

Union Calendar No. 451

104<sup>TH</sup> CONGRESS  
2<sup>D</sup> SESSION

**H. R. 2508**

[Report No. 104-823]

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**A BILL**

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.

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SEPTEMBER 24, 1996

Reported with an amendment, committed to the Committee of the Whole House on the State of the Union, and ordered to be printed

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## IN THE HOUSE OF REPRESENTATIVES

OCTOBER 19, 1995

Mr. ALLARD (for himself, Mr. KLUG, Mr. STENHOLM, Mr. DINGELL, Mr. GANSKE, Mr. BARRETT of Nebraska, Mr. BEREUTER, Mr. BOEHNER, Mr. BROWN of California, Mr. BRYANT of Texas, Mr. BURTON of Indiana, Mr. BUYER, Mr. CHAMBLISS, Mrs. CHENOWETH, Mr. COBLE, Mr. COMBEST, Mr. CONDIT, Mr. COOLEY of Oregon, Mr. COSTELLO, Mr. CRAPO, Mrs. CUBIN, Mr. DE LA GARZA, Mr. DOOLEY of California, Mr. EHLERS, Mr. EMERSON, Mr. ENSIGN, Mr. EWING, Mr. GOODLATTE, Mr. GORDON, Mr. GUNDERSON, Mr. HAMILTON, Mr. HEFLEY, Mr. HOLDEN, Mr. HOSTETTLER, Mr. JOHNSON of South Dakota, Mr. KLECZKA, Mr. LAHOOD, Mrs. LINCOLN, Mr. LARGENT, Mr. LATHAM, Mr. LEACH, Mr. LEWIS of Kentucky, Mr. LIGHTFOOT, Mr. LUCAS of Oklahoma, Mr. MCINNIS, Mr. MCINTOSH, Ms. MCKINNEY, Mr. MILLER of Florida, Mr. MINGE, Ms. MOLINARI, Mr. MYERS of Indiana, Mr. NORWOOD, Mr. PASTOR, Mr. PAXON, Mr. PETERSON of Minnesota, Mr. POMBO, Mr. POMEROY, Mr. POSHARD, Mr. ROBERTS, Mr. ROEMER, Mr. ROSE, Mr. SCHAEFER, Mr. SKEEN, Mr. SOUDER, Mr. STUMP, Mr. TAYLOR of North Carolina, Mr. THORNBERRY, Mr. THORNTON, Mrs. THURMAN, Mr. WALSH, Mr. WATTS of Oklahoma, and Mr. WHITFIELD) introduced the following bill; which was referred to the Committee on Commerce

SEPTEMBER 24, 1996

Additional sponsors: Mr. BURR, Mrs. CLAYTON, Mr. GILLMOR, Mr. ROTH, Mr. GUTKNECHT, Mr. JACOBS, Ms. DANNER, Mr. STUPAK, Mr. VOLKMER, Mr. FUNDERBURK, Mr. FRAZER, Mr. HINCHEY, Mr. BARTON of Texas, Mr. DEUTSCH, Mr. SKELTON, Mr. WICKER, Mr. GEJDENSON, Mr. DURBIN, Mr. RAHALL, Ms. FURSE, Mr. FROST, Mr. HANCOCK, Mr. SMITH of Texas, Mr. HUTCHINSON, Mr. BREWSTER, Mr. HANSEN, Mr.

BONILLA, Mr. MONTGOMERY, Mr. LAUGHLIN, Mr. WAMP, Ms. WOOLSEY, Mr. MANTON, Mr. FIELDS of Texas, Mr. FRISA, Mr. SMITH of Michigan, Mr. CASTLE, Mr. FORBES, Mr. RADANOVICH, Mr. BILBRAY, Mr. CHRISTENSEN, Mr. FARR of California, Mr. BARCIA, Mr. DICKEY, Mr. HEINEMAN, Mr. PORTER, Mr. NEY, Mr. CRAMER, Mr. JONES, Mr. JEFFERSON, Mr. GREENWOOD, Mr. TOWNS, Ms. PRYCE, Mr. KENNEDY of Massachusetts, Mr. CHRYSLER, Mr. KILDEE, Mr. LIVINGSTON, Mr. BARR of Georgia, Mr. CALLAHAN, Mr. CANADY of Florida, Mr. WISE, Mrs. MEYERS of Kansas, Mr. MATSUI, Mr. BEVILL, Mr. TRAFICANT, Mr. ABERCROMBIE, Mr. BACHUS, Ms. DUNN of Washington, Mr. SOLOMON, Mr. FAZIO of California, Mr. UPTON, Mr. DEAL of Georgia, Mr. PALLONE, Mr. ROHRABACHER, Mr. KNOLLENBERG, Mr. LINDER, Mr. BUNNING of Kentucky, Mr. CUNNINGHAM, Mr. BALLENGER, Mr. INGLIS of South Carolina, Mr. EDWARDS, Mr. NUSSLE, Mr. WYNN, Mr. LAFALCE, Mr. COLLINS of Georgia, Ms. RIVERS, Mr. FOLEY, Mr. HAYWORTH, Ms. MCCARTHY, Mr. BRYANT of Tennessee, Mr. BISHOP, Mr. SENSENBRENNER, Mrs. MYRICK, Mr. KASICH, Mr. PICKETT, Mr. NETHERCUTT, and Mr. CREMEANS

SEPTEMBER 24, 1996

Reported with an amendment, committed to the Committee of the Whole House on the State of the Union, and ordered to be printed

[Strike out all after the enacting clause and insert the part printed in *italie*]

[For text of introduced bill, see copy of bill as introduced on October 19, 1995]

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## A BILL

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,*

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

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

6        (b) *REFERENCE.*—*Whenever in this Act an amend-*  
 7        *ment or repeal is expressed in terms of an amendment to,*

1 *or repeal of, a section or other provision, the reference shall*  
2 *be considered to be made to a section or other provision*  
3 *of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.*  
4 *321 et seq.).*

5 **SEC. 2. EVIDENCE OF EFFECTIVENESS.**

6 (a) *ORIGINAL APPLICATIONS.*—*Paragraph (3) of sec-*  
7 *tion 512(d) (21 U.S.C. 360b(d)) is amended to read as fol-*  
8 *lows:*

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

12 “(A) *a study in a target species;*

13 “(B) *a study in laboratory animals;*

14 “(C) *any field investigation that may be re-*  
15 *quired under this section and that meets the require-*  
16 *ments of subsection (b)(3) if a presubmission con-*  
17 *ference is requested by the applicant;*

18 “(D) *a bioequivalence study; or*

19 “(E) *an in vitro study;*

20 *by experts qualified by scientific training and experience*  
21 *to evaluate the effectiveness of the drug involved, on the*  
22 *basis of which it could fairly and reasonably be concluded*  
23 *by such experts that the drug will have the effect it purports*  
24 *or is represented to have under the conditions of use pre-*

1 *scribed, recommended, or suggested in the labeling or pro-*  
2 *posed labeling thereof.”.*

3 (b) *CONFORMING AMENDMENTS.—*

4 (1) *Clauses (ii) and (iii) of section 512(c)(2)(F)*  
5 *(21 U.S.C. 360b(c)(2)(F)) are each amended—*

6 (A) *by striking “reports of new clinical or*  
7 *field investigations (other than bioequivalence or*  
8 *residue studies) and,” and inserting “substantial*  
9 *evidence of the effectiveness of the drug involved,*  
10 *any studies of animal safety, or,”; and*

11 (B) *by striking “essential to” and inserting*  
12 *“required for”.*

13 (2) *Section 512(c)(2)(F)(v) (21 U.S.C.*  
14 *360b(c)(2)(F)(v)) is amended—*

15 (A) *by striking “subparagraph (B)(iv)”*  
16 *each place it appears and inserting “clause*  
17 *(iv)”;*

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

22 (C) *by striking “essential to” and inserting*  
23 *“required for”.*

1           (c) *COMBINATION DRUGS.—Section 512(d) (21 U.S.C.*  
2 *360b(d)), as amended by subsection (a) is amended by add-*  
3 *ing at the end the following:*

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

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

17           “(i) *none of the active ingredients or drugs*  
18 *intended for use in the combination, respectively,*  
19 *at the longest withdrawal time of any of the ac-*  
20 *tive ingredients or drugs in the combination, re-*  
21 *spectively, exceeds its established tolerance; or*

22           “(ii) *none of the active ingredients or drugs*  
23 *in the combination interferes with the methods of*  
24 *analysis for another of the active ingredients or*  
25 *drugs in the combination, respectively;*

1           “(B) the Secretary shall not issue an order under  
2           paragraph (1)(A), (1)(B), or (1)(D) refusing to ap-  
3           prove the application for such combination on target  
4           animal safety grounds unless the Secretary finds  
5           that—

6                   “(i)(I) there is a substantiated scientific  
7                   issue, specific to one or more of the active ingre-  
8                   dients or animal drugs in the combination, that  
9                   cannot adequately be evaluated based on infor-  
10                  mation contained in the application for the com-  
11                  bination (including any investigations, studies,  
12                  or tests for which the applicant has a right of  
13                  reference or use from the person by or for whom  
14                  the investigations, studies, or tests were con-  
15                  ducted); or

16                   “(II) there is a scientific issue raised by  
17                  target animal observations contained in studies  
18                  submitted to the Secretary as part of the appli-  
19                  cation; and

20                   “(ii) based on the Secretary’s evaluation of  
21                  the information contained in the application  
22                  with respect to the issues identified in clauses  
23                  (i)(I) and (II), paragraph (1)(A), (B), or (D)  
24                  apply;

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

9                   “(i) *there is substantial evidence that any*  
10                  *active ingredient or animal drug intended only*  
11                  *for the same use as another active ingredient or*  
12                  *animal drug in the combination makes a con-*  
13                  *tribution to labeled effectiveness;*

14                  “(ii) *each active ingredient or animal drug*  
15                  *intended for at least one use that is different*  
16                  *from all other active ingredients or animal drugs*  
17                  *used in the combination provides appropriate*  
18                  *concurrent use for the intended target popu-*  
19                  *lation; or*

20                  “(iii) *where based on scientific information*  
21                  *the Secretary has reason to believe the active in-*  
22                  *gredients or animal drugs may be physically in-*  
23                  *compatible or have disparate dosing regimens,*  
24                  *such active ingredients or animal drugs are*

1           *physically compatible or do not have disparate*  
2           *dosing regimens; and*

3           “(D) *the Secretary shall not issue an order*  
4           *under paragraph (1)(E) refusing to approve an ap-*  
5           *plication for a combination animal drug intended for*  
6           *use in animal feed or drinking water unless the Sec-*  
7           *retary finds that the application fails to demonstrate*  
8           *that—*

9                     “(i) *there is substantial evidence that any*  
10            *active ingredient or animal drug intended only*  
11            *for the same use as another active ingredient or*  
12            *animal drug in the combination makes a con-*  
13            *tribution to the labeled effectiveness;*

14                    “(ii) *each of the active ingredients or ani-*  
15            *mal drugs intended for at least one use that is*  
16            *different from all other active ingredients or ani-*  
17            *mal drugs used in the combination provides ap-*  
18            *propriate concurrent use for the intended target*  
19            *population;*

20                    “(iii) *where a combination contains more*  
21            *than one nontopical antibacterial ingredient or*  
22            *animal drug, there is substantial evidence that*  
23            *each of the nontopical antibacterial ingredients*  
24            *or animal drugs makes a contribution to the la-*  
25            *beled effectiveness; or*

1           “(iv) where based on scientific information  
2           the Secretary has reason to believe the active in-  
3           gredients or animal drugs intended for use in  
4           drinking water may be physically incompatible,  
5           such active ingredients or animal drugs intended  
6           for use in drinking water are physically compat-  
7           ible.”.

8           (d) *PRESUBMISSION CONFERENCE*.—Section 512(b)  
9           (21 U.S.C. 360b(b)) is amended by adding at the end the  
10          following:

11          “(3) Any person intending to file an application under  
12          paragraph (1) or a request for an investigational exemption  
13          under subsection (j) shall be entitled to one or more con-  
14          ferences prior to such submission to reach an agreement ac-  
15          ceptable to the Secretary establishing a submission or an  
16          investigational requirement, which may include a require-  
17          ment for a field investigation. A decision establishing a sub-  
18          mission or an investigational requirement shall bind the  
19          Secretary and the applicant or requestor unless (A) the Sec-  
20          retary and the applicant or requestor mutually agree to  
21          modify the requirement, or (B) the Secretary by written  
22          order determines that a substantiated scientific requirement  
23          essential to the determination of safety or effectiveness of  
24          the animal drug involved has appeared after the conference.  
25          No later than 25 calendar days after each such conference,

1 *the Secretary shall provide a written order setting forth a*  
2 *scientific justification specific to the animal drug and in-*  
3 *tended uses under consideration if the agreement referred*  
4 *to in the first sentence requires more than one field inves-*  
5 *tigation as being essential to provide substantial evidence*  
6 *of effectiveness for the intended uses of the drug. Nothing*  
7 *in this paragraph shall be construed as compelling the Sec-*  
8 *retary to require a field investigation.”.*

9 *(e) IMPLEMENTATION.—*

10 *(1) IN GENERAL.—Not later than 6 months after*  
11 *the date of enactment of this Act, the Secretary of*  
12 *Health and Human Services shall issue proposed reg-*  
13 *ulations implementing the amendments made by this*  
14 *Act as described in paragraph (2)(A) of this sub-*  
15 *section, and not later than 18 months after the date*  
16 *of enactment of this Act, the Secretary shall issue*  
17 *final regulations implementing such amendments. Not*  
18 *later than 12 months after the date of enactment of*  
19 *this Act, the Secretary shall issue proposed regula-*  
20 *tions implementing the other amendments made by*  
21 *this Act as described in paragraphs (2)(B) and (2)(C)*  
22 *of this subsection, and not later than 24 months after*  
23 *the date of enactment of this Act, the Secretary shall*  
24 *issue final regulations implementing such amend-*  
25 *ments.*

1           (2) *CONTENTS.*—*In issuing regulations imple-*  
2           *menting the amendments made by this Act, and in*  
3           *taking an action to review an application for ap-*  
4           *proval of a new animal drug under section 512 of the*  
5           *Federal Food, Drug, and Cosmetic Act (21 U.S.C.*  
6           *360b), or a request for an investigational exemption*  
7           *for a new animal drug under subsection (j) of such*  
8           *section, that is pending or has been submitted prior*  
9           *to the effective date of the regulations, the Secretary*  
10          *shall—*

11                   (A) *further define the term “adequate and*  
12                   *well controlled”, as used in subsection (d)(3) of*  
13                   *section 512 of such Act, to require that field in-*  
14                   *vestigations be designed and conducted in a sci-*  
15                   *entifically sound manner, taking into account*  
16                   *practical conditions in the field and differences*  
17                   *between field conditions and laboratory condi-*  
18                   *tions;*

19                   (B) *further define the term “substantial evi-*  
20                   *dence”, as defined in subsection (d)(3) of such*  
21                   *section, in a manner that encourages the submis-*  
22                   *sion of applications and supplemental applica-*  
23                   *tions; and*

24                   (C) *take into account the proposals con-*  
25                   *tained in the citizen petition (FDA Docket No.*

1           91P–0434/CP) jointly submitted by the Amer-  
2           ican Veterinary Medical Association and the  
3           Animal Health Institute, dated October 21, 1991.

4           Until the regulations required by subparagraph (A)  
5           are issued, nothing in the regulations published at 21  
6           C.F.R. 514.111(a)(5) (April 1, 1996) shall be con-  
7           strued to compel the Secretary of Health and Human  
8           Services to require a field investigation under section  
9           512(d)(1)(E) of the Federal Food, Drug, and Cosmetic  
10          Act (21 U.S.C. 360b(d)(1)(E)) or to apply any of its  
11          provisions in a manner inconsistent with the consid-  
12          erations for scientifically sound field investigations  
13          set forth in subparagraph (A).

14          (f) *MINOR SPECIES AND USES.*—The Secretary of  
15          Health and Human Services shall consider legislative and  
16          regulatory options for facilitating the approval under sec-  
17          tion 512 of the Federal Food, Drug, and Cosmetic Act of  
18          animal drugs intended for minor species and for minor uses  
19          and, within 18 months after the date of enactment of this  
20          Act, announce proposals for legislative or regulatory change  
21          to the approval process under such section for animal drugs  
22          intended for use in minor species or for minor uses.

23          **SEC. 3. LIMITATION ON RESIDUES.**

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

1           “(F) upon the basis of information submitted to  
2           the Secretary as part of the application or any other  
3           information before the Secretary with respect to such  
4           drug, any use prescribed, recommended, or suggested  
5           in labeling proposed for such drug will result in a  
6           residue of such drug in excess of a tolerance found by  
7           the Secretary to be safe for such drug;”.

8   **SEC. 4. IMPORT TOLERANCES.**

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

11          “(6) For purposes of section 402(a)(2)(D), a use or in-  
12          tended use of a new animal drug shall not be deemed unsafe  
13          under this section if the Secretary establishes a tolerance  
14          for such drug and any edible portion of any animal im-  
15          ported into the United States does not contain residues ex-  
16          ceeding such tolerance. In establishing such tolerance, the  
17          Secretary shall rely on data sufficient to demonstrate that  
18          a proposed tolerance is safe based on similar food safety  
19          criteria used by the Secretary to establish tolerances for ap-  
20          plications for new animal drugs filed under subsection  
21          (b)(1). The Secretary may consider and rely on data sub-  
22          mitted by the drug manufacturer, including data submitted  
23          to appropriate regulatory authorities in any country where  
24          the new animal drug is lawfully used or data available from  
25          a relevant international organization, to the extent such

1 *data are not inconsistent with the criteria used by the Sec-*  
2 *retary to establish a tolerance for applications for new ani-*  
3 *mal drugs filed under subsection (b)(1). For purposes of this*  
4 *paragraph, ‘relevant international organization’ means the*  
5 *Codex Alimentarius Commission or other international or-*  
6 *ganization deemed appropriate by the Secretary. The Sec-*  
7 *retary may, under procedures specified by regulation, re-*  
8 *voke a tolerance established under this paragraph if infor-*  
9 *mation demonstrates that the use of the new animal drug*  
10 *under actual use conditions results in food being imported*  
11 *into the United States with residues exceeding the tolerance*  
12 *or if scientific evidence shows the tolerance to be unsafe.”.*

13 **SEC. 5. VETERINARY FEED DIRECTIVES.**

14 (a) SECTION 503.—Section 503(f)(1)(A) (21 U.S.C.  
15 353(f)(1)(A)) is amended by inserting after “other than  
16 man” the following: “, other than a veterinary feed directive  
17 drug intended for use in animal feed or an animal feed  
18 bearing or containing a veterinary feed directive drug,”.

19 (b) SECTION 504.—The Federal Food, Drug, and Cos-  
20 metic Act is amended by inserting after section 503 the fol-  
21 lowing:

22 “VETERINARY FEED DIRECTIVE DRUGS

23 “SEC. 504. (a)(1) A drug intended for use in or on  
24 animal feed which is limited by an approved application  
25 filed pursuant to section 512(b) to use under the profes-  
26 sional supervision of a licensed veterinarian is a veterinary

1 *feed directive drug. Any animal feed bearing or containing*  
2 *a veterinary feed directive drug shall be fed to animals only*  
3 *by or upon a lawful veterinary feed directive issued by a*  
4 *licensed veterinarian in the course of the veterinarian’s pro-*  
5 *fessional practice. When labeled, distributed, held, and used*  
6 *in accordance with this section, a veterinary feed directive*  
7 *drug and any animal feed bearing or containing a veteri-*  
8 *nary feed directive drug shall be exempt from section 502(f).*

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

10               “(A) *contains such information as the Secretary*  
11 *may by general regulation or by order require; and*

12               “(B) *is in compliance with the conditions and*  
13 *indications for use of the drug set forth in the notice*  
14 *published pursuant to section 512(i).*

15       “(3)(A) *Any persons involved in the distribution or use*  
16 *of animal feed bearing or containing a veterinary feed di-*  
17 *rective drug and the licensed veterinarian issuing the veteri-*  
18 *nary feed directive shall maintain a copy of the veterinary*  
19 *feed directive applicable to each such feed, except in the case*  
20 *of a person distributing such feed to another person for fur-*  
21 *ther distribution. Such person distributing the feed shall*  
22 *maintain a written acknowledgment from the person to*  
23 *whom the feed is shipped stating that that person shall not*  
24 *ship or move such feed to an animal production facility*  
25 *without a veterinary feed directive or ship such feed to an-*

1 *other person for further distribution unless that person has*  
2 *provided the same written acknowledgment to its immediate*  
3 *supplier.*

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

10       “(C) *Any person who distributes animal feed bearing*  
11 *or containing a veterinary feed directive drug shall upon*  
12 *first engaging in such distribution notify the Secretary of*  
13 *that person’s name and place of business. The failure to*  
14 *provide such notification shall be deemed to be an act which*  
15 *results in the drug being misbranded.*

16       “(b) *A veterinary feed directive drug and any feed*  
17 *bearing or containing a veterinary feed directive drug shall*  
18 *be deemed to be misbranded if their labeling fails to bear*  
19 *such cautionary statement and such other information as*  
20 *the Secretary may by general regulation or by order pre-*  
21 *scribe, or their advertising fails to conform to the conditions*  
22 *and indications for use published pursuant to section 512(i)*  
23 *or fails to contain the general cautionary statement pre-*  
24 *scribed by the Secretary.*

1       “(c) Neither a drug subject to this section, nor animal  
2 feed bearing or containing such a drug, shall be deemed to  
3 be a prescription article under any Federal or State law.”.

4       (c) CONFORMING AMENDMENT.—Section 512 (21  
5 U.S.C. 360b) is amended in subsection (i) by inserting after  
6 “(including special labeling requirements” the following:  
7 “and any requirement that an animal feed bearing or con-  
8 taining the new animal drug be limited to use under the  
9 professional supervision of a licensed veterinarian”.

10       (d) SECTION 301(e).—Section 301(e) (21 U.S.C.  
11 331(e)) is amended by inserting after “by section 412” the  
12 following: “, 504,”; and by inserting after “under section  
13 412,” the following: “504,”.

14 **SEC. 6. FEED MILL LICENSES.**

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

18       “(a)(1) A new animal drug shall, with respect to any  
19 particular use or intended use of such drug, be deemed un-  
20 safe for the purposes of section 501(a)(5) and section  
21 402(a)(2)(D) unless —

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

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

3 *A new animal drug shall also be deemed unsafe for such*  
4 *purposes in the event of removal from the establishment of*  
5 *a manufacturer, packer, or distributor of such drug for use*  
6 *in the manufacture of animal feed in any State unless at*  
7 *the time of such removal such manufacturer, packer, or dis-*  
8 *tributor has an unrevoked written statement from the con-*  
9 *signee of such drug, or notice from the Secretary, to the*  
10 *effect that, with respect to the use of such drug in animal*  
11 *feed, such consignee (i) holds a license issued under sub-*  
12 *section (m) and has in its possession current approved la-*  
13 *beling for such drug in animal feed; or (ii) will, if the con-*  
14 *signee is not a user of the drug, ship such drug only to*  
15 *a holder of a license issued under subsection (m) .*

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

20           “(A) *there is in effect an approval of an applica-*  
21 *tion filed pursuant to subsection (b) with respect to*  
22 *such drug, as used in such animal feed,*

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

1       to subsection (m)(1) to manufacture such animal feed,  
2       and

3               “(C) such animal feed and its labeling, distribu-  
4       tion, holding, and use conform to the conditions and  
5       indications of use published pursuant to subsection  
6       (i).”.

7       (b) *SECTION 512(m).*—*Section 512(m) (21 U.S.C.*  
8       *360b(m)) is amended to read as follows:*

9               “(m)(1) *Any person may file with the Secretary an*  
10       *application for a license to manufacture animal feeds bear-*  
11       *ing or containing new animal drugs. Such person shall sub-*  
12       *mit to the Secretary as part of the application (A) a full*  
13       *statement of the business name and address of the specific*  
14       *facility at which the manufacturing is to take place and*  
15       *the facility’s registration number, (B) the name and signa-*  
16       *ture of the responsible individual or individuals for that*  
17       *facility, (C) a certification that the animal feeds bearing*  
18       *or containing new animal drugs are manufactured and la-*  
19       *beled in accordance with the applicable regulations pub-*  
20       *lished pursuant to subsection (i), and (D) a certification*  
21       *that the methods used in, and the facilities and controls*  
22       *used for, manufacturing, processing, packaging, and hold-*  
23       *ing such animal feeds are in conformity with current good*  
24       *manufacturing practice as described in section*  
25       *501(a)(2)(B).*

1           “(2) Within 90 days after the filing of an application  
2 pursuant to paragraph (1), or such additional period as  
3 may be agreed upon by the Secretary and the applicant,  
4 the Secretary shall (A) issue an order approving the appli-  
5 cation if the Secretary then finds that none of the grounds  
6 for denying approval specified in paragraph (3) applies,  
7 or (B) give the applicant notice of an opportunity for a  
8 hearing before the Secretary under paragraph (3) on the  
9 question whether such application is approvable. The proce-  
10 dure governing such a hearing shall be the procedure set  
11 forth in the last two sentences of subsection (c)(1).

12           “(3) If the Secretary, after due notice to the applicant  
13 in accordance with paragraph (2) and giving the applicant  
14 an opportunity for a hearing in accordance with such para-  
15 graph, finds, on the basis of information submitted to the  
16 Secretary as part of the application, on the basis of a  
17 preapproval inspection, or on the basis of any other infor-  
18 mation before the Secretary—

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

21           “(B) that the methods used in, and the facilities  
22 and controls used for, the manufacture, processing,  
23 and packing of such animal feed are inadequate to  
24 preserve the identity, strength, quality, and purity of  
25 the new animal drug therein; or

1           “(C) that the facility manufactures animal feeds  
2           bearing or containing new animal drugs in a manner  
3           that does not accord with the specifications for manu-  
4           facture or labels animal feeds bearing or containing  
5           new animal drugs in a manner that does not accord  
6           with the conditions or indications of use that are pub-  
7           lished pursuant to subsection (i),  
8           the Secretary shall issue an order refusing to approve the  
9           application. If, after such notice and opportunity for hear-  
10          ing, the Secretary finds that subparagraphs (A) through (C)  
11          do not apply, the Secretary shall issue an order approving  
12          the application. An order under this subsection approving  
13          an application for a license to manufacture animal feeds  
14          bearing or containing new animal drugs shall permit a fa-  
15          cility to manufacture only those animal feeds bearing or  
16          containing new animal drugs for which there are in effect  
17          regulations pursuant to subsection (i) relating to the use  
18          of such drugs in or on such animal feed.

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

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

1           “(ii) that the applicant has made changes that  
2           would cause the application to contain any untrue  
3           statements of material fact or that would affect the  
4           safety or effectiveness of the animal feeds manufac-  
5           tured at the facility unless the applicant has supple-  
6           mented the application by filing with the Secretary  
7           adequate information respecting all such changes and  
8           unless there is in effect an approval of the supple-  
9           mental application.

10          If the Secretary (or in the Secretary’s absence the officer  
11          acting as the Secretary) finds that there is an imminent  
12          hazard to the health of humans or of the animals for which  
13          such animal feed is intended, the Secretary may suspend  
14          the license immediately, and give the applicant prompt no-  
15          tice of the action and afford the applicant the opportunity  
16          for an expedited hearing under this subsection; but the au-  
17          thority conferred by this sentence shall not be delegated.

18                 “(B) The Secretary may also, after due notice and op-  
19          portunity for hearing to the applicant, revoke a license to  
20          manufacture animal feed under this subsection if the Sec-  
21          retary finds—

22                 “(i) that the applicant has failed to establish a  
23          system for maintaining required records, or has re-  
24          peatedly or deliberately failed to maintain such  
25          records or to make required reports in accordance

1       with a regulation or order under paragraph (5)(A) of  
2       this subsection or section 504(a)(3)(A), or the appli-  
3       cant has refused to permit access to, or copying or  
4       verification of, such records as required by subpara-  
5       graph (B) of such paragraph or section 504(a)(3)(B);

6               “(ii) that on the basis of new information before  
7       the Secretary, evaluated together with the evidence be-  
8       fore the Secretary when such license was issued, the  
9       methods used in, or the facilities and controls used  
10      for, the manufacture, processing, packing, and hold-  
11      ing of such animal feed are inadequate to assure and  
12      preserve the identity, strength, quality, and purity of  
13      the new animal drug therein, and were not made ade-  
14      quate within a reasonable time after receipt of writ-  
15      ten notice from the Secretary, specifying the matter  
16      complained of;

17              “(iii) that on the basis of new information before  
18      the Secretary, evaluated together with the evidence be-  
19      fore the Secretary when such license was issued, the  
20      labeling of any animal feeds, based on a fair evalua-  
21      tion of all material facts, is false or misleading in  
22      any particular and was not corrected within a rea-  
23      sonable time after receipt of written notice from the  
24      Secretary specifying the matter complained of; or

1           “(iv) that on the basis of new information before  
2           the Secretary, evaluated together with the evidence be-  
3           fore the Secretary when such license was issued, the  
4           facility has manufactured, processed, packed, or held  
5           animal feed bearing or containing a new animal drug  
6           adulterated under section 501(a)(6) and the facility  
7           did not discontinue the manufacture, processing,  
8           packing, or holding of such animal feed within a rea-  
9           sonable time after receipt of written notice from the  
10          Secretary specifying the matter complained of.

11          “(C) The Secretary may also revoke a license to manu-  
12          facture animal feeds under this subsection if an applicant  
13          gives notice to the Secretary of intention to discontinue the  
14          manufacture of all animal feed covered under this sub-  
15          section and waives an opportunity for a hearing on the  
16          matter.

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

19          “(5) When a license to manufacture animal feeds bear-  
20          ing or containing new animal drugs has been issued—

21                 “(A) the applicant shall establish and maintain  
22                 such records, and make such reports to the Secretary,  
23                 or (at the option of the Secretary) to the appropriate  
24                 person or persons holding an approved application  
25                 filed under subsection (b), as the Secretary may by

1        *general regulation, or by order with respect to such*  
2        *application, prescribe on the basis of a finding that*  
3        *such records and reports are necessary in order to en-*  
4        *able the Secretary to determine, or facilitate a deter-*  
5        *mination, whether there is or may be ground for in-*  
6        *voaking subsection (e) or paragraph (4); and*

7                *“(B) every person required under this subsection*  
8        *to maintain records, and every person in charge or*  
9        *custody thereof, shall, upon request of an officer or*  
10        *employee designated by the Secretary, permit such of-*  
11        *ficer or employee at all reasonable times to have ac-*  
12        *cess to and copy and verify such records.*

13                *“(6) To the extent consistent with the public health,*  
14        *the Secretary may promulgate regulations for exempting*  
15        *from the operation of this subsection facilities that manu-*  
16        *facture, process, pack, or hold animal feeds bearing or con-*  
17        *taining new animal drugs.”.*

18                *(c) TRANSITIONAL PROVISION.—A person engaged in*  
19        *the manufacture of animal feeds bearing or containing new*  
20        *animal drugs who holds at least one approved medicated*  
21        *feed application for an animal feed bearing or containing*  
22        *new animal drugs, the manufacture of which was not other-*  
23        *wise exempt from the requirement for an approved medi-*  
24        *cated feed application on the date of the enactment of this*  
25        *Act, shall be deemed to hold a license for the manufacturing*

1 *site identified in the approved medicated feed application.*  
2 *The revocation of license provisions of section 512(m)(4) of*  
3 *the Federal Food, Drug, and Cosmetic Act, as amended by*  
4 *this Act, shall apply to such licenses. Such license shall ex-*  
5 *pire within 18 months from the date of enactment of this*  
6 *Act unless the person submits to the Secretary a completed*  
7 *license application for the manufacturing site accompanied*  
8 *by a copy of an approved medicated feed application for*  
9 *such site, which license application shall be deemed to be*  
10 *approved upon receipt by the Secretary.*