignated under section 571 of the Federal Food,
18 Drug, and Cosmetic Act.

19 “(c) COORDINATION WITH CREDIT FOR INCREASING
20 RESEARCH EXPENDITURES.—

21 “(1) IN GENERAL.—Except as provided in para-
22 graph (2), any qualified animal clinical testing ex-
23 penses for a taxable year to which an election under
24 this section applies shall not be taken into account

1 for purposes of determining the credit allowable
2 under section 41 for such taxable year.

3 “(2) EXPENSES INCLUDED IN DETERMINING
4 BASE PERIOD RESEARCH EXPENSES.—Any qualified
5 animal clinical testing expenses for any taxable year
6 which are qualified research expenses (within the
7 meaning of section 41(b)) shall be taken into ac-
8 count in determining base period research expenses
9 for purposes of applying section 41 to subsequent
10 taxable years.

11 “(d) DEFINITION AND SPECIAL RULES.—

12 “(1) MINOR USE.—For purposes of this section,
13 the term ‘minor use’ has the meaning given such
14 term by section 201(l) of the Federal Food, Drug,
15 and Cosmetic Act. Determinations under the pre-
16 ceding sentence with respect to any drug shall be
17 made on the basis of the facts and circumstances as
18 of the date such drug is designated under section
19 571 of the Federal Food, Drug, and Cosmetic Act.

20 “(2) DENIAL OF CREDIT FOR TESTING CON-
21 DUCTED BY CORPORATIONS TO WHICH SECTION 936
22 APPLIES.—No credit shall be allowed under this sec-
23 tion with respect to any animal clinical testing con-
24 ducted by a corporation to which an election under
25 section 936 applies.

1 “(3) CERTAIN RULES MADE APPLICABLE.—
2 Rules similar to the rules of paragraphs (1) and (2)
3 of section 41(f) shall apply for purposes of this sec-
4 tion.

5 “(4) ELECTION.—This section shall apply to
6 any taxpayer for any taxable year only if such tax-
7 payer elects (at such time and in such manner as
8 the Secretary may by regulations prescribe) to have
9 this section apply for such taxable year.”.

10 (b) CONFORMING AMENDMENTS.—

11 (1) Section 38(b) of such Code is amended—

12 (A) by striking “plus” at end of paragraph
13 (11),

14 (B) by striking the period at the end of
15 paragraph (12) and inserting “, plus”, and

16 (C) by adding at the end the following new
17 paragraph:

18 “(13) the minor use animal drug credit deter-
19 mined under section 45D(a).”.

20 (2) Section 280C(b) of such Code is amended—

21 (A) in paragraph (1), by striking “section
22 45C(b)” and inserting “section 45C(b) or
23 45D(b)”, and

1 (B) in paragraphs (1) and (2), by striking
2 “section 45C” each place it appears and insert-
3 ing “section 45C or 45D”.

4 (c) CLERICAL AMENDMENT.—The table of sections
5 for subpart D of part IV of subchapter A of chapter 1
6 of such Code is amended by inserting after the item relat-
7 ing to section 45C the following new item:

“Sec. 45D. Clinical testing expenses for certain animal drugs for
minor uses.”.

8 (d) EFFECTIVE DATE.—The amendments made by
9 this section shall apply to taxable years beginning after
10 the date of the enactment of this Act.

11 (e) REGULATIONS.—The Secretary of the Treasury
12 shall publish proposed regulations to implement amend-
13 ments to the Internal Revenue Code of 1986 made by this
14 Act within 6 months after the date of the enactment of
15 this Act, and final regulations within 24 months after such
16 date.

○