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H. R. 2508

IN THE SENATE OF THE UNITED STATES

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Received

AN ACT

To amend the Federal Food, Drug, and Cosmetic Act to provide for improvements in the process of approving and using animal drugs, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

1 **SECTION 1. SHORT TITLE; REFERENCE.**

2 (a) **SHORT TITLE.**—This Act may be cited as the
3 “Animal Drug Availability Act of 1996”.

4 (b) **REFERENCE.**—Whenever in this Act an amend-
5 ment or repeal is expressed in terms of an amendment
6 to, or repeal of, a section or other provision, the reference
7 shall be considered to be made to a section or other provi-
8 sion of the Federal Food, Drug, and Cosmetic Act (21
9 U.S.C. 321 et seq.).

10 **SEC. 2. EVIDENCE OF EFFECTIVENESS.**

11 (a) **ORIGINAL APPLICATIONS.**—Paragraph (3) of sec-
12 tion 512(d) (21 U.S.C. 360b(d)) is amended to read as
13 follows:

14 “(3) As used in this section, the term ‘substantial evi-
15 dence’ means evidence consisting of one or more adequate
16 and well controlled investigations, such as—

17 “(A) a study in a target species;

18 “(B) a study in laboratory animals;

19 “(C) any field investigation that may be re-
20 quired under this section and that meets the require-
21 ments of subsection (b)(3) if a presubmission con-
22 ference is requested by the applicant;

23 “(D) a bioequivalence study; or

24 “(E) an in vitro study;

25 by experts qualified by scientific training and experience
26 to evaluate the effectiveness of the drug involved, on the

1 basis of which it could fairly and reasonably be concluded
2 by such experts that the drug will have the effect it
3 purports or is represented to have under the conditions
4 of use prescribed, recommended, or suggested in the label-
5 ing or proposed labeling thereof.”.

6 (b) CONFORMING AMENDMENTS.—

7 (1) Clauses (ii) and (iii) of section 512(c)(2)(F)
8 (21 U.S.C. 360b(c)(2)(F)) are each amended—

9 (A) by striking “reports of new clinical or
10 field investigations (other than bioequivalence
11 or residue studies) and,” and inserting “sub-
12 stantial evidence of the effectiveness of the drug
13 involved, any studies of animal safety, or,”; and

14 (B) by striking “essential to” and inserting
15 “required for”.

16 (2) Section 512(c)(2)(F)(v) (21 U.S.C.
17 360b(c)(2)(F)(v)) is amended—

18 (A) by striking “subparagraph (B)(iv)”
19 each place it appears and inserting “clause
20 (iv)”;

21 (B) by striking “reports of clinical or field
22 investigations” and inserting “substantial evi-
23 dence of the effectiveness of the drug involved,
24 any studies of animal safety,”; and

1 (C) by striking “essential to” and inserting
2 “required for”.

3 (c) COMBINATION DRUGS.—Section 512(d) (21
4 U.S.C. 360b(d)), as amended by subsection (a) is amended
5 by adding at the end the following:

6 “(4) In a case in which an animal drug contains more
7 than one active ingredient, or the labeling of the drug pre-
8 scribes, recommends, or suggests use of the drug in com-
9 bination with one or more other animal drugs, and the
10 active ingredients or drugs intended for use in the com-
11 bination have previously been separately approved for par-
12 ticular uses and conditions of use for which they are in-
13 tended for use in the combination—

14 “(A) the Secretary shall not issue an order
15 under paragraph (1)(A), (1)(B), or (1)(D) refusing
16 to approve the application for such combination on
17 human food safety grounds unless the Secretary
18 finds that the application fails to establish that—

19 “(i) none of the active ingredients or drugs
20 intended for use in the combination, respec-
21 tively, at the longest withdrawal time of any of
22 the active ingredients or drugs in the combina-
23 tion, respectively, exceeds its established toler-
24 ance; or

1 “(ii) none of the active ingredients or
2 drugs in the combination interferes with the
3 methods of analysis for another of the active in-
4 gredients or drugs in the combination, respec-
5 tively;

6 “(B) the Secretary shall not issue an order
7 under paragraph (1)(A), (1)(B), or (1)(D) refusing
8 to approve the application for such combination on
9 target animal safety grounds unless the Secretary
10 finds that—

11 “(i)(I) there is a substantiated scientific
12 issue, specific to one or more of the active in-
13 gredients or animal drugs in the combination,
14 that cannot adequately be evaluated based on
15 information contained in the application for the
16 combination (including any investigations, stud-
17 ies, or tests for which the applicant has a right
18 of reference or use from the person by or for
19 whom the investigations, studies, or tests were
20 conducted); or

21 “(II) there is a scientific issue raised by
22 target animal observations contained in studies
23 submitted to the Secretary as part of the appli-
24 cation; and

1 “(ii) based on the Secretary’s evaluation of
2 the information contained in the application
3 with respect to the issues identified in clauses
4 (i)(I) and (II), paragraph (1)(A), (B), or (D)
5 apply;

6 “(C) except in the case of a combination that
7 contains a nontopical antibacterial ingredient or ani-
8 mal drug, the Secretary shall not issue an order
9 under paragraph (1)(E) refusing to approve an ap-
10 plication for a combination animal drug intended for
11 use other than in animal feed or drinking water un-
12 less the Secretary finds that the application fails to
13 demonstrate that—

14 “(i) there is substantial evidence that any
15 active ingredient or animal drug intended only
16 for the same use as another active ingredient or
17 animal drug in the combination makes a con-
18 tribution to labeled effectiveness;

19 “(ii) each active ingredient or animal drug
20 intended for at least one use that is different
21 from all other active ingredients or animal
22 drugs used in the combination provides appro-
23 priate concurrent use for the intended target
24 population; or

1 “(iii) where based on scientific information
2 the Secretary has reason to believe the active
3 ingredients or animal drugs may be physically
4 incompatible or have disparate dosing regimens,
5 such active ingredients or animal drugs are
6 physically compatible or do not have disparate
7 dosing regimens; and

8 “(D) the Secretary shall not issue an order
9 under paragraph (1)(E) refusing to approve an ap-
10 plication for a combination animal drug intended for
11 use in animal feed or drinking water unless the Sec-
12 retary finds that the application fails to demonstrate
13 that—

14 “(i) there is substantial evidence that any
15 active ingredient or animal drug intended only
16 for the same use as another active ingredient or
17 animal drug in the combination makes a con-
18 tribution to the labeled effectiveness;

19 “(ii) each of the active ingredients or ani-
20 mal drugs intended for at least one use that is
21 different from all other active ingredients or
22 animal drugs used in the combination provides
23 appropriate concurrent use for the intended tar-
24 get population;

1 “(iii) where a combination contains more
2 than one nontopical antibacterial ingredient or
3 animal drug, there is substantial evidence that
4 each of the nontopical antibacterial ingredients
5 or animal drugs makes a contribution to the la-
6 beled effectiveness; or

7 “(iv) where based on scientific information
8 the Secretary has reason to believe the active
9 ingredients or animal drugs intended for use in
10 drinking water may be physically incompatible,
11 such active ingredients or animal drugs in-
12 tended for use in drinking water are physically
13 compatible.”.

14 (d) PRESUBMISSION CONFERENCE.—Section 512(b)
15 (21 U.S.C. 360b(b)) is amended by adding at the end the
16 following:

17 “(3) Any person intending to file an application
18 under paragraph (1) or a request for an investigational
19 exemption under subsection (j) shall be entitled to one or
20 more conferences prior to such submission to reach an
21 agreement acceptable to the Secretary establishing a sub-
22 mission or an investigational requirement, which may in-
23 clude a requirement for a field investigation. A decision
24 establishing a submission or an investigational require-
25 ment shall bind the Secretary and the applicant or reques-

1 tor unless (A) the Secretary and the applicant or requestor
2 mutually agree to modify the requirement, or (B) the Sec-
3 retary by written order determines that a substantiated
4 scientific requirement essential to the determination of
5 safety or effectiveness of the animal drug involved has ap-
6 peared after the conference. No later than 25 calendar
7 days after each such conference, the Secretary shall pro-
8 vide a written order setting forth a scientific justification
9 specific to the animal drug and intended uses under con-
10 sideration if the agreement referred to in the first sentence
11 requires more than one field investigation as being essen-
12 tial to provide substantial evidence of effectiveness for the
13 intended uses of the drug. Nothing in this paragraph shall
14 be construed as compelling the Secretary to require a field
15 investigation.”.

16 (e) IMPLEMENTATION.—

17 (1) IN GENERAL.—Not later than 6 months
18 after the date of enactment of this Act, the Sec-
19 retary of Health and Human Services shall issue
20 proposed regulations implementing the amendments
21 made by this Act as described in paragraph (2)(A)
22 of this subsection, and not later than 18 months
23 after the date of enactment of this Act, the Sec-
24 retary shall issue final regulations implementing
25 such amendments. Not later than 12 months after

1 the date of enactment of this Act, the Secretary
2 shall issue proposed regulations implementing the
3 other amendments made by this Act as described in
4 paragraphs (2)(B) and (2)(C) of this subsection,
5 and not later than 24 months after the date of en-
6 actment of this Act, the Secretary shall issue final
7 regulations implementing such amendments.

8 (2) CONTENTS.—In issuing regulations imple-
9 menting the amendments made by this Act, and in
10 taking an action to review an application for ap-
11 proval of a new animal drug under section 512 of
12 the Federal Food, Drug, and Cosmetic Act (21
13 U.S.C. 360b), or a request for an investigational ex-
14 emption for a new animal drug under subsection (j)
15 of such section, that is pending or has been submit-
16 ted prior to the effective date of the regulations, the
17 Secretary shall—

18 (A) further define the term “adequate and
19 well controlled”, as used in subsection (d)(3) of
20 section 512 of such Act, to require that field in-
21 vestigations be designed and conducted in a sci-
22 entifically sound manner, taking into account
23 practical conditions in the field and differences
24 between field conditions and laboratory condi-
25 tions;

1 (B) further define the term “substantial
2 evidence”, as defined in subsection (d)(3) of
3 such section, in a manner that encourages the
4 submission of applications and supplemental
5 applications; and

6 (C) take into account the proposals con-
7 tained in the citizen petition (FDA Docket No.
8 91P-0434/CP) jointly submitted by the Amer-
9 ican Veterinary Medical Association and the
10 Animal Health Institute, dated October 21,
11 1991.

12 Until the regulations required by subparagraph (A)
13 are issued, nothing in the regulations published at
14 21 C.F.R. 514.111(a)(5) (April 1, 1996) shall be
15 construed to compel the Secretary of Health and
16 Human Services to require a field investigation
17 under section 512(d)(1)(E) of the Federal Food,
18 Drug, and Cosmetic Act (21 U.S.C. 360b(d)(1)(E))
19 or to apply any of its provisions in a manner incon-
20 sistent with the considerations for scientifically
21 sound field investigations set forth in subparagraph
22 (A).

23 (f) MINOR SPECIES AND USES.—The Secretary of
24 Health and Human Services shall consider legislative and
25 regulatory options for facilitating the approval under sec-

1 tion 512 of the Federal Food, Drug, and Cosmetic Act
2 of animal drugs intended for minor species and for minor
3 uses and, within 18 months after the date of enactment
4 of this Act, announce proposals for legislative or regu-
5 latory change to the approval process under such section
6 for animal drugs intended for use in minor species or for
7 minor uses.

8 **SEC. 3. LIMITATION ON RESIDUES.**

9 Section 512(d)(1)(F) (21 U.S.C. 360b(d)(1)(F)) is
10 amended to read as follows:

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

19 **SEC. 4. IMPORT TOLERANCES.**

20 Section 512(a) (21 U.S.C. 360b(a)) is amended by
21 adding the following new paragraph at the end:

22 “(6) For purposes of section 402(a)(2)(D), a use or
23 intended use of a new animal drug shall not be deemed
24 unsafe under this section if the Secretary establishes a tol-
25 erance for such drug and any edible portion of any animal

1 imported into the United States does not contain residues
2 exceeding such tolerance. In establishing such tolerance,
3 the Secretary shall rely on data sufficient to demonstrate
4 that a proposed tolerance is safe based on similar food
5 safety criteria used by the Secretary to establish toler-
6 ances for applications for new animal drugs filed under
7 subsection (b)(1). The Secretary may consider and rely on
8 data submitted by the drug manufacturer, including data
9 submitted to appropriate regulatory authorities in any
10 country where the new animal drug is lawfully used or
11 data available from a relevant international organization,
12 to the extent such data are not inconsistent with the cri-
13 teria used by the Secretary to establish a tolerance for
14 applications for new animal drugs filed under subsection
15 (b)(1). For purposes of this paragraph, ‘relevant inter-
16 national organization’ means the Codex Alimentarius
17 Commission or other international organization deemed
18 appropriate by the Secretary. The Secretary may, under
19 procedures specified by regulation, revoke a tolerance es-
20 tablished under this paragraph if information dem-
21 onstrates that the use of the new animal drug under actual
22 use conditions results in food being imported into the
23 United States with residues exceeding the tolerance or if
24 scientific evidence shows the tolerance to be unsafe.”.

1 **SEC. 5. VETERINARY FEED DIRECTIVES.**

2 (a) SECTION 503.—Section 503(f)(1)(A) (21 U.S.C.
3 353(f)(1)(A)) is amended by inserting after “other than
4 man” the following: “, other than a veterinary feed direc-
5 tive drug intended for use in animal feed or an animal
6 feed bearing or containing a veterinary feed directive
7 drug.”.

8 (b) SECTION 504.—The Federal Food, Drug, and
9 Cosmetic Act is amended by inserting after section 503
10 the following:

11 “VETERINARY FEED DIRECTIVE DRUGS

12 “SEC. 504. (a)(1) A drug intended for use in or on
13 animal feed which is limited by an approved application
14 filed pursuant to section 512(b) to use under the profes-
15 sional supervision of a licensed veterinarian is a veterinary
16 feed directive drug. Any animal feed bearing or containing
17 a veterinary feed directive drug shall be fed to animals
18 only by or upon a lawful veterinary feed directive issued
19 by a licensed veterinarian in the course of the veterinar-
20 ian’s professional practice. When labeled, distributed,
21 held, and used in accordance with this section, a veteri-
22 nary feed directive drug and any animal feed bearing or
23 containing a veterinary feed directive drug shall be exempt
24 from section 502(f).

25 “(2) A veterinary feed directive is lawful if it—

1 “(A) contains such information as the Secretary
2 may by general regulation or by order require; and

3 “(B) is in compliance with the conditions and
4 indications for use of the drug set forth in the notice
5 published pursuant to section 512(i).

6 “(3)(A) Any persons involved in the distribution or
7 use of animal feed bearing or containing a veterinary feed
8 directive drug and the licensed veterinarian issuing the
9 veterinary feed directive shall maintain a copy of the vet-
10 erinary feed directive applicable to each such feed, except
11 in the case of a person distributing such feed to another
12 person for further distribution. Such person distributing
13 the feed shall maintain a written acknowledgment from
14 the person to whom the feed is shipped stating that that
15 person shall not ship or move such feed to an animal pro-
16 duction facility without a veterinary feed directive or ship
17 such feed to another person for further distribution unless
18 that person has provided the same written acknowledg-
19 ment to its immediate supplier.

20 “(B) Every person required under subparagraph (A)
21 to 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 “(C) Any person who distributes animal feed bearing
2 or containing a veterinary feed directive drug shall upon
3 first engaging in such distribution notify the Secretary of
4 that person’s name and place of business. The failure to
5 provide such notification shall be deemed to be an act
6 which results in the drug being misbranded.

7 “(b) A veterinary feed directive drug and any feed
8 bearing or containing a veterinary feed directive drug shall
9 be deemed to be misbranded if their labeling fails to bear
10 such cautionary statement and such other information as
11 the Secretary may by general regulation or by order pre-
12 scribe, or their advertising fails to conform to the condi-
13 tions and indications for use published pursuant to section
14 512(i) or fails to contain the general cautionary statement
15 prescribed by the Secretary.

16 “(c) Neither a drug subject to this section, nor ani-
17 mal feed bearing or containing such a drug, shall be
18 deemed to be a prescription article under any Federal or
19 State law.”.

20 (e) CONFORMING AMENDMENT.—Section 512 (21
21 U.S.C. 360b) is amended in subsection (i) by inserting
22 after “(including special labeling requirements” the follow-
23 ing: “and any requirement that an animal feed bearing
24 or containing the new animal drug be limited to use under
25 the professional supervision of a licensed veterinarian”.

1 (d) SECTION 301(e).—Section 301(e) (21 U.S.C.
2 331(e)) is amended by inserting after “by section 412”
3 the following: “, 504,”; and by inserting after “under sec-
4 tion 412,” the following: “504,”.

5 **SEC. 6. FEED MILL LICENSES.**

6 (a) SECTION 512(a).—Paragraphs (1) and (2) of sec-
7 tion 512(a) (21 U.S.C. 360b(a)) are amended to read as
8 follows:

9 “(a)(1) A new animal drug shall, with respect to any
10 particular use or intended use of such drug, be deemed
11 unsafe for the purposes of section 501(a)(5) and section
12 402(a)(2)(D) unless —

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

16 “(B) such drug, its labeling, and such use con-
17 form to such approved application.

18 A new animal drug shall also be deemed unsafe for such
19 purposes in the event of removal from the establishment
20 of a manufacturer, packer, or distributor of such drug for
21 use in the manufacture of animal feed in any State unless
22 at the time of such removal such manufacturer, packer,
23 or distributor has an unrevoked written statement from
24 the consignee of such drug, or notice from the Secretary,
25 to the effect that, with respect to the use of such drug

1 in animal feed, such consignee (i) holds a license issued
2 under subsection (m) and has in its possession current ap-
3 proved labeling for such drug in animal feed; or (ii) will,
4 if the consignee is not a user of the drug, ship such drug
5 only to a holder of a license issued under subsection (m).

6 “(2) An animal feed bearing or containing a new ani-
7 mal drug shall, with respect to any particular use or in-
8 tended use of such animal feed be deemed unsafe for the
9 purposes of section 501(a)(6) unless—

10 “(A) there is in effect an approval of an appli-
11 cation filed pursuant to subsection (b) with respect
12 to such drug, as used in such animal feed,

13 “(B) such animal feed is manufactured at a site
14 for which there is in effect a license issued pursuant
15 to subsection (m)(1) to manufacture such animal
16 feed, and

17 “(C) such animal feed and its labeling, distribu-
18 tion, holding, and use conform to the conditions and
19 indications of use published pursuant to subsection
20 (i).”.

21 (b) SECTION 512(m).—Section 512(m) (21 U.S.C.
22 360b(m)) is amended to read as follows:

23 “(m)(1) Any person may file with the Secretary an
24 application for a license to manufacture animal feeds bear-

1 ing or containing new animal drugs. Such person shall
2 submit to the Secretary as part of the application (A) a
3 full statement of the business name and address of the
4 specific facility at which the manufacturing is to take
5 place and the facility's registration number, (B) the name
6 and signature of the responsible individual or individuals
7 for that facility, (C) a certification that the animal feeds
8 bearing or containing new animal drugs are manufactured
9 and labeled in accordance with the applicable regulations
10 published pursuant to subsection (i), and (D) a certifi-
11 cation that the methods used in, and the facilities and con-
12 trols used for, manufacturing, processing, packaging, and
13 holding such animal feeds are in conformity with current
14 good manufacturing practice as described in section
15 501(a)(2)(B).

16 “(2) Within 90 days after the filing of an application
17 pursuant to paragraph (1), or such additional period as
18 may be agreed upon by the Secretary and the applicant,
19 the Secretary shall (A) issue an order approving the appli-
20 cation if the Secretary then finds that none of the grounds
21 for denying approval specified in paragraph (3) applies,
22 or (B) give the applicant notice of an opportunity for a
23 hearing before the Secretary under paragraph (3) on the
24 question whether such application is approvable. The pro-

1 cedure governing such a hearing shall be the procedure
2 set forth in the last two sentences of subsection (c)(1).

3 “(3) If the Secretary, after due notice to the appli-
4 cant in accordance with paragraph (2) and giving the ap-
5 plicant an opportunity for a hearing in accordance with
6 such paragraph, finds, on the basis of information submit-
7 ted to the Secretary as part of the application, on the basis
8 of a preapproval inspection, or on the basis of any other
9 information before the Secretary—

10 “(A) that the application is incomplete, false, or
11 misleading in any particular;

12 “(B) that the methods used in, and the facili-
13 ties and controls used for, the manufacture, process-
14 ing, and packing of such animal feed are inadequate
15 to preserve the identity, strength, quality, and purity
16 of the new animal drug therein; or

17 “(C) that the facility manufactures animal
18 feeds bearing or containing new animal drugs in a
19 manner that does not accord with the specifications
20 for manufacture or labels animal feeds bearing or
21 containing new animal drugs in a manner that does
22 not accord with the conditions or indications of use
23 that are published pursuant to subsection (i),

24 the Secretary shall issue an order refusing to approve the
25 application. If, after such notice and opportunity for hear-

1 ing, the Secretary finds that subparagraphs (A) through
2 (C) do not apply, the Secretary shall issue an order ap-
3 proving the application. An order under this subsection
4 approving an application for a license to manufacture ani-
5 mal feeds bearing or containing new animal drugs shall
6 permit a facility to manufacture only those animal feeds
7 bearing or containing new animal drugs for which there
8 are in effect regulations pursuant to subsection (i) relating
9 to the use of such drugs in or on such animal feed.

10 “(4)(A) The Secretary shall, after due notice and op-
11 portunity for hearing to the applicant, revoke a license to
12 manufacture animal feeds bearing or containing new ani-
13 mal drugs under this subsection if the Secretary finds—

14 “(i) that the application for such license con-
15 tains any untrue statement of a material fact; or

16 “(ii) that the applicant has made changes that
17 would cause the application to contain any untrue
18 statements of material fact or that would affect the
19 safety or effectiveness of the animal feeds manufac-
20 tured at the facility unless the applicant has supple-
21 mented the application by filing with the Secretary
22 adequate information respecting all such changes
23 and unless there is in effect an approval of the sup-
24 plemental application.

1 If the Secretary (or in the Secretary’s absence the officer
2 acting as the Secretary) finds that there is an imminent
3 hazard to the health of humans or of the animals for which
4 such animal feed is intended, the Secretary may suspend
5 the license immediately, and give the applicant prompt no-
6 tice of the action and afford the applicant the opportunity
7 for an expedited hearing under this subsection; but the
8 authority conferred by this sentence shall not be delegated.

9 “(B) The Secretary may also, after due notice and
10 opportunity for hearing to the applicant, revoke a license
11 to manufacture animal feed under this subsection if the
12 Secretary finds—

13 “(i) that the applicant has failed to establish a
14 system for maintaining required records, or has re-
15 peatedly or deliberately failed to maintain such
16 records or to make required reports in accordance
17 with a regulation or order under paragraph (5)(A)
18 of this subsection or section 504(a)(3)(A), or the ap-
19 plicant has refused to permit access to, or copying
20 or verification of, such records as required by sub-
21 paragraph (B) of such paragraph or section
22 504(a)(3)(B);

23 “(ii) that on the basis of new information be-
24 fore the Secretary, evaluated together with the evi-
25 dence before the Secretary when such license was is-

1 sued, the methods used in, or the facilities and con-
2 trols used for, the manufacture, processing, packing,
3 and holding of such animal feed are inadequate to
4 assure and preserve the identity, strength, quality,
5 and purity of the new animal drug therein, and were
6 not made adequate within a reasonable time after
7 receipt of written notice from the Secretary, specify-
8 ing the matter complained of;

9 “(iii) that on the basis of new information be-
10 fore the Secretary, evaluated together with the evi-
11 dence before the Secretary when such license was is-
12 sued, the labeling of any animal feeds, based on a
13 fair evaluation of all material facts, is false or mis-
14 leading in any particular and was not corrected
15 within a reasonable time after receipt of written no-
16 tice from the Secretary specifying the matter com-
17 plained of; or

18 “(iv) that on the basis of new information be-
19 fore the Secretary, evaluated together with the evi-
20 dence before the Secretary when such license was is-
21 sued, the facility has manufactured, processed,
22 packed, or held animal feed bearing or containing a
23 new animal drug adulterated under section
24 501(a)(6) and the facility did not discontinue the
25 manufacture, processing, packing, or holding of such

1 animal feed within a reasonable time after receipt of
2 written notice from the Secretary specifying the
3 matter complained of.

4 “(C) The Secretary may also revoke a license to man-
5 ufacture animal feeds under this subsection if an applicant
6 gives notice to the Secretary of intention to discontinue
7 the manufacture of all animal feed covered under this sub-
8 section and waives an opportunity for a hearing on the
9 matter.

10 “(D) Any order under this paragraph shall state the
11 findings upon which it is based.

12 “(5) When a license to manufacture animal feeds
13 bearing or containing new animal drugs has been issued—

14 “(A) the applicant shall establish and maintain
15 such records, and make such reports to the Sec-
16 retary, or (at the option of the Secretary) to the ap-
17 propriate person or persons holding an approved ap-
18 plication filed under subsection (b), as the Secretary
19 may by general regulation, or by order with respect
20 to such application, prescribe on the basis of a find-
21 ing that such records and reports are necessary in
22 order to enable the Secretary to determine, or facili-
23 tate a determination, whether there is or may be
24 ground for invoking subsection (e) or paragraph (4);
25 and

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

7 “(6) To the extent consistent with the public health,
8 the Secretary may promulgate regulations for exempting
9 from the operation of this subsection facilities that manu-
10 facture, process, pack, or hold animal feeds bearing or
11 containing new animal drugs.”.

12 (c) TRANSITIONAL PROVISION.—A person engaged in
13 the manufacture of animal feeds bearing or containing
14 new animal drugs who holds at least one approved medi-
15 cated feed application for an animal feed bearing or con-
16 taining new animal drugs, the manufacture of which was
17 not otherwise exempt from the requirement for an ap-
18 proved medicated feed application on the date of the en-
19 actment of this Act, shall be deemed to hold a license for
20 the manufacturing site identified in the approved medi-
21 cated feed application. The revocation of license provisions
22 of section 512(m)(4) of the Federal Food, Drug, and Cos-
23 metic Act, as amended by this Act, shall apply to such
24 licenses. Such license shall expire within 18 months from
25 the date of enactment of this Act unless the person sub-

1 mits to the Secretary a completed license application for
2 the manufacturing site accompanied by a copy of an ap-
3 proved medicated feed application for such site, which li-
4 cense application shall be deemed to be approved upon re-
5 ceipt by the Secretary.

Passed the House of Representatives September 24,
1996.

Attest:

ROBIN H. CARLE,

Clerk.