

106TH CONGRESS
2D SESSION

H. R. 4780

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 HOUSE OF REPRESENTATIVES

JUNE 28, 2000

Mr. PICKERING (for himself, Mr. HALL of Texas, Mr. COMBEST, Mr. STENHOLM, and Mr. POMBO) introduced the following bill; which was referred to the Committee on 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 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:

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

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

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

7 **SEC. 3. AMENDMENTS AFFECTING THE FOOD AND DRUG**
8 **ADMINISTRATION.**

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

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

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

17 “(1) in a minor species, or

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

23 “(mm) The term ‘species with no human food safety
24 concern’ means an animal species, or life stage of an ani-

1 mal species, that is not customarily used for food for man
2 and does not endanger the public health.”.

3 (b) MINOR USE ANIMAL DRUGS.—Chapter V of the
4 Federal Food, Drug, and Cosmetic Act is amended by
5 adding at the end the following new subchapter:

6 “SUBCHAPTER F—ANIMAL DRUGS FOR MINOR
7 USES

8 “DESIGNATION OF DRUGS FOR MINOR USES

9 “SEC. 571. (a) The manufacturer or the sponsor of
10 a drug may request the Secretary to designate the drug
11 as a drug for a minor use. A request for designation of
12 a drug shall be made before the submission of an applica-
13 tion under section 512(b) for the drug. If the Secretary
14 finds that a drug for which a request is submitted under
15 this subsection is being or will be investigated for a minor
16 use and if an application for such drug is approved under
17 section 512, the approval would be for such minor use,
18 the Secretary shall designate the drug as a drug for such
19 minor use. A request for a designation of a drug under
20 this subsection shall contain the consent of the applicant
21 to notice being given by the Secretary under subsection
22 (c) respecting the designation of the drug.

23 “(b) A designation of a drug under subsection (a)
24 shall be subject to the condition that—

1 “(1) if an application was approved for the
2 drug under section 512(c), the manufacturer of the
3 drug will notify the Secretary of any discontinuance
4 of the production of the drug at least one year be-
5 fore discontinuance; and

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

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

15 “PROTECTION FOR DRUGS FOR MINOR USES

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

17 “(1) If the Secretary approves an application
18 filed pursuant to section 512 for a drug designated
19 under section 571 for minor uses, no active ingre-
20 dient (including any salt or ester of the active ingre-
21 dient) of which has been approved in any other ap-
22 plication under section 512, the Secretary may not
23 approve or conditionally approve another application
24 submitted under section 512 or section 573 for such
25 drug for such minor use for a person who is not
26 the holder of such approved application until the ex-

1 piration of ten years from the date of the approval
2 of the application.

3 “(2) If the Secretary approves an application
4 filed pursuant to section 512 for a drug designated
5 under section 571 for minor uses, which includes an
6 active ingredient (including an ester or salt of the
7 active ingredient) that has been approved in any
8 other application under section 512, the Secretary
9 may not approve or conditionally approve another
10 application submitted under section 512 or section
11 573 for such drug for such minor use for a person
12 who is not the holder of such approved application
13 until the expiration of seven years from the date of
14 approval of the application.

15 “(b) If an application filed pursuant to section 512
16 is approved for a drug designated under section 571, the
17 Secretary may, during the ten-year or seven-year period
18 beginning on the date of the application approval, approve
19 or conditionally approve another application under section
20 512 or section 573 for such drug for such minor use for
21 a person who is not the holder of such approved applica-
22 tion if—

23 “(1) the Secretary finds, after providing the
24 holder notice and opportunity for the submission of
25 views, that in such period the holder of the approved

1 application cannot assure the availability of suffi-
2 cient quantities of the drug to meet the needs for
3 which the drug was designated; or

4 “(2) such holder provides the Secretary in writ-
5 ing the consent of such holder for the approval or
6 conditional approval of other applications before the
7 expiration of such ten-year or seven-year period.

8 “CONDITIONAL APPROVAL FOR MINOR USE NEW ANIMAL
9 DRUGS

10 “SEC. 573. (a)(1) Except as provided in paragraph
11 (2), any person may file with the Secretary an application
12 for conditional approval of a new animal drug for minor
13 use. Such person shall submit to the Secretary as part
14 of an application—

15 “(A) reports of investigations which have been
16 made to show whether or not such drug is safe for
17 use;

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

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

3 “(D) a commitment that the applicant will con-
4 duct additional investigations to support approval of
5 an application under section 512 within the time
6 frame set forth in subsection (d)(1)(A);

7 “(E) reasonable data for establishing a condi-
8 tional dose; and

9 “(F) the information required by section
10 512(b)(1)(B)–(H).

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

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

1 “(2) A drug manufactured in a pilot or other small
2 facility may be used to demonstrate the safety and effec-
3 tiveness of the drug and to obtain conditional approval for
4 the drug prior to manufacture of the drug in a larger facil-
5 ity, unless the Secretary makes a determination that a full
6 scale production facility is necessary to ensure the safety
7 or effectiveness of the drug.

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

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

18 “(B) the results of such tests show that such
19 drug is unsafe for use under such conditions or do
20 not show that such drug is safe for use under such
21 conditions;

22 “(C) the methods used in, and the facilities and
23 controls used for, the manufacture, processing, and
24 packing of such drug are inadequate to preserve its
25 identity, strength, quality, and purity;

1 “(D) upon the basis of the information sub-
2 mitted to the Secretary as part of the application, or
3 upon the basis of any other information before the
4 Secretary with respect to such drug, the Secretary
5 has insufficient information to determine whether
6 such drug is safe for use under such conditions;

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

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

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

4 “(H) such drug induces cancer when ingested
5 by man or animal or, after tests which are appro-
6 priate for the evaluation of the safety of such drug,
7 induces cancer in man or animal, except that the
8 foregoing provisions of this subparagraph shall not
9 apply with respect to such drug if the Secretary
10 finds that, under the conditions for use specified in
11 proposed labeling and reasonably certain to be fol-
12 lowed in practice (i) such drug will not adversely af-
13 fect the animals for which it is intended, and (ii) no
14 residue of such drug will be found (by methods of
15 examination prescribed or approved by the Secretary
16 by regulations, which regulations shall not be subject
17 to subsections (c)), in any edible portion of such ani-
18 mals after slaughter or in any food yielded by or de-
19 rived from the living animals; or

20 “(I) another person has received approval under
21 section 512 for a drug with the same active ingre-
22 dient or ingredients and the same conditions of use,
23 and that person is able to assure the availability of
24 sufficient quantities of the drug to meet the needs
25 for which the drug is intended;

1 the Secretary shall issue an order refusing to conditionally
2 approve the application. If, after such notice and oppor-
3 tunity for hearing, the Secretary finds that subparagraphs
4 (A) through (I) do not apply, the Secretary shall issue an
5 order conditionally approving the application.

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

23 “(d)(1) A conditional approval granted by the Sec-
24 retary under this section shall be effective for a one-year
25 period. The Secretary shall, upon request, renew a condi-

1 tional approval for up to four additional one-year terms,
2 unless the Secretary by order makes a finding that—

3 “(A) the applicant is not making appropriate
4 progress toward meeting approval requirements
5 under section 512, and is unlikely to be able to ful-
6 fill those requirements and obtain an approval under
7 section 512 before the expiration of the five year
8 maximum term of the conditional approval;

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

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

17 “(2) If the Secretary does not renew a conditional
18 approval, the Secretary shall provide due notice and an
19 opportunity for an expedited informal hearing to the appli-
20 cant.

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

1 “(A) that experience or scientific data show
2 that such drug is unsafe for use under the condi-
3 tions of use upon the basis of which the application
4 was conditionally approved;

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

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

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

3 “(E) that the applicant has made any changes
4 from the standpoint of safety or effectiveness beyond
5 the variations provided for in the application unless
6 the applicant has supplemented the application by
7 filing with the Secretary adequate information re-
8 specting all such changes and unless there is in ef-
9 fect a conditional approval of the supplemental ap-
10 plication, which supplemental application shall be
11 treated in the same manner as the original applica-
12 tion.

13 If the Secretary finds that there is an imminent hazard
14 to the health of man or of the animals for which such
15 drug is intended, the Secretary may suspend the condi-
16 tional approval of such application immediately, and give
17 the applicant prompt notice of the Secretary’s action and
18 afford the applicant the opportunity for an expedited in-
19 formal hearing, but the authority conferred by this sen-
20 tence to suspend the conditional approval of an application
21 shall not be delegated below the Commissioner of Food
22 and Drugs.

23 “(2) The Secretary may also, after due notice and
24 opportunity for an expedited informal hearing to the appli-
25 cant, issue an order withdrawing the conditional approval

1 of an application with respect to any new animal drug
2 under this section if the Secretary finds—

3 “(A) that the applicant has failed to establish
4 a system for maintaining required records, or has
5 repeatedly or deliberately failed to maintain such
6 records or to make required reports in accordance
7 with a regulation or order under subsection (h), or
8 the applicant has refused to permit access to, or
9 copying or verification of, such records as required
10 by paragraph (2) of such subsection;

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

22 “(C) that on the basis of new information be-
23 fore the Secretary, evaluated together with the evi-
24 dence before the Secretary when the application was
25 conditionally approved, the labeling of such drug,

1 based on a fair evaluation of all material facts, is
2 false or misleading in any particular and was not
3 corrected within a reasonable time after receipt of
4 written notice from the Secretary specifying the
5 matter complained of.

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

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

11 “(g) When an application filed pursuant to subsection
12 (a) is conditionally approved, the Secretary shall by notice
13 publish in the Federal Register the name and address of
14 the applicant and the conditions and indications of use of
15 the new animal drug covered by such application, includ-
16 ing any tolerance and withdrawal period or other use re-
17 striction and, if such new animal drug is intended for use
18 in animal feed, appropriate purposes and conditions of use
19 (including special labeling requirements and any require-
20 ment that an animal feed bearing or containing the new
21 animal drug be limited to use under the professional su-
22 pervision of a licensed veterinarian) applicable to any ani-
23 mal feed for use in which such drug is conditionally ap-
24 proved, the expiration date of the conditional approval,
25 and such other information, upon the basis of which such

1 application was conditionally approved, as the Secretary
2 deems necessary to assure the safe and effective use of
3 such drug. Upon withdrawal of conditional approval of
4 such new animal drug application or upon its suspension,
5 the Secretary shall publish a notice in the Federal Reg-
6 ister.

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

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

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

10 “(2) Conditions of use that are the subject of an con-
11 ditional approval under this section shall not be combined
12 in product labeling with any conditions of use approved
13 under section 512.

14 “(j)(1) Safety and effectiveness data and information
15 which has been submitted in an application filed under
16 subsection (a) for a drug and which has not previously
17 been disclosed to the public shall be made available to the
18 public, upon request, unless extraordinary circumstances
19 are shown—

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

22 “(B) if the Secretary has determined that the
23 application is not conditionally approvable and all
24 legal appeals have been exhausted,

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

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

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

11 “(A) for the purpose of, or as part of a plan,
12 scheme, or device for, obtaining the right to make,
13 use, or market, or making, using, or marketing, out-
14 side the United States, the drug identified in the ap-
15 plication filed under subsection (a), and

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

21 “(k) To the extent consistent with the public health,
22 the Secretary shall promulgate regulations for exempting
23 from the operation of this section new animal drugs, and
24 animal feeds bearing or containing new animal drugs, in-
25 tended solely for investigational use by experts qualified

1 by scientific training and experience to investigate the
2 safety and effectiveness of animal drugs. Such regulations
3 may, in the discretion of the Secretary, among other con-
4 ditions relating to the protection of the public health, pro-
5 vide for conditioning such exemption upon the establish-
6 ment and maintenance of such records, and the making
7 of such reports to the Secretary, by the manufacturer or
8 the sponsor of the investigation of such article, of data
9 (including but not limited to analytical reports by inves-
10 tigators) obtained as a result of such investigational use
11 of such article, as the Secretary finds will enable the Sec-
12 retary to evaluate the safety and effectiveness of such arti-
13 cle in the event of the filing of an application pursuant
14 to this section. Such regulations, among other things, shall
15 set forth the conditions (if any) upon which animals treat-
16 ed with such articles, and any products of such animals
17 (before or after slaughter), may be marketed for food use.

18 “INDEX OF LEGALLY MARKETED UNAPPROVED MINOR
19 USE ANIMAL DRUGS FOR MINOR SPECIES WITH NO
20 HUMAN FOOD SAFETY CONCERN

21 “SEC. 574. (a) The Secretary shall establish an index
22 of unapproved minor use new animal drugs that may be
23 lawfully marketed for use in minor species with no human
24 food safety concern. The index is intended to benefit pri-
25 marily zoo and wildlife species, aquarium and bait fish,
26 reptiles and amphibians, caged birds, and small pet mam-

1 mals as well as some commercially produced species such
2 as cricket, earthworms and possibly nonfood life stages of
3 some minor species used for human food such as oysters
4 and shellfish. The index shall conform to the requirements
5 in subsection (d).

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

10 “(A) information regarding the proposed spe-
11 cies, conditions of use, and anticipated annual pro-
12 duction;

13 “(B) information regarding product formulation
14 and manufacturing; and

15 “(C) information sufficient for the Secretary to
16 determine that there does not appear to be human
17 food safety, environmental safety, occupational safe-
18 ty, or bioavailability concerns with the proposed use
19 of the drug.

20 “(2) Within 90 days after the submission of a request
21 for a preliminary determination under paragraph (1), the
22 Secretary shall grant or deny the request, and notify the
23 submitter of the Secretary’s conclusion. The Secretary
24 shall grant the request if it appears that—

1 “(A) the request addresses the need for a minor
2 use animal drug for which there is no approved or
3 conditionally approved drug, and

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

7 If the Secretary denies the request, the Secretary shall
8 provide due notice and an opportunity for an expedited
9 informal hearing. If the Secretary does not grant or deny
10 the request within 90 days, the Secretary shall provide the
11 Committee on Commerce of the House of Representatives
12 and the Committee on Health, Education, Labor, and
13 Pensions of the Senate with the reasons action on the re-
14 quest did not occur within such 90 days. The decision of
15 the Secretary under this paragraph shall constitute a final
16 agency decision for purposes of judicial review.

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

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

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

1 “(C) a proposed index entry;

2 “(D) proposed labeling;

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

4 and

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

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

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

17 “(B) addresses all available target animal safe-
18 ty and effectiveness information, including anecdotal
19 information where necessary;

20 “(C) addresses proposed labeling;

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

24 “(E) addresses whether, in the expert panel’s
25 opinion, the benefits of using the drug outweigh its

1 risks, taking into account the harm being caused by
2 the absence of an approved or conditionally approved
3 new animal drug for the minor use in question.

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

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

1 “(A) The name and address of the sponsor of
2 the index listing.

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

5 “(C) Labeling.

6 “(D) Production limits or other conditions the
7 Secretary deems necessary to prevent misuse of the
8 drug.

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

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

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

16 “(A) on the basis of new information before the
17 Secretary, evaluated together with the evidence
18 available to the Secretary when the drug was listed
19 in the index, the benefits of using the drug do not
20 outweigh its risks; or

21 “(B) the conditions and limitations of use in
22 the index listing have not been followed, the Sec-
23 retary shall remove the drug from the index. The
24 decision of the Secretary shall constitute final agen-
25 cy decision for purposes of judicial review.

1 “(2) If the Secretary finds that there is an imminent
2 hazard to the health of man or of the animals for which
3 such drug is intended, the Secretary may suspend the list-
4 ing of such drug immediately, and give the sponsor prompt
5 notice of the Secretary’s action and afford the sponsor the
6 opportunity for an expedited informal hearing, but the au-
7 thority conferred by this sentence to suspend the listing
8 of a drug shall not be delegated below the Commissioner
9 of Food and Drugs.

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

1 such regulation or order is applicable, of similar informa-
2 tion received or otherwise obtained by the Secretary.

3 “(2) Every person required under this subsection to
4 maintain records, and every person in charge or custody
5 thereof, shall, upon request of an officer or employee des-
6 ignated by the Secretary, permit such officer or employee
7 at all reasonable times to have access to and copy and
8 verify such records.

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

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

19 “(i) To the extent consistent with the public health,
20 the Secretary shall promulgate regulations for exempting
21 from the operation of this section new animal drugs in-
22 tended solely for investigational use by experts qualified
23 by scientific training and experience to investigate the
24 safety and effectiveness of animal drugs. Such regulations
25 may, in the discretion of the Secretary, among other con-

1 ditions relating to the protection of the public health, pro-
2 vide for conditioning such exemption upon the establish-
3 ment and maintenance of such records, and the making
4 of such reports to the Secretary, by the manufacturer or
5 the sponsor of the investigation of such article, of data
6 (including but not limited to analytical reports by inves-
7 tigators) obtained as a result of such investigational use
8 of such article, as the Secretary finds will enable the Sec-
9 retary to evaluate the safety and effectiveness of such arti-
10 cle in the event of the filing of a request for an index list-
11 ing pursuant to this section. Such regulations, among
12 other things, shall set forth the conditions (if any) upon
13 which animals treated with such articles, and any products
14 of such animals (before or after slaughter), may be mar-
15 keted for food use.

16 “GRANTS AND CONTRACTS FOR DEVELOPMENT OF
17 ANIMAL DRUGS FOR MINOR USES

18 “SEC. 575. (a) The Secretary may make grants to
19 and enter into contracts with public and private entities
20 and individuals to assist in defraying the costs of qualified
21 testing expenses and manufacturing expenses incurred in
22 connection with the development of drugs for minor uses.

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

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

25 “(A) clinical testing—

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

4 “(ii) which occurs after the date such
5 drug is designated under section 571 and
6 before the date on which an application
7 with respect to such drug is submitted
8 under section 512; and

9 “(B) preclinical testing involving a drug
10 for minor use which occurs after the date such
11 drug is designated under section 571 and before
12 the date on which an application with respect to
13 such drug is submitted under section 512.

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

21 “(c) For grants and contracts under subsection (a),
22 there are authorized to be appropriated \$1,000,000 for fis-
23 cal year 2001, \$1,500,000 for fiscal year 2002, and
24 \$2,000,000 for fiscal year 2003.”.

1 (c) THREE-YEAR EXCLUSIVITY FOR MINOR USE AP-
2 PROVALS.—Section 512(c)(2)(F)(ii), (iii), and (v) of the
3 Federal Food, Drug, and Cosmetic Act is amended by
4 striking “(other than bioequivalence or residue studies)”
5 and inserting the following: “(other than bioequivalence
6 studies or, except in the case of a new animal drug for
7 minor uses, residue studies)”.

8 (d) SCOPE OF REVIEW FOR MINOR USE APPLICA-
9 TIONS.—Section 512(d) of the Federal Food, Drug, and
10 Cosmetic Act is amended by adding the following new
11 paragraph at the end:

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

17 (e) PRESUMPTION OF NEW ANIMAL DRUG STA-
18 TUS.—Section 709 of the Federal Food, Drug, and Cos-
19 metic Act is amended by designating the existing text as
20 subsection (a), and by adding the following new subsection
21 (b):

22 “(b) In any action to enforce the requirements of this
23 Act respecting a drug for minor use that is not the subject
24 of an approval under section 512, a conditional approval

1 under section 573, or an index listing under section 574,
2 it shall be presumed that the drug is a new animal drug.”.

3 (f) CONFORMING AMENDMENTS.—

4 (1) Section 512(a)(1) of the Federal Food,
5 Drug, and Cosmetic Act is amended by striking sub-
6 paragraphs (A) and (B) and inserting the following:

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

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

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

23 (2) Section 512(a)(4) of the Federal Food,
24 Drug, and Cosmetic Act is amended by adding after
25 “if an approval of an application filed under sub-

1 section (b)” the following: “or a conditional approval
2 of an application filed under section 573”.

3 (3) Section 503(f) of the Federal Food, Drug,
4 and Cosmetic Act is amended as follows:

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

10 (B) In paragraph (3) by striking “section
11 512” and inserting the following: “sections 512,
12 573, or 574.”.

13 (4) Section 504(a)(1) of the Federal Food,
14 Drug, and Cosmetic Act is amended by striking
15 “512(b)” and inserting the following: “512(b), a
16 conditionally approved application filed pursuant to
17 section 573, or an index listing pursuant to section
18 574.”.

19 (5) Section 504(a)(2)(B) and (b) of the Federal
20 Food, Drug, and Cosmetic Act are amended by
21 striking “512(i)” and inserting the following:
22 “512(i) or section 573(g), or the index listing pursu-
23 ant to section 574.”.

24 (6) Section 403(a) of the Food and Drug Ad-
25 ministration Modernization Act (Public Law 105–

1 115) is amended by adding the following sentence at
2 the end: “For purposes of this section, an approved
3 article includes a new animal drug that is the sub-
4 ject of a conditional approval or an index listing
5 under sections 573 and 574 of the Federal Food,
6 Drug, and Cosmetic Act, respectively.”.

7 (g) REGULATIONS.—The Secretary of Health and
8 Human Services shall publish proposed regulations to im-
9 plement amendments to the Federal Food, Drug, and Cos-
10 metic Act made by this Act within 6 months of the date
11 of enactment, and final regulations within 24 months of
12 the date of enactment.

13 (h) OFFICE OF MINOR USE ANIMAL DRUG DEVEL-
14 OPMENT.—

15 (1) The Secretary shall establish within the
16 Food and Drug Administration, Center of Veteri-
17 nary Medicine, an Office of Minor Use Animal Drug
18 Development that reports directly to the Director of
19 the Center for Veterinary Medicine. This office shall
20 be responsible for designating minor use animal
21 drugs under section 571 of the Federal Food, Drug,
22 and Cosmetic Act, for administering grants and con-
23 tracts for the development of animal drugs for minor
24 uses under section 575 of the Federal Food, Drug,
25 and Cosmetic Act, and for serving as liaison with

1 any party interested in minor use animal drug devel-
2 opment.

3 (2) For this office, there are authorized to be
4 appropriated \$1,200,000 for each of the fiscal years
5 2001 through 2003.

6 **SEC. 4. CREDIT FOR CLINICAL TESTING EXPENSES FOR**
7 **CERTAIN ANIMAL DRUGS FOR MINOR USES.**

8 (a) IN GENERAL.—Subpart D of part IV of sub-
9 chapter A of chapter 1 of the Internal Revenue Code of
10 1986 is amended by inserting after section 45C the fol-
11 lowing new section:

12 **“SEC. 45D. CLINICAL TESTING EXPENSES FOR CERTAIN**
13 **ANIMAL DRUGS FOR MINOR USES.**

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

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

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

23 “(A) IN GENERAL.—Except as otherwise
24 provided in this paragraph, the term ‘qualified
25 animal clinical testing expenses’ means the

1 amounts which are paid or incurred by the tax-
2 payer during the taxable year which would be
3 described in subsection (b) of section 41 if such
4 subsection were applied with the modifications
5 set forth in subparagraph (B).

6 “(B) MODIFICATIONS.—For purposes of
7 subparagraph (A), subsection (b) of section 41
8 shall be applied—

9 “(i) by substituting ‘animal clinical
10 testing’ for ‘qualified research’ each place
11 it appears in paragraphs (2) and (3) of
12 such subsection, and

13 “(ii) by substituting ‘100 percent’ for
14 ‘65 percent’ in paragraph (3)(A) of such
15 subsection.

16 “(C) EXCLUSION FOR AMOUNTS FUNDED
17 BY GRANTS, ETC.—The term ‘qualified animal
18 clinical testing expenses’ shall not include any
19 amount to the extent such amount is funded by
20 any grant, contract, or otherwise by another
21 person (or any governmental entity).

22 “(D) SPECIAL RULE.—For purposes of
23 this paragraph:

1 “(i) section 41 shall be deemed to re-
2 main in effect for periods after June 30,
3 2000; and

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

9 “(2) ANIMAL CLINICAL TESTING.—

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

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

18 “(ii) which occurs—

19 “(I) after the date such drug is
20 designated under section 571 of such
21 Act, and

22 “(II) before the date on which an
23 application with respect to such drug
24 is approved under section 512(c) of
25 such Act, and

1 “(iii) which is conducted by or on be-
2 half of—

3 “(I) the taxpayer to whom the
4 designation under such section 571
5 applies, or

6 “(II) the owner of the animals
7 that are the subject of clinical testing.

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

15 “(c) COORDINATION WITH CREDIT FOR INCREASING
16 RESEARCH EXPENDITURES.—

17 “(1) IN GENERAL.—Except as provided in para-
18 graph (2), any qualified animal clinical testing ex-
19 penses for a taxable year to which an election under
20 this section applies shall not be taken into account
21 for purposes of determining the credit allowable
22 under section 41 for such taxable year.

23 “(2) EXPENSES INCLUDED IN DETERMINING
24 BASE PERIOD RESEARCH EXPENSES.—Any qualified
25 animal clinical testing expenses for any taxable year

1 which are qualified research expenses (within the
2 meaning of section 41(b)) shall be taken into ac-
3 count in determining base period research expenses
4 for purposes of applying section 41 to subsequent
5 taxable years.

6 “(d) DEFINITION AND SPECIAL RULES.—

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

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

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

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

6 (b) CONFORMING AMENDMENTS.—

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

8 (A) by striking “plus” at end of paragraph
9 (11),

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

12 (C) by adding at the end the following new
13 paragraph:

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

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

17 (A) in paragraph (1), by striking “section
18 45C(b)” and inserting “section 45C(b) or
19 45D(b)”, and

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

23 (c) CLERICAL AMENDMENT.—The table of sections
24 for subpart D of part IV of subchapter A of chapter 1

1 of such Code is amended by inserting after the item relat-
2 ing to section 45C the following new item:

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

3 (d) **EFFECTIVE DATE.**—The amendments made by
4 this section shall apply to taxable years beginning after
5 the date of the enactment of this Act.

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

○