Public Law 90-398

July 11, 1968
[S. 2837]

AN ACT

To authorize the Secretary of Agriculture to establish the Cradle of Forestry in America in the Pisgah National Forest in North Carolina, and for other purposes.

Cradle of Forestry in America, Pisgah National Forest, N.C.
Establishment.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That, in order to preserve, develop, and make available to this and future generations the birthplace of forestry and forestry education in America and to promote, demonstrate, and stimulate interest in and knowledge of the management of forest lands under principles of multiple use and sustained yield and the development and progress of management of forest lands in America, the Secretary of Agriculture is hereby authorized to establish the Cradle of Forestry in America in the Pisgah National Forest, North Carolina. As soon as possible after this Act takes effect, the Secretary of Agriculture shall publish notice of the designation thereof in the Federal Register together with a map showing the boundaries which shall be those shown on the map entitled "Cradle of Forestry in America" dated April 12, 1967, which shall be on file and available for public inspection in the office of the Chief, Forest Service, Department of Agriculture.

Publication in Federal Register.

SEC. 2. The area designated as the Cradle of Forestry in America shall be administered, protected, and developed within and as a part of the Pisgah National Forest by the Secretary of Agriculture in accordance with the laws, rules, and regulations applicable to national forests in such manner as in his judgment will best provide for the purposes of this Act and for such management, utilization, and disposal of the natural resources as in his judgment will promote or is compatible with and does not significantly impair the purposes for which the Cradle of Forestry in America is established.

SEC. 3. The Secretary of Agriculture is hereby authorized to cooperate with and receive the cooperation of public and private agencies and organizations and individuals in the development, administration, and operation of the Cradle of Forestry in America. The Secretary of Agriculture is authorized to accept contributions and gifts to be used to further the purposes of this Act.

Approved July 11, 1968.

Public Law 90-399

July 13, 1968
[H. R. 3639]

AN ACT

To protect the public health by amending the Federal Food, Drug, and Cosmetic Act to consolidate certain provisions assuring the safety and effectiveness of new animal drugs, and for other purposes.

Animal Drug Amendments of 1968.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That this Act may be cited as the "Animal Drug Amendments of 1968."

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NEW ANIMAL DRUGS

SEC. 101. (a) Section 501(a) of the Federal Food, Drug, and Cosmetic Act, as amended, is amended by inserting before the period at the end thereof a semicolon and the following: "or (5) if it is a new animal drug which is unsafe within the meaning of section 512; or (6) if it is an animal feed bearing or containing a new animal drug, and such animal feed is unsafe within the meaning of section 512". 52 Stat. 1049. 21 USC 351. *Infra.*

(b) Chapter V of such Act is amended by adding at the end thereof the following: 79 Stat. 227. 21 USC 351-360a.

"NEW ANIMAL DRUGS

"SEC. 512. (a)(1) A new animal drug shall, with respect to any particular use or intended use of such drug, be deemed unsafe for the purposes of section 501(a)(5) and section 402(a)(2)(D) unless— *Supra.* *Post*, p. 352.

"(A) there is in effect an approval of an application filed pursuant to subsection (b) of this section with respect to such use or intended use of such drug,

"(B) such drug, its labeling, and such use conform to such approved application, and

"(C) in the case of a new animal drug subject to subsection (n) of this section and not exempted therefrom by regulations it is from a batch with respect to which a certificate or release issued pursuant to subsection (n) is in effect with respect to such drug.

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

"(i) is the holder of an approved application under subsection (m) of this section; or

"(ii) will, if the consignee is not a user of the drug, ship such drug only to a holder of an approved application under subsection (m) of this section.

"(2) An animal feed bearing or containing a new animal drug shall, with respect to any particular use or intended use of such animal feed, be deemed unsafe for the purposes of section 501(a)(6) unless— *Supra.*

"(A) there is in effect an approval of an application filed pursuant to subsection (b) of this section with respect to such drug, as used in such animal feed,

"(B) there is in effect an approval of an application pursuant to subsection (m)(1) of this section with respect to such animal feed, and

"(C) such animal feed, its labeling, and such use conform to the conditions and indications of use published pursuant to subsection (i) of this section and to the application with respect thereto approved under subsection (m) of this section.

"(3) A new animal drug or an animal feed bearing or containing a new animal drug shall not be deemed unsafe for the purposes of section 501(a) (5) or (6) if such article is for investigational use and conforms to the terms of an exemption in effect with respect thereto under section 512(j).

Ante, p. 343.

"(b) Any person may file with the Secretary an application with respect to any intended use or uses of a new animal drug. Such person shall submit to the Secretary as a part of the application (1) full reports of investigations which have been made to show whether or not such drug is safe and effective for use; (2) a full list of the articles used as components of such drug; (3) a full statement of the composition of such drug; (4) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug; (5) such samples of such drug and of the articles used as components thereof, of any animal feed for use in or on which such drug is intended, and of the edible portions or products (before or after slaughter) of animals to which such drug (directly or in or on animal feed) is intended to be administered, as the Secretary may require; (6) specimens of the labeling proposed to be used for such drug, or in case such drug is intended for use in animal feed, proposed labeling appropriate for such use, and specimens of the labeling for the drug to be manufactured, packed, or distributed by the applicant; (7) a description of practicable methods for determining the quantity, if any, of such drug in or on food, and any substance formed in or on food, because of its use; and (8) the proposed tolerance or withdrawal period or other use restrictions for such drug if any tolerance or withdrawal period or other use restrictions are required in order to assure that the proposed use of such drug will be safe.

Opportunity for hearing.

"(c) Within one hundred and eighty days after the filing of an application pursuant to subsection (b), or such additional period as may be agreed upon by the Secretary and the applicant, the Secretary shall either (1) issue an order approving the application if he then finds that none of the grounds for denying approval specified in subsection (d) applies, or (2) give the applicant notice of an opportunity for a hearing before the Secretary under subsection (d) on the question whether such application is approvable. If the applicant elects to accept the opportunity for a hearing by written request within thirty days after such notice, such hearing shall commence not more than ninety days after the expiration of such thirty days unless the Secretary and the applicant otherwise agree. Any such hearing shall thereafter be conducted on an expedited basis and the Secretary's order thereon shall be issued within ninety days after the date fixed by the Secretary for filing final briefs.

"(d)(1) If the Secretary finds, after due notice to the applicant in accordance with subsection (c) and giving him an opportunity for a hearing, in accordance with said subsection, that—

"(A) the investigations, reports of which are required to be submitted to the Secretary pursuant to subsection (b), do not include adequate tests by all methods reasonably applicable to show whether or not such drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof;

"(B) the results of such tests show that such drug is unsafe for use under such conditions or do not show that such drug is safe for use under such conditions;

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

"(D) upon the basis of the information submitted to him as

part of the application, or upon the basis of any other information before him with respect to such drug, he has insufficient information to determine whether such drug is safe for use under such conditions;

"(E) evaluated on the basis of the information submitted to him as part of the application and any other information before him with respect to such drug, there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof;

"(F) upon the basis of the information submitted to him as part of the application or any other information before him with respect to such drug, the tolerance limitation proposed, if any, exceeds that reasonably required to accomplish the physical or other technical effect for which the drug is intended;

"(G) based on a fair evaluation of all material facts, such labeling is false or misleading in any particular; or

"(H) such drug induces cancer when ingested by man or animal or, after tests which are appropriate for the evaluation of the safety of such drug, induces cancer in man or animal, except that the foregoing provisions of this subparagraph shall not apply with respect to such drug if the Secretary finds that, under the conditions of use specified in proposed labeling and reasonably certain to be followed in practice (i) such drug will not adversely affect the animals for which it is intended, and (ii) no residue of such drug will be found (by methods of examination prescribed or approved by the Secretary by regulations, which regulations shall not be subject to subsections (c), (d), and (h)), in any edible portion of such animals after slaughter or in any food yielded by or derived from the living animals;

he shall issue an order refusing to approve the application. If, after such notice and opportunity for hearing, the Secretary finds that subparagraphs (A) through (H) do not apply, he shall issue an order approving the application.

"(2) In determining whether such drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof, the Secretary shall consider, among other relevant factors, (A) the probable consumption of such drug and of any substance formed in or on food because of the use of such drug, (B) the cumulative effect on man or animal of such drug, taking into account any chemically or pharmacologically related substance, (C) safety factors which in the opinion of experts, qualified by scientific training and experience to evaluate the safety of such drugs, are appropriate for the use of animal experimentation data, and (D) whether the conditions of use prescribed, recommended, or suggested in the proposed labeling are reasonably certain to be followed in practice. Any order issued under this subsection refusing to approve an application shall state the findings upon which it is based.

"Substantial evidence."

"(3) As used in this subsection and subsection (e), the term 'substantial evidence' means evidence consisting of adequate and well-controlled investigations, including field investigation, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and reasonably be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof.

"(e)(1) The Secretary shall, after due notice and opportunity for hearing to the applicant, issue an order withdrawing approval of an

application filed pursuant to subsection (b) with respect to any new animal drug if the Secretary finds—

"(A) that experience or scientific data show that such drug is unsafe for use under the conditions of use upon the basis of which the application was approved;

"(B) that new evidence not contained in such application or not available to the Secretary until after such application was approved, or tests by new methods, or tests by methods not deemed reasonably applicable when such application was approved, evaluated together with the evidence available to the Secretary when the application was approved, shows that such drug is not shown to be safe for use under the conditions of use upon the basis of which the application was approved or that subparagraph (H) of paragraph (1) of subsection (d) applies to such drug;

"(C) on the basis of new information before him with respect to such drug, evaluated together with the evidence available to him when the application was approved, that there is a lack of substantial evidence that such drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling thereof;

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

"(E) that the applicant has made any changes from the standpoint of safety or effectiveness beyond the variations provided for in the application unless he has supplemented the application by filing with the Secretary adequate information respecting all such changes and unless there is in effect an approval of the supplemental application. The supplemental application shall be treated in the same manner as the original application.

If the Secretary (or in his absence the officer acting as Secretary) finds that there is an imminent hazard to the health of man or of the animals for which such drug is intended, he may suspend the approval of such application immediately, and give the applicant prompt notice of his action and afford the applicant the opportunity for an expedited hearing under this subsection; but the authority conferred by this sentence to suspend the approval of an application shall not be delegated.

"(2) The Secretary may also, after due notice and opportunity for hearing to the applicant, issue an order withdrawing the approval of an application with respect to any new animal drug under this section if the Secretary finds—

"(A) that the applicant has failed to establish a system for maintaining required records, or has repeatedly or deliberately failed to maintain such records or to make required reports in accordance with a regulation or order under subsection (l), or the applicant has refused to permit access to, or copying or verification of, such records as required by paragraph (2) of such subsection;

"(B) that on the basis of new information before him, evaluated together with the evidence before him when the application was approved, the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of such drug are inadequate to assure and preserve its identity, strength, quality, and purity and were not made adequate within a reasonable time after receipt of written notice from the Secretary specifying the matter complained of; or

"(C) that on the basis of new information before him, evaluated together with the evidence before him when the application was approved, the labeling of such drug, based on a fair evaluation of all material facts, is false or misleading in any particular

and was not corrected within a reasonable time after receipt of written notice from the Secretary specifying the matter complained of.

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

"(f) Whenever the Secretary finds that the facts so require, he shall revoke any previous order under subsection (d), (e), or (m) refusing, withdrawing, or suspending approval of an application and shall approve such application or reinstate such approval, as may be appropriate.

"(g) Orders of the Secretary issued under this section (other than orders issuing, amending, or repealing regulations) shall be served (1) in person by any officer or employee of the department designated by the Secretary or (2) by mailing the order by registered mail or by certified mail addressed to the applicant or respondent at his last known address in the records of the Secretary.

"(h) An appeal may be taken by the applicant from an order of the Secretary refusing or withdrawing approval of an application filed under subsection (b) or (m) of this section. The provisions of subsection (h) of section 505 of this Act shall govern any such appeal. 52 Stat. 1052; 76 Stat. 784, 785. 21 USC 355.

"(i) When a new animal drug application filed pursuant to subsection (b) is approved, the Secretary shall by notice, which upon publication shall be effective as a regulation, publish in the Federal Register the name and address of the applicant and the conditions and indications of use of the new animal drug covered by such application, including any tolerance and withdrawal period or other use restrictions and, if such new animal drug is intended for use in animal feed, appropriate purposes and conditions of use (including special labeling requirements) applicable to any animal feed for use in which such drug is approved, and such other information, upon the basis of which such application was approved, as the Secretary deems necessary to assure the safe and effective use of such drug. Upon withdrawal of approval of such new animal drug application or upon its suspension, the Secretary shall forthwith revoke or suspend, as the case may be, the regulation published pursuant to this subsection (i) insofar as it is based on the approval of such application. Publication in Federal Register.

"(j) To the extent consistent with the public health, the Secretary shall promulgate regulations for exempting from the operation of this section new animal drugs, and animal feeds bearing or containing new animal drugs, intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety and effectiveness of animal drugs. Such regulations may, in the discretion of the Secretary, among other conditions relating to the protection of the public health, provide for conditioning such exemption upon the establishment and maintenance of such records, and the making of such reports to the Secretary, by the manufacturer or the sponsor of the investigation of such article, of data (including but not limited to analytical reports by investigators) obtained as a result of such investigational use of such article, as the Secretary finds will enable him to evaluate the safety and effectiveness of such article in the event of the filing of an application pursuant to this section. Such regulations, among other things, shall set forth the conditions (if any) upon which animals treated with such articles, and any products of such animals (before or after slaughter), may be marketed for food use. Exemptions.

"(k) While approval of an application for a new animal drug is effective, a food shall not, by reason of bearing or containing such drug or any substance formed in or on the food because of its use in accordance with such application (including the conditions and indi-

52 Stat. 1046.
21 USC 342.
Recordkeeping.

cations of use prescribed pursuant to subsection (i)), be considered adulterated within the meaning of clause (1) of section 402(a).

"(l) (1) In the case of any new animal drug for which an approval of an application filed pursuant to subsection (b) is in effect, the applicant shall establish and maintain such records, and make such reports to the Secretary, of data relating to experience and other data or information, received or otherwise obtained by such applicant with respect to such drug, or with respect to animal feeds bearing or containing such drug, as the Secretary may by general regulation, or by order with respect to such application, prescribe on the basis of a finding that such records and reports are necessary in order to enable the Secretary to determine, or facilitate a determination, whether there is or may be ground for invoking subsection (e) or subsection (m) (4) of this section. Such regulation or order shall provide, where the Secretary deems it to be appropriate, for the examination, upon request, by the persons to whom such regulation or order is applicable, of similar information received or otherwise obtained by the Secretary.

"(2) Every person required under this subsection to maintain records, and every person in charge or custody thereof, shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to and copy and verify such records.

"(m) (1) Any person may file with the Secretary an application with respect to any intended use or uses of an animal feed bearing or containing a new animal drug. Such person shall submit to the Secretary as part of the application (A) a full statement of the composition of such animal feed, (B) an identification of the regulation or regulations (relating to the new animal drug or drugs to be used in such feed), published pursuant to subsection (i), on which he relies as a basis for approval of his application with respect to the use of such drug in such feed, (C) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such animal feed, (D) specimens of the labeling proposed to be used for such animal feed, and (E) if so requested by the Secretary, samples of such animal feed or components thereof.

"(2) Within ninety days after the filing of an application pursuant to subsection (m) (1), or such additional period as may be agreed upon by the Secretary and the applicant, the Secretary shall either (A) issue an order approving the application if he then finds that none of the grounds for denying approval specified in paragraph (3) applies, or (B) give the applicant notice of an opportunity for a hearing before the Secretary under paragraph (3) on the question whether such application is approvable. The procedure governing such a hearing shall be the procedure set forth in the last two sentences of subsection (c).

"(3) If the Secretary, after due notice to the applicant in accordance with paragraph (2) and giving him an opportunity for a hearing in accordance with such paragraph, finds, on the basis of information submitted to him as part of the application or on the basis of any other information before him—

"(A) that there is not in effect a regulation under subsection (i) (identified in such application) on the basis of which such application may be approved;

"(B) that such animal feed (including the proposed use of any new animal drug therein or thereon) does not conform to an applicable regulation published pursuant to subsection (i) referred to in the application, or that the purposes and conditions or indications of use prescribed, recommended, or suggested in the labeling of such feed do not conform to the applicable pur-

poses and conditions or indications of use (including warnings) published pursuant to subsection (i) or such labeling omits or fails to conform to other applicable information published pursuant to subsection (i);

"(C) that the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such animal feed are inadequate to preserve the identity, strength, quality, and purity of the new animal drug therein; or

"(D) that, based on a fair evaluation of all material facts, such labeling is false or misleading in any particular;

he shall issue an order refusing to approve the application. If, after such notice and opportunity for hearing, the Secretary finds that subparagraphs (A) through (D) do not apply, he shall issue an order approving the application. An order under this subsection approving an application with respect to an animal feed bearing or containing a new animal drug shall be effective only while there is in effect a regulation pursuant to subsection (i), on the basis of which such application (or a supplement thereto) was approved, relating to the use of such drug in or on such feed.

"(4) (A) The Secretary shall, after due notice and opportunity for hearing to the applicant, issue an order withdrawing approval of an application with respect to any animal feed under this subsection if the Secretary finds—

"(i) that the application contains any untrue statement of a material fact; or

"(ii) that the applicant has made any changes from the standpoint of safety or effectiveness beyond the variations provided for in the application unless he has supplemented the application by filing with the Secretary adequate information respecting all such changes and unless there is in effect an approval of the supplemental application. The supplemental application shall be treated in the same manner as the original application.

If the Secretary (or in his absence the officer acting as Secretary) finds that there is an imminent hazard to the health of man or of the animals for which such animal feed is intended, he may suspend the approval of such application immediately, and give the applicant prompt notice of his action and afford the applicant the opportunity for an expedited hearing under this subsection; but the authority conferred by this sentence shall not be delegated.

"(B) The Secretary may also, after due notice and opportunity for hearing to the applicant, issue an order withdrawing the approval of an application with respect to any animal feed under this subsection if the Secretary finds—

"(i) that the applicant has failed to establish a system for maintaining required records, or has repeatedly or deliberately failed to maintain such records or to make required reports in accordance with a regulation or order under paragraph (5) (A) of this subsection, or the applicant has refused to permit access to, or copying or verification of, such records as required by subparagraph (B) of such paragraph;

"(ii) that on the basis of new information before him, evaluated together with the evidence before him when such application was approved, the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of such animal feed are inadequate to assure and preserve the identity, strength, quality, and purity of the new animal drug therein, and were not made adequate within a reasonable time after receipt of written notice from the Secretary, specifying the matter complained of; or

"(iii) that on the basis of new information before him, evaluated together with the evidence before him when the application was approved, the labeling of such animal feed, based on a fair evaluation of all material facts, is false or misleading in any particular and was not corrected within a reasonable time after receipt of written notice from the Secretary specifying the matter complained of.

"(C) Any order under paragraph (4) of this subsection shall state the findings upon which it is based.

Recordkeeping.

"(5) In the case of any animal feed for which an approval of an application filed pursuant to this subsection is in effect—

"(A) the applicant shall establish and maintain such records, and make such reports to the Secretary, or (at the option of the Secretary) to the appropriate person or persons holding an approved application filed under subsection (b), as the Secretary may by general regulation, or by order with respect to such application, prescribe on the basis of a finding that such records and reports are necessary in order to enable the Secretary to determine, or facilitate a determination, whether there is or may be ground for invoking subsection (e) or paragraph (4) of this subsection.

"(B) every person required under this subsection to maintain records, and every person in charge or custody thereof, shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to and copy and verify such records.

Certification.

"(n)(1) The Secretary, pursuant to regulations promulgated by him, shall provide for the certification of batches of a new animal drug composed wholly or partly of any kind of penicillin, streptomycin, chlortetracycline, chloramphenicol, or bacitracin, or any derivative thereof. A batch of any such drug shall be certified if an approval of an application filed pursuant to subsection (b) is effective with respect to such drug and such drug has the characteristics of identity and such batch has the characteristics of strength, quality, and purity upon the basis of which the application was approved, but shall not otherwise be certified. Prior to the effective date of such regulations the Secretary, in lieu of certification, shall issue a release for any batch which, in his judgment, may be released without risk as to the safety and efficacy of its use. Such release shall prescribe the date of its expiration and other conditions under which it shall cease to be effective as to such batch and as to portions thereof.

"(2) Regulations providing for such certifications shall contain such provisions as are necessary to carry out the purposes of this subsection, including provisions prescribing—

"(A) tests and methods of assay to determine compliance with applicable standards of identity and of strength, quality, and purity;

"(B) effective periods for certificates, and other conditions under which they shall cease to be effective as to certified batches and as to portions thereof;

"(C) administration and procedure; and

"(D) such fees, specified in such regulations, as are necessary to provide, equip, and maintain an adequate certification service.

Such regulations shall prescribe only such tests and methods of assay as will provide for certification or rejection within the shortest time consistent with the purposes of this subsection.

"(3) Whenever, in the judgment of the Secretary, the requirements of this subsection with respect to any drug or class of drugs are not necessary to insure that such drug conforms to the standards of identity, strength, quality, and purity applicable thereto under paragraph (1) of this subsection, the Secretary shall promulgate regulations exempting such drug or class of drugs from such requirements. The provisions of subsection (c) of section 507 of this Act (other than the first sentence thereof) shall apply under this paragraph. 59 Stat. 464; 76 Stat. 786. 21 USC 357.

"(4) The Secretary shall promulgate regulations exempting from any requirement of this subsection— Exemptions.

"(A) drugs which are to be stored, processed, labeled, or repacked at establishments other than those where manufactured, on condition that such drugs comply with all such requirements upon removal from such establishments; and

"(B) drugs which conform to applicable standards of identity, strength, quality, and purity prescribed pursuant to this subsection and are intended for use in manufacturing other drugs.

"(5) On petition of any interested person for the issuance, amendment, or repeal of any regulation contemplated by this subsection, the procedure shall be in accordance with subsection (f) of section 507 of this Act.

"(6) Where any drug is subject to this subsection and not exempted therefrom by regulations, the compliance of such drug with sections 501(b) and 502(g) shall be determined by the application of the standards of strength, quality, and purity applicable under paragraph (1) of this subsection, the tests and methods of assay applicable under provisions of regulations referred to in paragraph (2)(A) of this subsection, and the requirements of packaging and labeling on the basis of which the application with respect to such drug filed under subsection (b) of this section was approved." 52 Stat. 1049. 21 USC 351, 352.

DEFINITIONS

SEC. 102. Section 201 of the Federal Food, Drug, and Cosmetic Act, as amended, is amended by—

(a) inserting "(except a new animal drug or an animal feed bearing or containing a new animal drug)" after "Any drug" in subparagraph (1) of paragraph (p); 52 Stat. 1041. 21 USC 321.

(b) inserting "(except a new animal drug or an animal feed bearing or containing a new animal drug)" after "Any drug" in subparagraph (2) of paragraph (p);

(c) striking out the period at the end of subparagraph (4) of paragraph (s) and inserting in lieu thereof "; or", and by adding a new subparagraph (5) to read as follows: "(5) a new animal drug."; 72 Stat. 1784; 74 Stat. 397.

(d) inserting ", 512," after "409" in paragraph (u); and

(e) adding at the end of such section the following new paragraphs: 79 Stat. 227.

"(w) The term 'new animal drug' means any drug intended for use for animals other than man, including any drug intended for use in animal feed but not including such animal feed,— "New animal drug."

"(1) the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of animal drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof;

Exception.

except that such a drug not so recognized shall not be deemed to be a 'new animal drug' if at any time prior to June 25, 1938, it was subject to the Food and Drug Act of June 30, 1906, as amended, and if at such time its labeling contained the same representations concerning the conditions of its use; or

34 Stat. 768; 52 Stat. 1059. 21 USC 1-15 notes.

"(2) the composition of which is such that such drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions; or

"(3) which drug is composed wholly or partly of any kind of penicillin, streptomycin, chlortetracycline, chloramphenicol, or bacitracin, or any derivative thereof, except when there is in effect a published order of the Secretary declaring such drug not to be a new animal drug on the grounds that (A) the requirement of certification of batches of such drug, as provided for in section 512(n), is not necessary to insure that the objectives specified in paragraph (3) thereof are achieved and (B) that neither subparagraph (1) nor (2) of this paragraph (w) applies to such drug.

Ante, p. 350.

"Animal feed."

"(x) The term 'animal feed', as used in paragraph (w) of this section, in section 512, and in provisions of this Act referring to such paragraph or section, means an article which is intended for use for food for animals other than man and which is intended for use as a substantial source of nutrients in the diet of the animal, and is not limited to a mixture intended to be the sole ration of the animal."

Ante, pp. 351, 343.

PROHIBITED ACTS AND PENALTIES

SEC. 103. Section 301 of the Federal Food, Drug, and Cosmetic Act, as amended, is amended by—

(1) striking out "or" before "507," and inserting ", or 512 (j), (l), or (m)" after "507 (d) or (g)" in paragraph (e), and

76 Stat. 784, 788. 21 USC 331.

(2) adding "512," after "507," in paragraph (j).

52 Stat. 1042; 61 Stat. 11.

ANIMAL DRUGS IN FEEDS AND RESIDUES THEREOF IN OTHER FOOD

SEC. 104. Section 402 of the Federal Food, Drug, and Cosmetic Act, as amended, is amended by—

(1) striking out the word "or" before "(iii)" in clause (A) of subparagraph (2) of paragraph (a) and inserting "; or (iv) a new animal drug" after the words "color additive" therein; and

72 Stat. 1784; 74 Stat. 397. 21 USC 342.

(2) adding before the semicolon following "commodity" at the end of the proviso to clause (C) of subparagraph (2) of paragraph (a) the following: "; or (D) if it is, or it bears or contains, a new animal drug (or conversion product thereof) which is unsafe within the meaning of section 512".

ANTIBIOTIC DRUGS FOR ANIMALS

SEC. 105. (a) Section 502 of the Federal Food, Drug, and Cosmetic Act, as amended, is amended by inserting "(except a drug for use in animals other than man)" after "represented as a drug" in paragraph (l).

59 Stat. 463. 21 USC 352.

(b) Section 507 of such Act is amended by inserting "(except drugs for use in animals other than man)" after "drugs" in the first sentence of subsection (a).

21 USC 357.

ANIMAL DRUGS FOR EXPORT

SEC. 106. Section 801(d) of the Federal Food, Drug, and Cosmetic Act, as amended, is amended by adding at the end thereof the following: "Nothing in this subsection shall authorize the exportation of any new animal drug, or an animal feed bearing or containing a new animal drug, which is unsafe within the meaning of section 512 of this Act." 52 Stat. 1058. 21 USC 381. *Ante*, p. 343.

AMENDMENT WITH RESPECT TO VIRUS, SERUM, TOXIN, AND ANALOGOUS PRODUCTS ACTS

SEC. 107. Section 902(c) of the Federal Food, Drug, and Cosmetic Act is amended by striking out "the virus, serum, and toxin Act of July 1, 1902 (U.S.C., 1934 ed., title 42, chap. 4);" and inserting in lieu thereof the following: "section 351 of Public Health Service Act (relating to viruses, serums, toxins, and analogous products applicable to man); the virus, serum, toxin, and analogous products provisions, applicable to domestic animals, of the Act of Congress approved March 4, 1913 (37 Stat. 832–833);". 21 USC 392. 58 Stat. 702. 42 USC 262. 21 USC 151-158.

EFFECTIVE DATE AND TRANSITIONAL PROVISIONS

SEC. 108. (a) Except as otherwise provided in this section, the amendments made by the foregoing sections shall take effect on the first day of the thirteenth calendar month which begins after the date of enactment of this Act.

(b)(1) As used in this subsection, the term "effective date" means the effective date specified in subsection (a) of this section; the term "basic Act" means the Federal Food, Drug, and Cosmetic Act; and other terms used both in this section and the basic Act shall have the same meaning as they have, or had, at the time referred to in the context, under the basic Act. Definitions.

(2) Any approval, prior to the effective date, of a new animal drug or of an animal feed bearing or containing a new animal drug, whether granted by approval of a new-drug application, master file, antibiotic regulation, or food additive regulation, shall continue in effect, and shall be subject to change in accordance with the provisions of the basic Act as amended by this Act.

(3) In the case of any drug (other than a drug subject to section 512(n) of the basic Act as amended by this Act) intended for use in animals other than man which, on October 9, 1962, (A) was commercially used or sold in the United States, (B) was not a new drug as defined by section 201(p) of the basic Act as then in force, and (C) was not covered by an effective application under section 505 of that Act, the words "effectiveness" and "effective" contained in section 201(w) as added by this Act to the basic Act shall not apply to such drug when intended solely for use under conditions prescribed, recommended, or suggested in labeling with respect to such drug on that day. *Ante*, p. 350. 52 Stat. 1041. 21 USC 321. 76 Stat. 781-785. 21 USC 355. *Ante*, p. 351.

(4) Regulations providing for fees (and advance deposits to cover fees) which on the day preceding the effective date applicable under subsection (a) of this section were in effect pursuant to section 507 of the basic Act shall, except as the Secretary may otherwise prescribe, be deemed to apply also under section 512(n) of the basic Act, and appropriations of fees (and of advance deposits to cover fees) available for the purposes specified in such section 507 as in effect prior to the effective date shall also be available for the purposes specified in section 512(n), including preparatory work or proceedings prior to that date. 59 Stat. 463; 76 Stat. 785-788. 21 USC 357.

Approved July 13, 1968.