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89-36 ANIMAL DRUG AMENDMENTS OF 1965

GOVERNMENT

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HEARING
BEFORE THE
SUBCOMMITTEE ON PUBLIC HEALTH
AND WELFARE
OF THE
COMMITTEE ON
INTERSTATE AND FOREIGN COMMERCE
HOUSE OF REPRESENTATIVES
EIGHTY-NINTH CONGRESS

SECOND SESSION

ON

H.R. 7655, H.R. 7797, H.R. 7815, H.R. 8377,
H.R. 9542

BILLS TO PROTECT THE PUBLIC HEALTH BY AMENDING THE
FEDERAL FOOD, DRUG, AND COSMETIC ACT TO CONSOLIDATE
CERTAIN PROVISIONS ASSURING THE SAFETY AND EFFEC-
TIVENESS OF NEW ANIMAL DRUGS, AND FOR OTHER PURPOSES

JUNE 13, 1966

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ANIMAL DRUG AMENDMENTS OF 1965

MONDAY, JUNE 13, 1966

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON PUBLIC HEALTH AND WELFARE
OF THE COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE,
Washington, D.C.

The subcommittee met at 10 a.m., pursuant to call, in room 2123, Rayburn House Office Building, Hon. John Jarman (chairman of the subcommittee) presiding.

Mr. JARMAN. The subcommittee will please be in order.

The hearings today are on H.R. 7655, introduced by our colleague on the committee, Mr. O'Brien, and four identical bills: H.R. 7815 by our colleague on the committee, Mr. Rogers of Florida; H.R. 9542 by our colleague on the committee, Mr. Nelsen; H.R. 7797 by Mr. Hull; and H.R. 8377 by Mr. Watts.

Under existing law, the manufacturer of an animal feed which contains a drug is treated as a new drug manufacturer, and is required to comply with section 505 of the Food and Drug Act which relates to new drugs, and section 409 of the act which relates to food additives.

In addition, if the feed contains an antibiotic, the manufacturer must comply with the provisions of section 507 of the Food and Drug Act.

These provisions of law were initially designed from the point of view of their applicability to drugs, antibiotics, and food additives primarily for use by humans.

The purpose of these bills is to consolidate into one place in the law all of the current provisions relating to drugs for administration to animals, both directly and in their feed or water.

There have been a number of recent developments in the administration of the Food and Drug Act in this area, including the establishment of a separate bureau to deal with this area under Dr. Clarkson. It is hoped that this legislation will assist the Food and Drug Administration in some simplification of procedures so as to enable that agency to act as promptly.

At this point in the record there will be included the text of H.R. 7655 and the agency reports thereon.

(The bill, H.R. 7655, and agency reports thereon, follow:)

[H.R. 7655, 89th Cong., 1st sess.]

A BILL 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

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 1965".

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 511 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 511".

(b) Chapter V of such Act is amended by adding at the end thereof the following:

"NEW ANIMAL DRUGS

"SEC. 511. (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—

"(A) There is in effect an approval of an application filed pursuant to subsection (b) of this section with respect to such drug by the manufacturer, packer, or distributor of such drug or of any of its drug components, or the manufacturer, packer, or distributor of the animal feed bearing or containing 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.

"(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—

"(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 filed by its manufacturer, packer, or distributor 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 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 511(j).

"(b) Any person specified in subsection (a) (1) 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, or in the case of such a drug which consists of two or more drug components and which is intended for use in animal feed, a description of the methods, facilities, and controls used in the preparation of each new drug component of such drug; (5) such samples of such drug and of the articles used as components thereof 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 for such drug if any tolerance or withdrawal period is required in order to assure that the proposed use of such drug will be safe.

"(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 and each new drug component 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 subsection (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 hereinbefore set forth, (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 generally recognized as 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.

"(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 responsibly 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; or

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

"(E) that the applicant has made any significant changes from the standpoint of safety or effectiveness beyond the variations provided for in the application (unless the article is no longer a new animal drug) 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 section; 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 (1), 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.

"(i) When a new animal drug application filed pursuant to subsection (b) is approved, the Secretary shall publish in the Federal Register the name and address of the applicant and the indications for use of the new animal drug covered by such application, including any tolerance and withdrawal period, 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.

"(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.

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

"(1) (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 specified in subsection (a) (2) 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) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such animal feed, (C) specimens of the labeling proposed to be used for such animal feed, and (D) 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 finds, after due notice to the applicant in accordance with paragraph (2) and giving him an opportunity for a hearing in accordance with said subsection, that—

"(A) upon the basis of information submitted to him as part of the application, or upon the basis of any other information before him with respect to such animal feed, the purposes and conditions of use prescribed, recommended, or suggested in the labeling of such animal feed do not conform to the applicable purposes and conditions 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);

"(B) 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

"(C) 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 (C) do not apply, he shall issue an order approving the application.

"(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 one or more of the grounds set forth in subsection (e) requires the withdrawal of the approval of the application filed pursuant to subsection (b), on the basis of which approval the approval of such application filed pursuant to paragraph (1) was granted;

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

"(iii) that the applicant has made any significant changes from the standpoint of safety or effectiveness beyond the variations provided for in the application (unless the animal feed no longer bears or contains a new animal drug) 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.

"(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.

"(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, except for any such drug intended for use in animal feed. 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 period 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.

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

"(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) The procedure for the issuance, amendment, or repeal of any regulation contemplated by this subsection 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."

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);

(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,";

(d) inserting ", 511," after "409" in paragraph (u); and

(e) adding at the end of such section the following new paragraphs:

"(v) 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—

"(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; 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

"(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.

"(w) The term 'animal feed', as used in paragraph (v) of this section, in section 511, 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."

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 511 (j), (l), or (m)" after "507 (d) or (g)" in paragraph (e), and

(2) adding "511," after "507," in paragraph (j).

ANIMAL DRUGS IN FEEDS

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 (a) and inserting "; or (iv) a new animal drug" after the words "color additive" therein; and

(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 which is unsafe within the meaning of section 511".

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 subsection (1).

(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).

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 511 of this Act."

EFFECTIVE DATE AND TRANSITIONAL PROVISIONS

SEC. 107. (a) Except as otherwise provided in this section, the amendments made by the foregoing sections shall take effect on the first day of the seventh 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 date specified in subsection (a) of this section; and the term "basic Act" means the Federal Food, Drug, and Cosmetic Act.

(2) An application filed, or considered under regulations to have been filed, pursuant to section 505(b) of the basic Act which, on the day immediately preceding the effective date, was, or was deemed to be, an application "approved" under section 505 of that Act, or a new drug master file considered approvable except for final printed labeling under section 505 of that Act, shall as of the effective date, if such application for master file covered a new animal drug, or an animal feed bearing or containing a new animal drug, be deemed, upon notification to the Secretary by the holder of such application for master file (which notification may be filed before the effective date) to be an application "approved" with respect to such drug or animal feed by the Secretary under the applicable provisions of section 511 of the basic Act as amended by this Act, but section 511(i) shall not apply to such drug or animal feed except as provided in paragraph (3) of this subsection.

(3) (A) If, on the day immediately preceding the effective date, a published regulation then in force under section 409 of the basic Act set forth the conditions of use of a food additive and if, with respect to such use, such substance is a new animal drug or an animal feed bearing or containing such a drug within the meaning of that Act as amended by this Act, the conditions of use specified in such regulation for such drug, or for such animal feed, including but not limited to any specified tolerance limitation or withdrawal period, shall, beginning with the effective date, be considered as conditions of use published under section 511(i) of that Act as added by this Act, but nothing in this subparagraph shall be construed to dispense with any requirement of that Act, as amended by this Act, for the filing and approval of an application under such section 511 with respect to such drug or animal feed unless by reason of other provisions of this section such an approval is deemed to be in effect.

(B) If, on the day immediately preceding the effective date, an application or master file covering a new animal drug, was an application approved, or deemed to be approved, under section 505 or 507 of the basic Act but such drug was then excluded from the term "food additive" by reason of clause (4) of section 201(s) of the basic Act, and if, as of the effective date, such application or master file is to be deemed, under other provisions of this section, an appli-

ication approved under section 511 as added to that Act by this Act, the Secretary shall, as soon as practicable, comply with the publication requirements of subsection (1) of such section 511 with respect to such drug in the same manner as though such application had been initially approved under such section.

(4) An approved initial request, including approved amendments thereto for certification of a drug pursuant to section 507 of the basic Act, which was covered by a regulation in effect on the date immediately preceding the effective date shall, if such application covers a new animal drug, be deemed, as of the effective date, to be an application "approved" by the Secretary under section 511 of the basic Act as amended by this Act, but section 511(i) shall not apply to such drug except as provided in paragraph (3) of this subsection.

(5) If, on the day immediately preceding the effective date, a new animal drug, or an animal feed bearing or containing such a drug, was, with respect to any particular use or intended use thereof, exempt from the requirement of batch certification under section 507 of the basic Act by virtue of a regulation then in effect pursuant to subsection (c) of that section, the initial request for such certification or exemption (with any subsequent amendments thereto) filed pursuant to section 507 shall, upon notice by the holder of such exemption to the Secretary, be deemed, as of the date of such notice, an application approved under section 511 of the basic Act as amended by this Act with respect to such use of such drug or animal feed. The Secretary shall, as soon as practicable, comply with the publication requirements of subsection (1) of such section 511 with respect to such drug in the same manner as though such application had been initially approved under such section.

(6) Any application or petition under section 409, 505 or 507 of the basic Act which is pending on the effective date shall be deemed, if it covers a new animal drug, or an animal feed bearing or containing a new animal drug, to be an application pending under the applicable provisions of section 511 of the basic Act as amended by this Act, and the filing date under such section 511 shall be deemed to be the date on which the petition or application was actually filed.

(7) In the case of any drug (other than a drug subject to section 511(m) 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 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(v) 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.

(8) (A) If a drug with respect to which, by virtue of paragraph (4) of this subsection, an approved initial request for batch certification pursuant to section 507 of the basic Act is deemed, with respect to any particular use of such drug, to be an application approved by the Secretary under section 511 of that Act and if, with respect to such use, such drug is also subject to subsection (n) of section 511 on the effective date, the standards of identity and of strength, quality, and purity applicable to such drug with respect to such use under regulations in force pursuant to section 507 on the day preceding the effective date shall be deemed to be the standards applicable thereto under section 511(n) beginning with the effective date, unless and until such standards are changed by approval of a supplemental application filed under section 511(b) or, pending such filing and approval, by amendment of such regulations by the Secretary, in which event such new standards shall apply.

(B) Subject to subparagraph (A) of this paragraph, regulations (including exempting regulations) under section 507 of the basic Act that, on the day preceding the effective date, were applicable to a drug with respect to any use with respect to which it is subject to section 511(n) on the effective date, shall, beginning with the latter date, apply (with any applicable subsequent amendments) to such drug with respect to such use as if issued under section 511(n), unless and until regulations specifically applicable thereto under section 511(n) are in effect except that references in such regulations to section 502(1) and to section 507 of the basic Act shall be deemed to refer to subparagraph (C) of subsection (a)(1), and to subsection (n), respectively, of section 511.

(C) Regulations providing for fees (and advance deposits to cover fees) which on the day preceding the effective date 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 511(n) of the basic Act, and appropriations of fees (and

advance deposits) 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 511(n), including preparatory work or proceedings prior to the effective date.

(9) Terms used in this section shall have the same meaning as they have when used in the basic Act, as amended by this Act.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
Washington, D.C., June 13, 1966.

HON. HARLEY O. STAGGERS,
Chairman, Committee on Interstate and Foreign Commerce,
House of Representatives, Washington, D.C.

DEAR MR. CHAIRMAN: This is in response to the request for a report on H.R. 7655, the proposed "Animal Drug Amendments of 1965" to the Federal Food, Drug, and Cosmetic Act.

The bill would (1) establish a separate category of "new animal drugs" (a term defined along the lines of the present "new-drug definition") but limited to drugs intended for use for animals; (2) exclude such drugs and medicated animal feed containing such drugs from the present new-drug requirements of the Act, from the food additive requirements of the Act with respect to food additives, and from the section (§ 507) of the Act requiring batch-by-batch certification of antibiotics, and would replace these three types of requirements with a new set of requirements for "new animal drugs" and medicated feeds containing the substantive equivalent of most of the above-mentioned provisions which the bill would supersede, including batch-by-batch certification for those veterinary antibiotics referred to in § 507 of the present Act except those intended for use in animal feed. (The bill also contains certain "transitional provisions" which are referred to below in this report.)

The bill is the outgrowth of H.R. 7247, 88th Congress, which we were constrained to oppose strongly in the form in which it was then introduced because it would have reduced, rather than advanced, the protection afforded the public under present law. Such protection is important not only with respect to the animals themselves to which drugs are administered, whether "straight" or in the form of medicated feed, but also to the ultimate consumer who eats the meat of animals and the products of living animals such as milk, eggs, butter, and cheese.

Since the hearings on the 88th Congress bill, staff of this Department have cooperated with Committee staff and representatives of the Animal Health Institute in an effort to overcome, if possible, the deficiencies from the public health standpoint which in our view were incorporated in the 88th Congress version.

The present bill, H.R. 7655, thus reflects considerable progress in the direction of achieving a bill which would accomplish the purpose of consolidating the requirements with respect to "new animal drugs" and feeds medicated with such drugs in one comprehensive section of the Act without impairing the protection to the public afforded by present law, although as pointed out below we believe that certain additional modifications are necessary to achieve that end.

To the extent that the bill is motivated by a desire for simplification and expedition of procedure, it may not assist measurably to that end because of the need for familiarizing staff and the industry and other interested segments of the public with the new provisions. Transition from the old to the new might, for a period, deter the processes of expedition and simplification of procedure in the animal drug area in which the Food and Drug Administration has already made substantial progress. No amount of consolidation, however, whether accomplished by statute or administratively, would warrant the elimination of any of the essential steps in scientific review of the safety data. If, for instance, administration of a veterinary drug were likely to result in residues in food for man, the application would have to be reviewed not only from the standpoint of safety and effectiveness for the animal but also the safety of drug residues (or the conversion products thereof) in food for human consumption.

We are, however, not prepared to object to favorable consideration of this bill, if it is modified to contain the amendments that are suggested by us below, and in the enclosure to this report, in the interest of public health protection and of facilitating understanding and administration of the bill and of the transition from the present to the new law. We are also including below our understanding of the import of certain provisions of the bill.

1. *Veterinary antibiotics.* a. The bill would remove those veterinary antibiotics that are now subject to batch-by-batch certification under § 507 and § 502(1) of the Act from the scope of those sections and would include such antibiotics in the proposed consolidated section for animal drugs only if they come within the proposed definition of "new animal drug" in the bill (page 24, line 12, through page 25, line 9; and see page 2, lines 18-22, and page 20, line 21, through page 23, line 17). We see no reason why veterinary antibiotics that, under present law, are (in the absence of an exemption granted by the Secretary) subject to batch-by-batch certification without regard to whether they are so-called "new drugs", should hereafter be subject to such certification only if we can meet the burden or bringing them within the definition of "new animal drug" which is patterned after the present definition of "new drug". The considerations calling for batch-by-batch certification may exist in the case of particular drugs or classes of drugs even if they are not, technically, "new drugs." We therefore recommend that the bill be amended as proposed in the enclosed staff memorandum so as to bring it into line with present law in this respect.

b. In addition, the bill (page 20, line 25; page 21, line 1) would except veterinary antibiotics from batch-by-batch certification when they are intended for use in animal feed, even if such antibiotics come squarely within the definition of "new animal drug". To be sure, most of the antibiotics intended for use in animal feed have been exempted by the Department from batch-by-batch certification under the discretionary authority of § 507 and we have no present intention to withdraw these exemptions. It does not follow, however, that we should, by an amendment to the law, be precluded from modifying or even repealing the present exemptions, as we are now authorized to do, if we should find that such a step is needed in the interest of public health protection. We therefore recommend the deletion of this exempting clause from the bill.

2. *Residue of veterinary drugs in food for humans.* A major purpose in the requirement of premarketing clearance of animal drugs is to make sure that if the drug (and food containing it) is properly used no residue of the drug will remain in the edible portions of the animal after slaughter or in any product (such as milk or eggs) of the living animal, or that if such a residue results it will be safe for the human beings who consume such food. This is especially important because of the great potency of many of the veterinary drugs involved. We should therefore like to make clear our understanding that in the event of the appearance of a residue of the drug in food for humans the food would be deemed adulterated, and hence subject to seizure and condemnation, unless such residue were in conformity with the approved application. In order to make explicit in the bill our understanding that this applies also to residues of conversion products of the drug in food, the enclosed staff memorandum proposes an amendment to that effect.

3. *Assurance that drug manufacturer will ship only to feed manufacturer holding an approved application for use of the drug.* Under the provisions of present law as implemented by established procedure a manufacturer of a new drug for use in medicated feed is not authorized to ship the drug to the manufacturer of a medicated feed unless the latter is an applicant holding an approved new-drug application for use of that drug by that applicant in making medicated feed. The bill does not contain an equivalent safeguard. We believe that the manufacturer of potent animal drugs for use in feed should have the responsibility of assuring himself that such drugs will be shipped only to those authorized to use them. We therefore recommend that § 511(a)(1) of the bill be amended to that effect. The staff memorandum enclosed herewith contains draft language to accomplish this.

4. *Data to be submitted by manufacturer of medicated feed, and conditions of approval of his application.* The proposed new animal-drug section (§ 511) of the Act contained in H.R. 7655 contemplates that a manufacturer of medicated feed containing a "new animal drug" must submit an application to the Secretary for that purpose, and that in the manufacture of such feed, after approval of the application, a new animal drug may be used only if there is also in effect an approval by the Secretary of the drug itself with respect to that particular kind of use, judged from the point of view of its safety and effectiveness for that use. In order that feed manufacturers desiring to make medicated feed may have all the information in relation to the approved drug and its suppliers that they require, subsection (1) of section 511 provides that, upon approval of the drug maker's application, the Secretary shall publish in the Federal Register the drug maker's name and address, appropriate purposes

and conditions of use (including special labeling requirements) applicable to any animal feed for which the drug is authorized to be used, and such other information as the Secretary deems necessary to assure the safe and effective use of the drug. (This published material would be a regulation analogous to those published under the Food Additives Amendment.) We recommend that subsection (m), stating what the feed manufacturer's application must contain, be amended so as to require the feed manufacturer to refer to the particular regulation or regulations under subsection (i) on which he relies as a basis for his application under subsection (m). If a number of drug manufacturers had received approval for use of the same drug in feed, this would be reflected in the regulations published under subsection (i), and the feed manufacturer, having referred to such regulations in his application, would upon approval of that application be authorized to obtain his drug from any of the suppliers listed for such drug in the regulations to which his application refers.

The enclosed staff memorandum contains language to carry out these suggestions.

5. *Effect of withdrawal of approval of a drug on the right to continue to use the drug in feed.* The bill (page 17, lines 18 through 22) provides that the Secretary, after notice and opportunity for hearing to the feed manufacturer who holds an approved application for making medicated animal feed containing a "new animal drug", shall withdraw approval of that application if he finds "that one or more of the grounds exist for withdrawal of the approval of the new-animal-drug application on the basis of which approval the feed manufacturer's application for making the feed was approved." This provision raises several problems. In the first place, it overlooks the above-mentioned possibility that there might be two or more approved drug applications for use of the drug involved in the feed, so that the withdrawal of approval from one drug manufacturer should not foreclose the feed manufacturer from relying on another approved source of supply listed in a regulation under subsection (i) identified in his application. Secondly, inherent in this provision of the bill is the possibility of *separate* contested proceedings for withdrawal of approval of a drug manufacturer's application and of a feed manufacturer's application on the same factual issue, i.e., whether a statutory ground for withdrawal of approval of the drug manufacturer's application exists.

We therefore urge that the bill be changed to provide that the listing of a drug manufacturer under subsection (i) with respect to the use of a particular drug in feed be canceled (or suspended) upon withdrawal of approval (or suspension) of the underlying new-animal-drug application, and that approval of a feed manufacturers' application be automatically withdrawn (or suspended) insofar as that approval is based on use of the drug involved made by that drug manufacturer.

Language to accomplish these changes is set forth in the enclosed staff memorandum.

6. *Additional amendments.* There are a number of other changes, albeit of somewhat detailed and technical character, which we believe should, in addition to the revision of the transitional provisions referred to below, be made in the bill. These are also set forth in the enclosed staff memorandum.

7. *Transitional provisions.* Section 107 of the bill (pages 27-33) contains extensive transitional provisions which would govern animal drugs and medicated animal feeds that are already on the market in compliance with now existing law or with respect to which action has been taken or initiated prior to the generally applicable deferred effective date of the bill, i.e., prior to the first day of the seventh calendar month which begins after the date of enactment. These provisions—in addition to being subject, we are advised by staff, to certain substantive objections—are highly complex, would require extensive paperwork by the Department, would be difficult to explain to the affected public, and would tend to disrupt current drug and feed clearance procedure by preempting to an inordinate extent the time of our scientific and administrative personnel in carrying out these transitional provisions. We believe that the simplified and flexible transitional provisions suggested in the enclosed staff memorandum as a substitute for § 107 of the bill would be in the interest both of the public and of the industries concerned in that that would permit a smooth transition to the new law with respect to the drugs and feeds covered by the bill. We are, therefore, not burdening this report with a detailed analysis of the transitional provisions now in the bill.

We are advised by the Bureau of the Budget that there is no objection to the submission of this report from the standpoint of the Administration's program. (The Bureau notes that time has not permitted review, by the Bureau of the staff memorandum enclosed with this report.)

Sincerely,

WILBUR J. COHEN,
Under Secretary.

STAFF MEMORANDUM WITH REPORT OF DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE ON H.R. 7655

1. *Veterinary antibiotics—Amendments to make statutory coverage of certification provisions of bill coextensive with present coverage under § 507 and § 502 (1) of the Federal Food, Drug, and Cosmetic Act.* Under the scheme of the bill veterinary antibiotics would be removed from the batch-by-batch certification requirements now contained in § 507 and § 502(1) of the Federal Food, Drug, and Cosmetic Act.¹ These provisions would, for veterinary antibiotics, be replaced, *insofar as they are replaced at all*, by new certification requirements,² but, as shown below, the substitute falls short of present law in two respects:

a. The proposed § 511(n) of the Act (pp. 20-23 of the bill) provides for batch-by-batch certification of only those veterinary antibiotics which are within the definition of "new animal drug".

The bill's definition of the term "new animal drug" parallels the present law's definition of "new drug"—i.e., a drug that either is not generally recognized by experts (on the basis of scientific investigation) as safe and effective or that has not (except in such investigations) been used to a material extent or for a material time—except that it is limited to animal drugs and excludes feed containing such drugs.³ *It thus makes no reference to antibiotics as such.* ("New animal drugs" and feeds medicated therewith would henceforth be excluded from the Act's definition of "new drug".)

Thus the bill would exempt from the batch-by-batch certification requirements for veterinary antibiotics any drug that does not satisfy the bill's definition of "new animal drug", merely because the antibiotic drug has been used to a material extent or for a material time and is generally recognized by experts as safe and effective for use under the conditions suggested in its labeling. The reason for the certification requirement is that, because of the drug's potency and importance in the treatment of serious infections, the public interest requires not only that the drug in question be of a character which, if it meets all of the specifications approved by the Secretary is generally recognized as safe and effective for its intended use, but also that there be additional assurance that each dose placed on the market does, in fact, have the characteristics of identity and of strength, quality, and purity that are required by the approved specifications. The certification provisions also make sure that in the case of an antibiotic which is subject to deterioration the drug cannot be placed or kept on the market after such expiration date as may be specified in the certification.

¹ See § 105 of the bill, p. 26, lines 13-20. The drugs involved are drugs composed wholly or partly of penicillin, streptomycin, chlortetracycline, chloramphenicol, and bacitracin. Incidentally, the reference on p. 26, line 17, of the bill, to "subsection (1)" should be changed to read "paragraph (1)".

² See, principally, § 511(n), on pp. 20-23 of the bill; § 511(a)(1)(C), on p. 2, lines 18-22 of the bill.

³ The bill would add the definition of "new animal drug" to § 201 of the Act as a new paragraph "(v)". This paragraph designation has been preempted by the definition of "depressant or stimulant drug" which was added to § 201 of the Act by the Drug Abuse Control Amendments of 1965 (P.L. 89-74). Inasmuch as Administration bills now pending in Congress (H.R. 13885; S. 3194) would add new paragraphs (w) and (x) to § 201 of the Act it is suggested that, instead of making the definition of "new animal drug" an independent lettered paragraph of § 201 of the Act, the definition be added to paragraph (p) of § 201 as a definition coordinate in rank with the definition of "new drug". This could be accomplished by inserting "(1)" after "(p)", redesignating subparagraphs (1) and (2) of paragraph (p) as clauses (A) and (B), and inserting at the end of present paragraph (p), as a new paragraph (2), the definition of "new animal drug", with its subordinate clauses designated by capital letters instead of Arabic numerals. Also, in view of the pendency of these Administration bills, it is suggested that the bill's definition of "animal feed" (p. 25, lines 10-17), which the bill would designate as paragraph (w) of § 201 of the Act, be inserted as a subparagraph (2) under paragraph (f) of § 201, coupled with designation of the present language of that paragraph as subparagraph (1) and its subordinate clauses as (A) and (B).

This basic deficiency in the bill with respect to certifiable veterinary antibiotics could be cured by changing the definition of "new animal drug" to read as follows:

"(v)⁴ 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—

"(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; 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

"(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 511(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 applies to such drug."

b. In addition, the proposed § 511(n) also flatly exempts from the certification requirement any drug intended for use in animal feed. For the reasons stated in the last paragraph under point 1 of the Secretary's letter, the matter of exemption in this respect, as in others, should be left to regulation as under existing law. The bill should therefore be amended by deleting the phrase ", except for any such drug intended for use in animal feed" on page 20, line 25, and page 21, line 1, of the bill.

2. *Residues of veterinary drugs in food for humans.* In order to make clear beyond doubt that food for humans containing any residue of an animal drug or conversion product thereof, except when in conformity with an approved application filed under § 511 of the Act, will be deemed adulterated, the following amendments are proposed:

a. On page 26, line 1, change the caption to read "Animal Drugs in Feeds and Residues Thereof in Other Food".

b. On page 26, change the new clause (D) in lines 11 and 12 to read as follows: "(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 511".

3. *Assurance that drug manufacturer will ship only to feed manufacturer holding an approved application for use of the drug.* In order to carry out the recommendation under point 3 of the Secretary's letter, it is recommended that on page 2 of the bill, between lines 22 and 23, the following be inserted flush with the outer margin.

"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, if at the time of such removal the operator of the establishment in which such drug is to be so used is not the holder of an approved application under subsection (m) of this section with respect to the use of such drug in animal feed manufactured at such establishment."

4. *Data to be submitted by manufacturer of medicated feed, and conditions of approval of his application.* In order to carry out the recommendations contained under point 4 of the Secretary's letter, the following changes are suggested in paragraphs (1) and (3) of the proposed § 511(m) (pages 15-17):

a. In the proposed § 511(i), on page 13, line 2, insert "by regulation" before "publish".

⁴ See footnote 3 for suggestion as to redesignation of this paragraph and its subordinate clauses.

b. Insert a new Clause (B) in the second sentence of the proposed § 511(m) (1), on page 15, and redesignate the other clauses, so as to make the sentence read as follows: "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 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 feed or components thereof."

c. Amend paragraph (3) of § 511(m) so as to read as follows:

"(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,⁵ 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 purposes 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 manufacturing, 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."

5. *Effect of withdrawal of approval of a drug on the right to continue to use the drug in feed.* In order to carry out the Secretary's recommendations under point 5 of his letter, the following changes are suggested in the bill:

a. Delete clause (i) on page 17, lines 18-22 of the bill, redesignate clauses (ii) and (iii) on pages 17 and 18 accordingly, and insert the following on page 17 at the end of line 13: "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."

b. On page 13, at the end of line 12, add the following sentence: "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."

6. *Additional amendments (other than amendments to transitional provisions).*

a. On page 2, lines 12-15, strike out "by the manufacturer, packer, or distributor of such drug or any of its drug components, or the manufacturer, packer, or distributor of the animal feed bearing or containing such drug"; on page 3, line 7, strike out "filed by its manufacturer, packer, or distributor"; on page 3, line 20, strike out "specified in subsection (a) (1)"; and on page 15, line 16, strike out "specified in subsection (a) (2)".

b. On page 2, line 12, insert "such use or intended use of" before "such drug".

c. On page 3, line 11, change "conditions of use" to read "conditions and indications of use"; on page 13, line 4, strike out "indications for use" and insert

⁵The bill (p. 16, lines 16 and 17) refers to "said subsection". The substitute version refers to "such paragraph", meaning paragraph (2) of § 511(m), which in turn incorporates the procedure set forth in the last two sentences of § 511(c).

⁶The regulation would not be considered "in effect" while suspended pursuant to the next amendment, below.

"conditions and indications of use"; on page 14, line 14, insert "and indications" after "conditions"; on page 16, line 24, insert "and indications" after "conditions".

d. On page 4, lines 7-11, strike out ", or in the case of such a drug which consists of two or more drug components and which is intended for use in animal feed, a description of the methods, facilities, and controls used in the preparation of each new drug component of each drug"; and on page 6, lines 8 and 9, strike out "and each new drug component of such drug".

e. On page 4, amend clause (5) to read: "(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;".

f. On page 4, insert "or other use restrictions" after "withdrawal period" in line 21 and in line 22.

g. On page 8, line 13, strike out "generally recognized as".

h. On page 10, line 10, and on page 18, line 1, strike out "significant".

i. On page 10, line 13, strike out "(unless the article is no longer a new animal drug)"; and on page 18, lines 4 and 5, strike out "(unless the animal feed no longer bears or contains a new animal drug)".

j. On page 1, line 4, strike out "1965" and insert "1966".

k. On page 2, line 10, strike out "There" and insert "there".

7. *Transitional provisions:* Revise the text of § 107 of the bill to read as follows:

Sec. 107. (a) Except as otherwise provided in this section, the amendments made by the foregoing sections shall take effect on the first day of the seventh 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 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.

(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, 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. The Secretary shall, as soon as feasible, publish such prior approvals in accordance with subsection (i) of section 511 of the basic Act.

(3) In the case of any drug (except a drug subject to section 511(n) of the basic Act as amended by this Act) intended for use in animals other than man which, as of October 9, 1962, (A) was being commercially used or sold in the United States, (B) was not, and had not previously been, a "new drug" as defined by section 201(p) of the basic Act as then in force, and (C) had never been the subject of an application by any person filed under section 505(b) of that Act, the words "effectiveness" and "effective" contained in section 201(p)(2)⁷ of the basic Act defining the term "new animal drug" shall not apply to such drug when intended solely for use under conditions prescribed, recommended, or suggested in labeling with respect to that drug on that day.

(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 511(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 511(n), including preparatory work or proceedings prior to that date.

⁷ The reference "201(p)(2)" should be inserted if the suggestion in footnote 3 is followed which proposes that the definition of "new animal drug" be inserted as a subparagraph (2) in § 201(p), with corresponding relettering of the present clauses (1) and (2) of paragraph (2).

DEPARTMENT OF AGRICULTURE,
OFFICE OF THE SECRETARY,
Washington, D.C., June 13, 1966.

HON. HARLEY O. STAGGERS,
Chairman, Committee on Interstate and Foreign Commerce, House of Representatives, Washington, D.C.

DEAR MR. CHAIRMAN: We wish to thank you for your letter of May 3, 1965, giving us the opportunity to report on H.R. 7655. The bill is entitled "A Bill 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."

This Department would not object to enactment of the bill if it is amended as suggested in this letter.

The proposed legislation contains substantive amendatory provisions to the Federal Food, Drug, and Cosmetic Act which, briefly stated, provide: (1) that a "new animal drug" is deemed to be "unsafe" and "adulterated" unless an application for such drug has been approved by the Secretary of Health, Education, and Welfare; (2) that an animal feed bearing or containing a "new animal drug" is deemed to be "unsafe" and "adulterated" unless applications for such drug and such feed, have been approved by said Secretary; (3) that a food is deemed to be "adulterated" if it is, or it bears or contains, a "new animal drug" unless an application for such drug has been approved by said Secretary; (4) an exception for a "new animal drug" from the definition of "food additive" contained in the Act; (5) an exception of drugs for use in animals other than man from the certification provisions of Sections 502(1) and 507 of the Act relating to antibiotics, and separate certification provisions for new animal drugs composed in whole or in part of certain antibiotics; (6) that a "new animal drug" or animal feed bearing or containing a "new animal drug" shall not be deemed "unsafe" and "adulterated" if it is for "investigational use" and conforms to the terms of exempting regulations promulgated by the Secretary of Health, Education, and Welfare as provided therein, and that such exempting regulations, among other things, shall set forth conditions (if any) upon which animals treated with such drugs, and their products, may be marketed for food use; (7) that a "new animal drug" which induces cancer in man or animals will not be approved unless there is a finding by said Secretary that, under conditions of use specified on proposed labeling and reasonably certain to be followed in practice, (i) such drug will not adversely affect 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 of Health, Education, and Welfare) in the edible portions of such animals after slaughter or in food yielding by or derived from the living animal; (8) that nothing in subsection 801(d) of the Act shall authorize the exportation of any new animal drug, which is "unsafe" within the meaning of the Act.

Section 301(a) of the Federal Food, Drug, and Cosmetic Act prohibits the introduction into "interstate commerce", as defined in the Act, of any food, drug, device, or cosmetic that is adulterated or misbranded. Under the provisions of H.R. 7655, a "new animal drug" for which an application has not been approved by the Secretary of Health, Education, and Welfare would be deemed to be adulterated and could not be shipped in interstate commerce even though such animal drug may be an animal virus, serum, toxin or analogous product regulated by the Secretary of Agriculture under the provisions of the Virus-Serum-Toxin Act (21 U.S.C. 151-158).

The Virus-Serum-Toxin Act prohibits the preparation, sale, or shipment in interstate commerce, or importation into the United States, of any worthless, contaminated, dangerous, or harmful virus, serum, toxin or analogous product intended for use in the treatment of domestic animals. It also prohibits the preparation, sale, or shipment as aforesaid, of any virus serum, toxin or analogous product intended for such use unless and until it shall have been prepared under and in compliance with regulations prescribed by the Secretary of Agriculture at an establishment holding an unsuspended and unrevoked license issued by him. It further prohibits the importation of such products without a permit from the Secretary of Agriculture. The Act provides penalties for violation of its provisions.

Regulations issued by the Secretary of Agriculture pursuant to the provisions of the Virus-Serum-Toxin Act set forth (1) requirements for a licensed establishment (establishments are inspected prior to licensing and are subject to con-

tinuing inspection); (2) standards, methods of production and testing, and other requirements for the products prepared at such establishment; (3) requirements for the labeling and packing of the products; (4) record-keeping requirements with respect to the production and testing of the products; (5) requirements for control of animals used in the production and testing of the products, their disinfection and disposition; and (6) provisions with respect to the suspension or revocation of a license or outline of production of a product. This Department has also issued regulations pursuant to this Act governing the production,

Under the provisions of H.R. 7655 it appears that an animal drug would be distributed and evaluation of experimental veterinary biologics under investigation prior to licensing, and the disposition of animals used to evaluate such products.

a "new animal drug" if it is not generally recognized as safe and effective under the Federal Food, Drug, and Cosmetic Act unless it was regulated under the Federal Food and Drugs Act of June 30, 1906, and its label representations concerning the conditions of its use are still the same.

The provisions of H.R. 7655 could be interpreted so as to bring viruses, serums, toxins and analogous products presently regulated by the Secretary of Agriculture, under the Virus-Serum-Toxin Act, within the scope of the term "new animal drug". The Secretary of Health, Education, and Welfare does not now approve applications for such animal biologics, which are excepted by regulation (21 CFR 130.2) from the "new drug" provisions of the Federal Food, Drug, and Cosmetic Act, and they might be deemed "unsafe" under the provisions of H.R. 7655 as new animal drugs. It is noted that the definition of "new animal drug" in the bill is very similar to the definition of "new drug" in the Act.

Viruses, serums, toxins, and analogous products coming within the purview of the Virus-Serum-Toxin Act are biological products. Historically the Secretary of Agriculture has regulated such animal biologics, many of which are not used for animals that are a source of human food. Under the provisions of H.R. 7655, these animal biological products, if considered to be new animal drugs, could not be shipped in interstate or foreign commerce, until applications therefor were approved by the Secretary of Health, Education, and Welfare. The processing of these applications would be a duplication of work already being performed by the Department of Agriculture and would serve no useful purpose. In order to obviate this problem, it is recommended that a new section 108 be added to the bill, providing exemption for viruses, serums, toxins, and analogous products intended for use in the treatment of domestic animals. to read as follows:

"Sec. 108. Section 90(c) of the Federal Food, Drug, and Cosmetic Act, as amended, is amended by inserting immediately after the words "Act of July 1, 1902;" the following: "or the virus, serum, toxin, and analogous products provisions of the Act of Congress, approved March 4, 1913 (37 Stat. 832-833)";".

It is not anticipated that enactment of the bill would result in any additional costs to this Department.

The Bureau of the Budget advises that there is no objection to the presentation of this report from the standpoint of the Administration's program.

Sincerely yours,

ORVILLE L. FREEMAN,
Secretary.

GENERAL COUNSEL OF THE DEPARTMENT OF COMMERCE,
Washington, D.C., June 15, 1966.

HON. HARLEY O. STAGGERS,
*Chairman, Committee on Interstate and Foreign Commerce,
House of Representatives, Washington, D.C.*

DEAR MR. CHAIRMAN: This is in further reply to your request for the views of this Department with respect to H.R. 7655, a bill "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."

The Federal Food, Drug, and Cosmetic Act (21 U.S.C. sec. 301 *et seq.*) now regulates the production and distribution of food and drugs both for human and for animal use. Under section 409 of the Act as amended (21 U.S.C. sec. 348) the Secretary must act within 180 days on any petition for clearance filed with respect to a proposed use of a food additive.

Section 505 of the Act, as amended (21 U.S.C. sec. 355) requires the Secretary to act within 180 days on any application to introduce a new drug into interstate commerce.

H.R. 7655 contains a large number of technical amendments to this Act to provide a separate set of provisions in the law dealing only with animal drugs and animal feeds bearing or containing new animal drugs. A new animal drug is deemed unsafe under the Act unless there is in effect an approval of an application filed by the manufacturer, packer, or distributor for clearance of the drug, a drug component, or animal feed bearing or containing the drug; and the drug, its labeling, and use conform to the approved conditions of use. The Secretary of Health, Education, and Welfare would be required to act within 90 days on any application for the Secretary's approval with respect to any intended use or uses of an animal feed bearing or containing a new animal drug. The Secretary would still have 180 days to act on applications for the use or uses of new animal drugs.

The bill apparently is intended to benefit the animal feed and animal drug industries by making possible the rapid introduction of new products in these fields under procedures specifically designed therefor. We sympathize with this objective since the improvement of animal health, particularly as it affects the food supply for humans is of obvious public benefit. However, we understand that HEW is currently endeavoring to speed the processing of animal drug applications within the limits of available appropriations and has recently established a separate Bureau of Veterinary Medicine.

Under the circumstances we would defer to the views of HEW as to the need for legislation such as H.R. 7655 and the administrative feasibility of the particular provisions of the bill.

We have been advised by the Bureau of the Budget that there would be no objection to the submission of this report from the standpoint of the Administration's program.

Sincerely,

ROBERT E. GILES,
General Counsel.

Mr. JARMAN. Our first witness this morning will be our distinguished colleague, the Honorable Leo O'Brien, member of this committee and author of H.R. 7655.

STATEMENT OF HON. LEO W. O'BRIEN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW YORK

Mr. O'BRIEN. Mr. Chairman and members of the subcommittee, I wish to thank you for calling this hearing to consider H.R. 7655, the animal drug amendments to the Food, Drug, and Cosmetic Act. This measure, which I introduced, will provide complete and adequate safeguards for public health and will improve statutory clearance procedures. Under the present food and drug statute, animal foods which contain antibiotics and other drugs require clearance under the certifiable antibiotic section of the act or the new drug section and, frequently, also the food additives section.

H.R. 7655 will revise the basic statute to bring into one section of the law all provisions governing the clearance of animal drugs. Under this bill, one section of the law calling for one procedure will control clearances instead of three sections. These amendments will streamline the procedure without diminishing public health safeguards.

The American farmer is the most efficient producer of food the world has ever known. Never have so few fed so many so bountifully. Yet farming, for all its efficiency, is one of the highest-risk businesses existing. Weather, fluctuating market conditions, and live-

stock and poultry diseases are but a few of the variables affecting the farmers' income.

Among the heaviest losses incurred by the farmer are those caused by farm animal diseases, parasites, and insects. The U.S. Department of Agriculture estimates this farm loss at nearly \$3 billion annually. Government, private research groups, and industry are all working on ways to reduce these staggering losses. Through the combined efforts of those working on this problem, many agricultural disease losses are being substantially reduced. The contribution of industry in this respect in its production of new animal drugs cannot be overlooked.

However, incredible losses are still being incurred. While current research may reduce these losses, the products of such research could be delayed by the present procedures mandated by the Food and Drug Act. Unnecessary duplication of clearance arrangements substantially increase the lapse of time from the development of new compounds to the time they reach the user.

H.R. 7655 will streamline these clearance procedures, accelerate the marketing of badly needed animal health products, and alleviate financial loss to America's farmers. In a period when our resources are strained by commitments at home and abroad, it is refreshing to introduce a bill that will result in little or no additional manpower or funds needed for the administration of the responsible agency.

The purpose of H.R. 7655 is to elevate the status and regulation of animal drugs, to eliminate unnecessary delays and to consolidate all animal drug clearances into a single section of the Food and Drug Act.

MR. JARMAN. Our next witness will be our former colleague on this committee and author of one of the bills, the Honorable Bill Hull of Missouri.

Mr. Hull, it is a pleasure to have you with us.

STATEMENT OF HON. W. R. HULL, JR., A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MISSOURI

MR. HULL. I am delighted to be here, Mr. Chairman.

Mr. Chairman and members of the subcommittee, I wish to express my appreciation for the opportunity you have given me to appear before you in support of H.R. 7655. I have introduced an identical bill, H.R. 7797.

H.R. 7655 will amend the Food, Drug, and Cosmetic Act. It will consolidate those provisions of the act applicable to animal drugs. The present act requires that new animal drugs frequently be considered under two separate sections. Quite often subsequent clearances are necessary if the drugs are batch-certified or are incorporated into animal feeds.

H.R. 7655 will consolidate these clearance procedures into one section of the law. This consolidation will in no manner remove present safeguards necessary for the protection of the public.

The United States is the best fed country in the world today. Our agricultural technology has enabled us to fill America's tables with an ever-increasing assortment of high-quality foods.

However, the population is growing at a fantastic pace, with an estimated 200 million Americans expected in 1967. These people must have an adequate nutritious food supply.

Today, animal diseases, parasites, and insects are stealing billions of dollars worth of food each year. The best efforts of research teams are needed in an all-out fight to reduce animal losses.

The passage of H.R. 7655 will be of enormous importance in this research effort. When enacted, it will streamline the procedures necessary to obtain clearances of new animal drugs needed to fight these livestock and poultry losses, and will encourage development of new drugs to combat yet unconquered food-animal diseases.

I am happy to note that Dr. Goddard is scheduled to testify here today. His interest in this measure is typical of the thoroughness with which he has taken hold of the FDA. His appointment of Dr. Clarkson, to head up the new Bureau of Veterinary Medicine also typifies his program of seeking highly qualified, competent people to carry on the work of this important agency.

I hope he will find, in H.R. 7655, a valuable tool which will help him and the Bureau of Veterinary Medicine, perform the difficult task of protecting the public health without unduly burdening an industry which must supply our Nation and much of the world with animal health and nutrition products.

I thank you very much for being able to appear before your committee this morning, Mr. Chairman.

Mr. JARMAN. Thank you.

Dr. Carter?

Mr. CARTER. No questions.

Mr. JARMAN. We appreciate your being here at this bright and shiny hour on Monday morning to help start the record on this important subject, Mr. Hull.

Mr. HULL. Thank you, Mr. Chairman.

Mr. JARMAN. We shall hear next from our colleague on the committee, and author of one of today's bills, H.R. 7815, the Honorable Paul Rogers.

STATEMENT OF HON. PAUL G. ROGERS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF FLORIDA

Mr. ROGERS of Florida. Mr. Chairman, I am appearing in support of H.R. 7655 sponsored by my colleague, the Honorable Leo W. O'Brien, of New York. I have introduced an identical measure, H.R. 7815. In introducing this legislation I have been aware of this subcommittee's responsibility for the efficient administration of Government health programs. It is our desire to provide regulatory procedures which will protect the public, but at the same time will not create inefficiency and waste in both Government and industry.

I would like to emphasize that the problems for which we seek a solution through introduction of H.R. 7655, are not caused by the Food and Drug Administration or by the Bureau of Veterinary Medicine. The problems appear to be with the law.

The present Food, Drug, and Cosmetic Act was passed and amended to establish necessary safeguards. In the enactment of the basic act and its many amendments, Congress has been concerned primarily

with the regulation of human drugs. Animal drugs have always been covered by the law but their clearance prior to use has almost by circumstance, rather than design, under the various sections also applicable to human drugs.

Human drugs and food additives may be cleared under one of three possible sections in the present law, but only one. Animal drugs, on the other hand, must be cleared under two sections in many cases and additional clearances under the same sections are necessary for many of those used in medicated feeds.

This situation has created delays and difficulties in administration of the law because of the multiple clearances involved. These delays which are not predicated on sound public health considerations are expensive for the Government, the industry, and the consumer.

Any roadblock to the most efficient production of meat, milk, and eggs should be eliminated if we are to continue to meet the needs of our rapidly growing Nation. H.R. 7655 will remove some of the statutory complications now facing manufacturers of animal health products. This bill will maintain existing safety and efficacy requirements while eliminating the ponderous and time-consuming procedures that currently delay the clearance of new animal drugs.

Mr. JARMAN. Thank you for your testimony Mr. Rogers. If there are no questions, we shall hear next from another colleague on the committee, the Honorable Ancher Nelsen, who has introduced a companion bill, H.R. 9542.

STATEMENT OF HON. ANCHER NELSEN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MINNESOTA

Mr. NELSEN. Mr. Chairman and members of the subcommittee, I am appreciative of the opportunity to appear before you to urge your favorable consideration of H.R. 7655. As you are aware, I have introduced an identical companion bill, H.R. 9542.

The animal health industry has made great strides in recent years in reducing food animal losses to farmers; reducing food costs to consumers; and improving the quality of meat, poultry, milk, and eggs, through development of a wide variety of animal health products and growth agents. These strides have been made despite cumbersome clearance procedures that delay and discourage development and marketing of new agents to combat diseases, parasites, and insects that afflict food-producing animals.

An example of the contributions made by the animal health industry is clearly demonstrated in the heavy use by poultry producers of a wide range of drugs. Broiler producers use drugs and feed additives from the day the chick hatches until it is ready for market. Twenty-five years ago it took 5 pounds of feed to make a pound of broiler meat. Ten years ago, it took 2½ pounds of feed to make a pound of broiler meat. Today, we can make a pound of broiler meat with just 2 pounds of feed. Scientific management with feed additives and health-protecting agents have made possible this remarkable feed conversion record.

Even greater advances are possible, but current clearance procedures for animal health products discourage research and development. It often takes 2 or more years to get premarketing clearance, after re-

search has been completed, safety and effectiveness demonstrated, and an application submitted for approval. Such costly and time-consuming redtape, based on rules developed for human drugs, is keeping from America's farmers the products they desperately need to further improve efficiency of food production.

The Commissioner of Food and Drugs, and the Director of Veterinary Medicine, have demonstrated a willingness and an ability to eliminate many of the unnecessary administrative procedures which have in the past added to the delays. This legislation, I feel, will assure us that absolute and unnecessary time-consuming methods will be set aside and will aid in efforts to streamline procedures.

H.R. 7655 calls for a single procedure for clearance of animal drugs. This simplified and effective procedure would greatly reduce clearance time and cost to producers without slackening the rigid controls in the present law that are designed to protect the public health. We need passage, without delay, of H.R. 7655.

Mr. JARMAN. Thank you for your testimony, Mr. Nelsen. If there are no questions, we shall hear next from our colleague from Kentucky, the Honorable John Watts. Mr. Watts is sponsor of one of the bills under consideration today, H.R. 8377.

STATEMENT OF HON. JOHN C. WATTS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF KENTUCKY

Mr. WATTS. Mr. Chairman and members of the subcommittee, I thank you for affording me the opportunity to make this statement in support of H.R. 7655. My strong conviction of its merit prompted me to introduce an identical bill, H.R. 8377.

You will recall that the need for legislation specifically relating to drugs for use in animals and in their feed was brought to the attention of your parent committee in 1962 during hearings on the bill H.R. 11581, which was enacted into law as the Drug Amendments of 1962. It was again presented to this subcommittee's predecessor in September of 1963 when hearings were held on H.R. 7247. I am advised that a number of amendments to that bill, suggested by the Food and Drug Administration, were promptly acquiesced in by its proponents, and additional amendments, believed to be necessary to the adequate protection of the public health, were worked out during a course of many meetings between representatives of the administering agency, the congressional staff, and industry. I understand and believe that all necessary features of this nature are incorporated in the bill before you today. I am firmly convinced that H.R. 7655 preserves all the safeguards presently contained in the Food, Drug, and Cosmetic Act.

The delay in favorable consideration and enactment of this legislation has been undue. I strongly urge your prompt action to report the bill as introduced by my esteemed colleague, the Honorable Leo W. O'Brien.

Mr. JARMAN. Thank you Mr. Watts. We appreciate your testimony.

Mr. WATTS. Thank you for the opportunity, Mr. Chairman.

Mr. JARMAN. Our colleague, Hon. Leonor K. Sullivan, has asked that I read to the committee the following letter:

HOUSE OF REPRESENTATIVES,
Washington, D.C., June 13, 1966.

HON. JOHN JARMAN,
Chairman, Subcommittee on Public Health and Welfare, Committee on Interstate and Foreign Commerce, House of Representatives, Washington, D.C.

DEAR CHAIRMAN JARMAN: If it is not possible for me to appear in person before your Subcommittee Monday morning because of an extremely important meeting of the Committee on Banking and Currency which I must attend, I would appreciate it very much if you will read this letter at the hearing on H.R. 7655 dealing with animal drug regulation under the Food, Drug, and Cosmetic Act.

As you know, I have long been interested in strengthening our consumer statutes relating to the health and safety of the American people, and I have an omnibus bill, H.R. 1235, pending before the Committee to rewrite the Food, Drug, and Cosmetic Act of 1938, as amended. Veterinary drugs are important to the health and safety of the public because of their effects upon the food we eat, and thus provisions to tighten the law dealing with such drugs are included in my bill.

I would prefer that the Subcommittee not proceed to deal with only this limited phase of the Food, Drug, and Cosmetic Act in your present hearings, since there are so many other—and to me, far more important—provisions of the law which require urgent attention. H.R. 7655 seems to be directed almost entirely at ameliorating some operating problems of the feed industry and those chemical firms which supply ingredients for such feeds or for animal drugs. I wish the needs of the consuming public for stronger protections could be given at least equal attention at this time.

However, since you are taking up H.R. 7655, I would like to ask that you amend this bill to make sure that every antibiotic drug—not just the five antibiotics listed on page 20 in subsection (n)(1), but all antibiotic drugs and any derivatives thereof—be made subject to batch-by-batch certification by the Food and Drug Administration, whether intended for use by man or by animals, and that this requirement extend to existing antibiotic animal drugs, not just to “a new animal drug.” This would bring the provisions of the law dealing with antibiotic animal drugs into line with the 1962 Act provisions applying to antibiotics intended for use by man. If the bill is so amended, it would accomplish in this respect one important objective of H.R. 1235, as contained in Section 5 of H.R. 1235, “Certification of all Veterinary Antibiotics.”

H.R. 1235 would also repeal the exemption in the 1962 Act for carcinogenic color additives used in animal feeds. I know of no rational explanation for the inclusion of that exemption in the 1962 Act. In fact, when I offered the amendment in the House in 1962 to delete that provision, the “explanation” given at the time for its inclusion gave no explanation at all. The provision constitutes a serious loophole for the possible adulteration of our meat supply, even though no animal feed manufacturer, so far, seems to have utilized this loophole to deliberately include a cancer-causing coloring ingredient in animal feeds. But the possibility exists. I realize that an amendment to H.R. 7655 to eliminate this provision from the section of the law dealing with Color Additives would be subject to a point of order, but if a clean bill should be introduced following Committee consideration of H.R. 7655, I urge that consideration be given to inclusion of an additional section dealing with the cancer-causing coloring matter in animal feeds.

In the meantime, however, I ask that H.R. 7655 be amended at 3 places on page 20 to assure batch-by-batch certification of all antibiotics used in animal drugs. First, on line 23, the words “a new” should be deleted and the word “any” inserted in lieu thereof, so that the provision applies to existing as well as new animal drugs. Next, I ask that on line 25, after the word “bacitracin” the following words be inserted: “or any other antibiotic drug.” Then, I ask that the comma following the word “thereof” on line 25 be changed to a period and everything which follows in that sentence be deleted.

These three amendments will give to the Food and Drug Administration the same powers in regulating antibiotic animal drugs as it has under the 1962 Act in

regulating antibiotic drugs intended for use by humans. The present law on animal antibiotic drugs, and the present provisions of H.R. 7655, maintain the myth that the only antibiotic drugs which are of any consequence are the five which happened to be in existence when antibiotics were first made subject to batch-by-batch certification. We have many more antibiotics now in existence than those five enumerated in the bill, and all of them should be made subject to batch-by-batch certification.

Sincerely yours,

LEONOR K. SULLIVAN,
Third District, Missouri.

Mr. JARMAN. Our next witness is Dr. James L. Goddard, Commissioner of the Food and Drug Administration.

Dr. Goddard, we are very glad to have you with us this morning and for the record would you introduce your colleagues from the Department.

STATEMENT OF HON. JAMES L. GODDARD, COMMISSIONER; ACCOMPANIED BY M. R. CLARKSON, DIRECTOR, BUREAU OF VETERINARY MEDICINE; AND WILLIAM W. GOODRICH, GENERAL COUNSEL, FOOD AND DRUG ADMINISTRATION

Dr. GODDARD. Thank you.

Mr. Chairman and members of the committee, on my left is Dr. M. R. Clarkson, Director of the Bureau of Veterinary Medicine of the Food and Drug Administration, and on my right is Mr. William W. Goodrich, the General Counsel for the Food and Drug Administration.

Mr. JARMAN. May I say for the committee that we are very pleased to have you here this morning in your first appearance before the committee since being sworn in.

Dr. GODDARD. It is a pleasure to be here this morning, Mr. Chairman, and with your permission I have a prepared statement which I will read.

Mr. JARMAN. All right.

Dr. GODDARD. I appreciate your invitation to discuss H.R. 7655, a bill to amend the Federal Food, Drug, and Cosmetic Act in relation to the safety and effectiveness of drugs intended for use for animals.

The principal effect of the bill would be to bring together in a new section a substantial part of the requirements of the Food, Drug, and Cosmetic Act for approvals of new animal drugs, including food additive clearances and the certifications of antibiotics.

The bill also includes transitional provisions to protect the holders of currently approved drugs and to assure that there will be no hindrance in the continued application of the enforcement provisions of the act during the period of changeover in administration from the provisions of the current act relating to animal drugs to the new provisions contained in the bill.

If the bill is amended, as we suggest, it would work in the following manner:

The manufacturer, packer, or distributor of a new animal drug, whether intended for direct action in animals or for use in feed or drinking water, would file an application to establish the conditions of safe and effective use.

Upon approval of the application, the Department would publish a regulation, giving the name and address of the applicant, and the

conditions attached to the approval to assure safe and effective use, including any authorized tolerance or required withdrawal period, any special labeling requirements, and any other information deemed necessary.

The feed manufacturer, desiring to use the new animal drug in medicated feed, would be required to file an application of his own describing how he intended to prepare the feed; listing the facilities and controls that would be used; and providing specimens of the labeling he proposed to use. The application would be approved only if it established safety and effectiveness for the animal feed containing the new animal drug.

Each applicant, the drug manufacturer as well as the feed producer, would be entitled to a hearing on a refusal to approve his application, or on any proposed withdrawal or modification of the approval. If the basic approval for the new animal drug were proposed to be withdrawn or modified, the drug manufacturer would be entitled to a hearing, and the feed manufacturer would be entitled to intervene. Final withdrawal of approval of the new animal drug application would automatically result in withdrawal of the approval of the medicated feed applications based upon it.

Antibiotics would continue to be handled in essentially the same manner as they now are.

Further, the bill has a transitional provision which continues all prior approvals in effect, and allows the holder of any such approval to propose amendments, or the Department to modify or withdraw any such approval under the new procedure that would be provided by the bill.

Since the Department is required to publish all approvals, it will take some time to pick up all of the prior approvals—particularly those granted in new drug applications filed over the past 28 years. This would be done as soon as feasible.

The bill continues the grandfather clause of the 1962 Drug Amendments, with a change in language to make it quite clear that any drug that has previously cleared through the new drug procedures on safety alone, by any person, will be subject to reevaluation as to its claims of effectiveness. As you will remember, the provisions requiring proof of effectiveness was one of the most important features of the 1962 amendments.

The Department is approaching that problem in an orderly way, both for human and animal drugs.

The forerunner of this bill, H.R. 7247, introduced in the 88th Congress was vigorously opposed by the administration on the ground that it would significantly reduce the protection afforded to the public under the present law. However, many changes have been made in the drafting of the current bill, thus removing many of the reasons for our previous objections.

Meanwhile, we in the Food and Drug Administration have taken a number of steps to expedite the handling of animal drug applications. The committee will recall that a major plea of the proponents of the legislation was the need to simplify procedures and to shorten the time for obtaining FDA clearances. Our veterinary medical staff was greatly overburdened with work, and consequently the handling of applications for clearances of new drugs was lagging very badly.

For example, in June 1965, we had on hand 198 applications for basic new drug approvals, and 579 applications for medicated feed supplements. The time consumed in handling all applications varied from 3 to 6 months. By contrast, we now have 97 basic new drug applications (NDA's) on hand, and 204 medicated feed supplements, and the time consumed in handling has been reduced to an average of 90 and 30 days, respectively.

Although this represents substantial progress in eliminating delays, it is still not enough. Our goal, which we hope to reach during the coming year, is to become completely current in taking up applications as they are received.

This does not mean, of course, instant approval or disapproval. As you know, many of these applications require critical determinations of safety and efficacy, including the resolution of difficult problems of residues in meat, milk, and eggs. There can be no shortcuts in the reviews of scientific data concerning these issues, and we must devote the necessary staff time to make a thorough evaluation and a sound decision in each case.

Several administrative changes have been made. With the cooperation of industry groups, the forms for medicated feed applications have been completely revised and simplified. The use of the new form 1800 should result in the submission of more complete and better organized information by the applicant thereby cutting down on the problems of review in FDA.

The regulations covering good manufacturing practices for medicated feeds have been separated from those for drugs generally, giving recognition to the special requirements for this type of manufacturing facility. Proposals for good manufacturing practices regulations covering the intermediate or "premix" facilities have been published in the Federal Register inviting comment from interested parties. Although good manufacturing practices requirements are not covered in the bill now before the committee, the recognition of the special needs in these areas helps to smooth out some of the problems we have had in the clearance of drugs for animal use.

Applications for clearing premixes are now handled as new drug applications rather than as master files. The master file concept is being retained to avoid the necessity for duplicating information in succeeding applications. With respect to master files now on hand, we are glad to consider requests from the holders of such files to change them over to NDA's. This does not change the current requirement that the applicant undertake to distribute premixes only to holders of approved medicated feed NDA's.

New regulations setting forth the rules for veterinary investigational drugs have been issued. By separating the requirement for veterinary drugs from those established for human drugs, we have often given attention to the particular needs for the development of laboratory and clinical data in this area with special reference to the protection of meat, milk, and eggs derived from animals used in investigations.

The former Division of Veterinary Medicine has been upgraded to full Bureau status with the responsibility for the handling of drugs for animals clearly established in this Bureau. Final authority has

been delegated to the Director of the Bureau for approval of medicated feed applications.

Veterinary personnel handling certifiable antibiotics applications previously assigned to the Division of Antibiotic and Insulin Certification, are now located in the Bureau of Veterinary Medicine. NDA's and medicated feed applications involving certifiable antibiotics are now handled along with other veterinary NDA's and medicated feed applications in the Bureau of Veterinary Medicine.

Responsibility for clearances of food additives for animal use along with the clearances of new drugs has been consolidated in the Bureau of Veterinary Medicine. Of course, in discharging this responsibility, the Bureau will continue to consult with toxicologists and pharmacologists of the Bureau of Science in coming to a decision. This is necessary not only because of the special competence available in the staff of that Bureau, but also to be sure that decisions concerning these food additives will not be inconsistent with decisions on the many other food additives which are the responsibility of the Bureau of Science.

Amendments to the regulations are being drafted to provide a separate part for the publication of approvals of veterinary new drugs and food additives for animal use. Under the proposed revision when approval is given to such a drug or additive, notice of such approval would be published in the Federal Register along with any limitations of use necessary to protect the animals for which the product is intended and to assure the safety of food products derived from such animals. This would be consistent with the proposal contained in subparagraph (i) on page 13 of the bill.

We believe these changes will further facilitate our handling of the large volume of submissions pertaining to drugs for animal use that must be reviewed each year. In addition, we are taking steps to increase the size of the staff of this Bureau, and, more importantly, to accomplish this by recruiting scientists of the highest qualifications to round out the capabilities of the current staff.

We are placing the highest emphasis upon a comprehensive program of continuing education for our staff, including special training in various scientific disciplines—particularly pharmacology, toxicology, physiology, and epidemiology—as well as the most up-to-date training in executive leadership and administration.

It is our belief that the steps that have been taken and those which are now underway go far to meet the objectives of the bill. Nevertheless, we have no objection to the enactment of this bill provided the amendments which are presented with the Department's report are incorporated in the language. Basically, these amendments are to assure that none of the substantive authority now available to the Food and Drug Administration to protect the safety and efficacy of drugs for animal use will be lost. There can be no doubt of the importance of these authorities when one considers that the health of the Nation's livestock and poultry, the wholesomeness of meat, milk, and eggs, and the protection of companion animals from disease are enhanced by a safe and effective animal drug and medicated feed supply. Conversely, these values would be damaged by unsafe or ineffective drugs.

A great many of our common diseases are readily transmissible between animals and man, including tuberculosis, salmonellosis, brucel-

losis, and anthrax, to name just a few. The Congress has wisely provided that drugs for animal use shall be safe and effective, based upon the best available scientific judgment. Considerations of "safety" necessarily include the safety of the meat, milk, and eggs derived from food-producing animals. This is important not only to the people of the United States, but also around the world, as this country continues to meet its global responsibilities to provide food for hungry peoples.

In summary, Mr. Chairman, we intend to carry out our responsibilities to the consumer under the present law to assure that drugs and food additives for animal use are safe and effective. We intend to meet these same objectives if H.R. 7655 is enacted with the amendments proposed in the Department's report. Members of our staff will of course, be glad to work with the committee staff to incorporate the amendments in the bill if this is desired.

Thank you, Mr. Chairman, for the opportunity to discuss this proposed legislation with you. My associates and I will be glad to respond to any questions which the committee may have.

Mr. JARMAN. Thank you, Doctor.

It is good to hear the statement that the time consumed in handling these applications has been reduced to 90 and 30 days, respectively, as indicated on page 3 of your statement.

Mr. Mackay?

Mr. MACKAY. No questions.

Mr. JARMAN. Mr. Nelsen?

Mr. NELSEN. Thank you, Mr. Chairman.

I want to compliment our witness on his statement because it does indicate an awareness of the problem that the feed manufacturers have been faced with, and those of us who have authored legislation certainly wish to assure the general public that it is not our intention in any way to cut corners on the safety of any product that is put to use and for sale to the farm people of our country or those who purchase any of these feeds. We have been seeking for a long time, however, to try to reduce the length of time that it takes to obtain clearance for the use of new drugs. We have found in so many cases inequities existing in the area of manufacturing where one manufacturer may be using a certain formula and another one has an application to do a similar thing, yet because of lengthy procedures he has been unable to market his product. It has been our hope that we could work out something to not only speed things up, but at the same time protect the public, so I want to thank Dr. Goddard for his statement. His comments indicate an awareness of the problem.

Mr. JARMAN. Mr. Gilligan?

Mr. GILLIGAN. No questions.

Mr. JARMAN. Dr. Carter?

Mr. CARTER. I would like to compliment Dr. Goddard on his excellent presentation. Certainly, I think he is doing a good job at the Food and Drug Administration as Administrator and I feel that this bill will be effective.

Thank you, sir.

Mr. JARMAN. Dr. Goddard, as we understand it then, the Department will have no objection to the enactment of the bill if the amendments you recommend are introduced?

Dr. GODDARD. That is correct, Mr. Chairman.

Mr. JARMAN. We are grateful to you and your colleagues for being with us this morning for this succinct and comprehensive presentation on the subject.

Dr. GODDARD. Thank you, sir.

Mr. JARMAN. Our next witness this morning is Mr. Hollis H. Brower, immediate past president of the Animal Health Institute.

Mr. Brower, would you care to identify the gentlemen who are with you.

STATEMENT OF HOLLIS H. BROWER, IMMEDIATE PAST PRESIDENT, ANIMAL HEALTH INSTITUTE; ACCOMPANIED BY BERTRAM H. LEBEIS, ATTORNEY, AMERICAN CYANAMID CO.; AND THOMAS W. FREEZE, CHAIRMAN, REGULATORY SECTION, ANIMAL HEALTH INSTITUTE

Mr. BROWER. Mr. Chairman, members of the subcommittee, accompanying me are Mr. Bertram H. Lebeis, attorney with the American Cyanamid Co. on my left, and Mr. Thomas W. Freeze, a vice president of Salsbury Laboratories, Charles City, Iowa, and also chairman of the regulatory section of the Animal Health Institute.

They are prepared to supplement my statement should you members of this subcommittee have any questions of a legal or technical nature.

I am Hollis H. Brower, marketing manager of animal byproducts, The Dow Chemical Co., Midland, Mich. Our company is engaged in the manufacture and sale of biologicals, feed additives, pharmaceuticals, and pesticide products.

Today I appear before this subcommittee as a director and former president of the Animal Health Institute, in support of H.R. 7655. The Institute was organized in 1941. Its membership includes more than 40 manufacturers which account for the major share of production of animal health and nutrition products manufactured and sold within the United States.

On behalf of the Animal Health Institute, I shall comment on the salient provisions and the intent of H.R. 7655.

It should be emphasized at the outset that this proposed legislation is enormously important to the food supply of this country and to the economic well-being of its farmer producers. Livestock enterprises add more than \$20 billion annually to the gross national product. This constitutes more than 55 percent of the total agricultural income.

Within the past two decades, the development of pharmaceutical preparations, biological products, and feed additives by the members of the Animal Health Institute and others have contributed enormously to animal disease control. These developments have helped improve the quality of farm products of animal origin and have played a vital part in providing consumers with an abundance of wholesome, reasonably priced meat, poultry, eggs, and dairy products.

In spite of these improvements, however, the battles for more efficient production and against the ravages of disease and economic loss due to disease, parasites, and nutritional deficiency are not won.

H.R. 7655 developed as a result of hearings conducted by this subcommittee's predecessor on H.R. 7247 in the fall of 1963. During

these hearings substantial evidence of the need for modification of the basic act was presented. Witnesses described the untoward delays in the processing of applications, the duplicate and triplicate requirements, and the difficulties encountered by the Food and Drug Administration and the industry in the premarketing clearance procedure required by the three separate sections of the act.

Members of the subcommittee and representatives of the Food and Drug Administration offered suggestions for the modifications of H.R. 7247 which would insure full and complete protection of the public health. All such suggestions have been incorporated in H.R. 7655.

During the 88th Congress the Animal Health Institute worked diligently with representatives of the Food and Drug Administration, the Department of Health, Education, and Welfare, and the Committee on Interstate and Foreign Commerce to make these amendments acceptable to Government, the health professions, and industry.

The measure you are considering today, as now drafted, includes all provisions necessary to safeguard the public health.

The purpose of these amendments is to consolidate the provisions of the Food, Drug, and Cosmetic Act relative to the premarketing clearance of new animal drugs into a single section of the statute specifically designed for such drugs. This purpose will be achieved without reduction in the rigid controls contained in existing law. The amendments are designed:

1. To consolidate the duplicate and triplicate controls currently imposed by sections 409, 505, and 507 of the act.

2. To create a single statutory standard of safety and effectiveness for animal drugs in a new section 512, thus elevating such drugs to a position equal to that of drugs and antibiotics for human use and of human food additives.

3. To establish a realistic statutory mechanism for the premarketing clearance of new animal drugs and of animal feeds bearing or containing them.

4. To provide appropriate controls over animal drug manufacturers and over feed manufacturers using such drugs.

5. To prevent recurring delays in the introduction of new animal drugs and to facilitate their availability to the producers of livestock and poultry following discovery and development.

H.R. 7655 includes all safety and efficacy requirements applicable to animal drugs under existing law.

We should note how biologicals and animal drugs are presently cleared for use. Veterinary biologicals are licensed under the Virus-Serum-Toxin Act of 1913 by the U.S. Department of Agriculture. Other animal drugs are subject to the Food, Drug, and Cosmetic Act of 1938, which is administered by the Food and Drug Administration of the Department of Health, Education, and Welfare.

H.R. 7655 will not change the responsibility of the Department of Agriculture for the licensing of veterinary biologicals and will not modify in any manner the authority of the Food and Drug Administration with respect to other animal drugs.

Much of the present food and drug law governing animal health products is the accidental byproduct of a series of legislative enactments designed to regulate substances intended for human use.

Fundamental to any consideration of H.R. 7655 is the realization that when the Federal Food, Drug, and Cosmetic Act was enacted in 1938, the number and type of drugs which were being marketed for use in animals were greatly different from those available today.

As a matter of fact, the medicated feed industry, as we know it, did not even exist in 1938. The practice of veterinary medicine has also changed dramatically. As a result, there is today a confusing and unwieldy regulatory structure for animal drugs which may subject them to three separate statutory procedures before they can obtain any marketing clearance.

The chief objective of legislation in the drug area has been to regulate drugs for human use. From the Food and Drug Act of 1906 through the Food, Drug, and Cosmetic Act of 1938 and its amendments, human drugs have been the prime consideration. The result is that the statute clearly establishes the procedures for handling human drugs. While animal drugs have always been regulated under the act, they have received stepchild treatment at best.

The bill before this subcommittee gives Congress the opportunity to express its intent with respect to animal drug clearances. It would solve the problem of multiple controls by consolidating into a single new section the diverse and overlapping clearance sections of the present Food and Drug Act, now applicable to animal drugs.

This section is designed specifically for the effective and efficient regulation of these products. The desirability of this approach to the processing of new animal drug submissions has been recognized by the Food and Drug Administration in its recent reorganization and the elevation of the Division of Veterinary Medicine to bureau status. This bureau is now under the direction of the very capable administrator, Dr. M. R. Clarkson.

In recent months the growing world population and food crisis have received an increasing amount of attention. Congressional committees have heard testimony that the end of our agricultural surpluses is in sight and that the exploding world population is eating its way into a food crisis of fantastic proportions.

A great many suggestions have been made for the relief of, if not the solutions to, the population and food problem. Aside from the various aspects of birth control, most of the suggestions involve food production and, more specifically, improvement of both quantity and quality of the world food supply. Proteins are the key to the improvement of world diets.

Animal agriculture, especially the animal agriculture of the United States, must be prepared to produce the high-quality protein needed to meet the challenges of the coming decades. The animal health industry will play a major role in that effort.

As I have stated, the development of veterinary pharmaceuticals and biologicals and feed additives by the members of the Animal Health Institute has contributed enormously in reducing losses caused by animal diseases.

We believe the provisions of H.R. 7655 will assist our industry in meeting the increasing demands for the control of livestock losses.

In conclusion, the Animal Health Institute heartily endorses and supports H.R. 7655, introduced by Representative O'Brien, and the identical bills, H.R. 7797, H.R. 7815, H.R. 8377, and H.R. 9542, intro-

duced by Representatives Hull, Rogers, Watts, and Nelsen, respectively.

We support these measures as constructive legislative programs which will advance the interest of our farmers and the consuming public. It is hoped that your subcommittee will report favorably on H.R. 7655.

With your permission, Mr. Chairman, I would like to submit for the record a copy of this prepared statement and its attachments, which are a brief summary of the provisions of H.R. 7655 and an analysis of the measure.

(The summary and analysis referred to follow :)

BRIEF SUMMARY OF H.R. 7655, THE ANIMAL DRUG AMENDMENTS OF 1965 TO THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

(Presented by the Animal Health Institute)

These amendments consolidate the provisions of the Federal Food, Drug, and Cosmetic Act, as amended, governing the premarketing clearance of animal drugs. These amendments add to the basic statute a new Section 511, which establishes the requirements of safety and effectiveness applicable to new animal drugs, including animal feeds bearing or containing such drugs. Proposed Section 511 replaces the application to animal drugs of the three separate premarketing section clearance procedures contained in existing law: Section 409 (food additives), Section 505 (new drugs) and Section 507 (antibiotic drugs). Any new animal drug, or any animal feed bearing or containing such a drug, is considered adulterated unless it meets the requirements of proposed Section 511.

Under the new Section 511, an application is filed with respect to each intended use of a new animal drug whether the drug is to be used in a finished pharmaceutical, in an animal feed, or as a component of such feed. Such application contains information necessary to demonstrate the safety and effectiveness of the proposed use, including practicable methods for determining residues in or on food, as well as a full description of the manufacturing and control procedures employed with other required data. Upon approval of the application, notice of the approval is published in the Federal Register. If the drug is to be used in animal feed, applicable purposes and conditions of use of the drug in animal feed are also published. The use of any new animal drug in animal feed is governed by the published purposes and conditions of use. Consequently, an application for an animal feed containing a drug component is approvable if its labeling conforms to the published purposes and conditions of use and if current good manufacturing practices are utilized.

Procedures are set forth in proposed Section 511 for the granting or withdrawing of approvals of new animal drugs and of animal feed bearing or containing such drugs, and for judicial review, including summary suspension of applications in the event of imminent hazard to health. This section also provides for the issuance of regulations governing investigational use of new animal drugs and the keeping of records and the making of reports with respect to the use of new animal drugs. In addition, this section continues batch certification of the five antibiotics for animal use currently subject to batch certification.

The remainder of the bill contains technical and conforming amendments and transitional provisions. These provisions carry out the purpose of the bill to consolidate existing provisions in the basic law. They also provide for the continuation of existing approvals granted under the present law.

ANALYSIS OF THE SECTIONS OF THE "ANIMAL DRUG AMENDMENTS OF 1965" (H.R.7655) TO THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

(Prepared by the Animal Health Institute)

The first section of the Bill would provide that the Act may be cited as the "Animal Drug Amendments of 1965."

Section 101 (a) of the Bill would amend section 501 (a) of the Federal Food, Drug, and Cosmetic Act (hereinafter referred to as the "basic Act") to deem

any new animal drug, or animal feed bearing or containing a new animal drug, to be adulterated if it is unsafe within the meaning of section 511(a)¹ as added to the basic Act by section 101(b) of the Bill. Thus, the provisions of chapter III of the basic Act, entitled "Prohibited Acts and Penalties," would apply to a new animal drug, or animal feed bearing or containing a new animal drug, in interstate commerce to the same extent as any other adulterated article unless an approval of an application filed pursuant to new sections 511(b) or 511(m), respectively, is effective with respect to that drug or animal feed.

Section 101(b) of the Bill would add to the basic Act new section 511, entitled "New Animal Drugs." New section 511 provides for the approval or refusal and withdrawal of approval of new animal drug applications by the Secretary and requires the sponsor of a new animal drug to demonstrate the safety and effectiveness of the proposed use or uses of that drug. Similar provisions are made for animal feeds bearing or containing new animal drugs. Section 511 is patterned after the new-drug section of the basic Act (section 505) as amended by the Drug Amendments of 1962, and it consolidates the pre-clearance provisions applicable to new animal drugs and animal feeds bearing or containing new animal drugs presently contained in the food additive section (section 409) and the antibiotic section (section 507) as well as section 505. Thus, uniform administration of pre-clearance requirements is assured.

New section 511(a)(1) would deem a new animal drug to be unsafe unless an approval of an application is effective with respect to such drug. New section 511(a)(2) would make similar provision for an animal feed bearing or containing a new animal drug.

New section 511(b) would replace section 505(b) of the basic Act for new animal drugs by specifying the information to be included in a new animal drug application. Clauses (1) through (6) would require the same information presently required in section 505(b). Clauses (7) and (8) are added to replace for new animal drugs sections 409(b)(2)(D) and 409(c)(4) of the basic Act. The latter two clauses are desirable in the event residues of the drug remain in the tissues of the animals used for food production and a tolerance or withdrawal period is proposed.

New section 511(c) is substantially identical with section 505(c) of the basic Act in setting forth the procedure for action by the Secretary upon a new animal drug application.

New section 511(d) would replace section 505(d) of the basic Act for new animal drugs by setting forth the grounds upon which the Secretary may refuse to approve a new animal drug application. Clauses (A), (B), (D), (E) and (G) of new section 511(d)(1) are identical to clauses (1) through (6) of section 505(d). Clause (F) of new section 511(d)(1) would replace for new animal drugs section 409(c)(4) of the basic Act, relating to tolerance limitations, but would not modify the Secretary's existing authority. Clause (H) of new section 511(d)(1) would replace for new animal drugs section 409(c)(3)(A) of the basic Act by requiring the Secretary to refuse approval of an application for a new animal drug which induces cancer when ingested by man or animal. This clause is substantially identical with the proviso in section 409(c)(3)(A) as amended by the Drug Amendments of 1962.

Clauses (A), (B) and (C) of new section 511(d)(2), in specifying certain factors to be considered by the Secretary in determining whether a new animal drug is safe, would replace section 409(c)(5) of the basic Act. Clause (D) of new section 511(d)(2) is intended to give the Secretary added authority to consider safety questions in those instances where the prescribed conditions of use will not be followed.

New section 511(d)(3) would incorporate the definition of "substantial evidence" of effectiveness inserted in section 505(d) of the basic Act by the Drug Amendments of 1962.

New section 511(e) is based upon and is substantially identical to section 505(e) of the basic Act. As in the case of section 505(e), the new section 511(e) would give the Secretary summary powers to act if he finds that there is an imminent hazard to the health of man or of the animals for which the drug is intended.

¹ Subsequent to the introduction of H.R. 7655, Section 511 was preempted by the Drug Abuse Control Amendments of 1965. Section 511, as proposed in H.R. 7655, will become Section 512 of the Act upon enactment.

New section 511(f) is substantially identical to and, for new animal drugs, would replace section 505(f) of the basic Act, relating to the reinstatement of applications. Such provisions would also be applicable to orders concerning applications for animal feeds bearing or containing new animal drugs.

New section 511(g) is substantially identical to and, for new animal drugs, would replace section 505(g) of the basic Act, relating to Service of Orders.

New section 511(h) adopts, for applications relating to new animal drugs and to animal feeds bearing or containing new animal drugs, the appeal procedures set forth in section 505(h) of the basic Act.

New section 511(i) would require the Secretary to publish the conditions of use and the name of the applicant for every new animal drug application which is approved. This is new, inasmuch as there is no provision for such publication in section 505 of the basic Act. However, in view of the practice of mixing two or more drugs, which may be purchased from different sources, in animal feeds, this provision has been included so as to enable feed manufacturers to ascertain those combinations of drugs which have been approved for use in animal feeds. This is necessary because the labeling for a particular drug may not indicate such combinations.

New section 511(j) provides for the promulgation by the Secretary of regulations for exempting from section 511 new animal drugs, and animal feeds bearing or containing new animal drugs, intended solely for investigational use by qualified experts. This section is based upon and would replace sections 409(i) and 505(i) insofar as these sections are pertinent to the investigation of such drugs and animal feeds. Of particular importance, the last sentence authorizes the Secretary to set forth the conditions upon which animals treated with such drugs may be marketed. The amendments made to section 505(i) of the basic Act by the Drug Amendments of 1962 relate to the clinical testing of new drugs for human use and are not pertinent to the investigation of new animal drugs. Therefore, they have not been included in new section 511(j).

New section 511(k) is based upon and would replace, for new animal drugs, the last sentence of section 409(a) of the basic Act relating to adulterated foods. The purpose of this section is to provide for an appropriate exemption from section 402(a) (1) of the basic Act for approved uses for new animal drugs.

New section 511(l) is based upon and would replace, for new animal drugs, section 505(j) of the basic Act, relating to recordkeeping and reporting requirements.

New section 511(m) would provide for appropriate premarketing approval procedures for animal feeds bearing or containing new animal drugs consistent with the provisions of new section 511(b) relating to approvals for new animal drugs. Only 90 days are provided in new section 511(m) for review of an application for an animal feed. A longer period is not necessary since the Secretary under new section 511(c) is permitted 180 days for review of the basic information relating to the safety and effectiveness of the drug component of such animal feed. The other provisions of new section 511(m) with respect to approvals, records, and reports are substantially the same as those applicable to new animal drugs.

Consistent with the Drug Amendments of 1962, new section 511(n) would provide for the certification of batches of new animal drugs composed wholly or partly of penicillin, streptomycin, chlortetracycline, chloramphenicol, and bacitracin and derivatives thereof except where such drugs are intended for use in animal feeds.

Section 102(a) and (b) of the Bill would amend section 201(p) of the basic Act to remove new animal drugs from section 505 of the basic Act. Henceforth the regulation of new animal drugs would be covered exclusively by new section 511.

Section 102(c) of the Bill would amend section 201(s) of the basic Act to remove new animal drugs from section 409 of the basic Act. The reason for this provision is that new section 511 would provide for the exclusive regulation of new animal drugs.

Section 102(d) contains a conforming amendment to the definition of the term "safe" in section 201(u) of the basic Act.

Section 102(e) of the Bill would add new paragraphs (v) and (w) to section 201 of the basic Act defining the terms "new animal drug" and "animal feed."

The definition "new animal drug" is patterned after the term "new drug" contained in section 201(p) of the basic Act. Henceforth, these terms would be mutually exclusive.

Section 103 of the Bill would amend section 301(e) and 301(j) of the basic Act. The effect of these amendments would permit the Secretary access to certain records and provide for the confidentiality of certain information contained in new animal drug applications.

Section 104 of the Bill would amend section 402(a) (2) of the basic Act relating to adulterated food to provide for appropriate exemptions for approved uses of new animal drugs.

Section 105 of the Bill would amend sections 502(1) and 507(a) of the basic Act by exempting therefrom animal drugs. The effect of these amendments is to require the certification of antibiotics listed in new section 511(n) in accordance with the provisions of such section.

Section 106 of the Bill would amend section 801(d) of the basic Act to prohibit the export of "unsafe" new animal drugs or animal feeds bearing or containing new animal drugs.

Section 107 of the Bill contains effective date and transitional provisions. Under this section, the Bill would take effect on the first day of the seventh calendar month following enactment. This section also contains provisions under which regulations in effect under section 409 and 507 of the basic Act on the enactment date, and effective or approved new drug applications on the enactment date, are deemed to be approved applications under section 511. Furthermore, this section provides that applications or petitions pending on the enactment date shall be deemed to be applications pending under section 511, and the filing date shall be deemed to be the date on which the petition or application was actually filed. Proof of effectiveness would not be required for any animal drug which was commercially sold, was not a new drug, and was not covered by an effective application on October 9, 1962, provided the conditions of use stated in the labeling of such drug are not changed. Animal drugs in commercial use prior to the enactment date and which had never been the subject of a new drug application are also not subject to proof of effectiveness so long as the labeling for such drugs contains the same recommendations for use.

Mr. BROWER. Mr. Chairman, with your permission I would like to call upon Mr. Freeze now to continue this presentation of a more technical nature and ask that any questions be delayed until after Mr. Freeze's presentation.

Mr. JARMAN. Unless the committee has questions at this point that will be a satisfactory procedure.

Mr. Freeze, we will be glad to hear you.

STATEMENT OF THOMAS W. FREEZE, CHAIRMAN, REGULATORY SECTION, ANIMAL HEALTH INSTITUTE

Mr. FREEZE. Mr. Chairman and members of the subcommittee, my name is Thomas W. Freeze. I am vice president of Salsbury Laboratories, Charles City, Iowa.

We would like to illustrate for you (1) why H.R. 7655 is necessary, (2) the present statutory clearance procedure for animal drugs, and (3) the procedures which would be followed if this measure is enacted.

The fantastic rate of population growth and our disappearing surpluses present grave problems of world food shortages.

Why does H.R. 7655 mean more meat, milk, and eggs?

To meet the challenge of the dwindling world food supply, more meat, milk, eggs, and grain must be produced more efficiently—waste cannot be tolerated. Disease, parasites, and insects are stealing billions of dollars' worth of food each year.

Of more paramount interest to the Congress, the Nation, and the animal health industry is the need to reduce animal losses. The enactment of H.R. 7655 will help America meet the critical demand for more milk, meat, and eggs.

Livestock and poultry losses add up. The U.S. Department of Agriculture estimates the toll to be \$2.8 billion. To give you a yardstick, that figure is more than one-half of the value of the annual corn crop. Most of these losses are preventable.

Twenty years ago it was much worse. It then equaled approximately 20 percent of the total value of the cash livestock receipts. Drugs have greatly reduced the impact of many serious animal disease problems. New drugs already tested promise further significant reductions in this annual \$2.8 billion toll.

Let us be more specific.

Disease cuts milk production 10 percent. The Nation's dairymen pay an annual toll of \$463 million to disease alone. Parasites and insects push this past the half-billion-dollar mark. Nearly two-thirds of the loss is in mastitis alone. Today, 1½ million U.S. dairymen live with this problem. Each dairyman loses \$750 per year.

Hog producers also have high losses due to disease. The U.S. Department of Agriculture estimates the total bill to be \$300 million per year. Diseases cost hog producers \$5.37 per head. The loss of litter pigs a few days after birth totals \$240 million. While some animal drugs are doing a good job, we have not found the final answer. Twenty-five percent of all pigs never make it to market. A typical hog farmer loses \$1,611 each year. The Nation's 1 million hog farmers urgently need better hog disease drugs.

Another heavy toll hits the cattle producers. The U.S. Department of Agriculture estimates that 22 percent of all beef calves are lost. Disease, parasites, and insects add up to a \$963 million loss per year. Our 1.8 million cattlemen are cognizant of this. A typical beef feeder loses \$1,800 each year.

Broiler growers have made extensive use of drugs in recent years to cut their losses down to 3 to 5 percent of their production. Chronic respiratory disease, salmonella, coccidiosis, and a host of other diseases have not been totally wiped out. A typical broiler grower loses \$2,250 per year.

Laying flock producers suffer losses from the time a hatching egg is set until the day the hen lays her last. An assortment of air sacnewcastle, coccidiosis parasites, et cetera, add up to 10 percent loss on the poultryman's income—\$1,600 per year.

Anything we can do to cut these losses will be good for 3 million livestock farmers and 30 million housewives.

Over the last decade, the use of new, exciting, and unique animal health products and growth agents has become standard practice. Some of the most dangerous health problems have been curbed. And some remarkable increases in more efficient conversion of feed have been achieved. More must be done.

What is holding up the availability of new and better animal drugs?

It often takes 2 or more years to get premarketing clearance after research is completed, safety and efficacy demonstrated, and an application submitted for approval. The problem arises because these compounds must be cleared under a food and drug law, designed without attention to animal drugs.

In many cases, the channels for clearing animal drugs are more complicated than clearance procedures for human drugs. The complexities of the current rules and the resulting long delays add to the cost of urgently needed new animal drugs, and prevent them from reaching farmers for months or even years.

In a recent informal survey on the status of new animal drug applications, excluding feed manufacturer applications, 11 companies reporting on a total of 37 applications disclosed the following information:

1. The time required to file an application following submission averaged 42 days, with a low of 1 day and a high of 212 days.
2. The time required from the submission of an application until approval was an average of 702 days, with a low of 180 days and a high of 1,406 days.
3. Of the 23 applications approved, there were 3 that required no additional data, yet under current procedures 285 days, 303 days, and 957 days were required to approve these applications.

Most of these, of course, involved food additive orders which meant that a food additive petition also had to be acted upon by the Petitions Control Branch of the Bureau of Scientific Standards and Evaluation. H.R. 7655 can greatly speed approval of new animal drugs.

The purpose of this bill is to provide a single procedure for clearance of animal drugs; for as things now stand animal drugs are an administrative orphan.

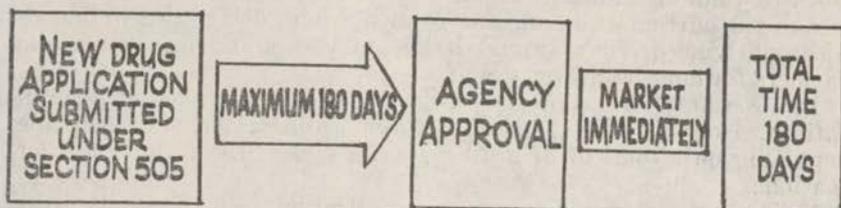
The chief objective of legislation in the food and drug area has been to regulate drugs for human use. From the Pure Food and Drug Act of 1906, through the 1938 act and its amendments, human drugs have been the prime consideration. Animal drugs have always been regulated under the act, but only as an administrative orphan at best.

Animal drugs are reviewed under one or more of three sections of the Food and Drug Act. Compounds for human use, however, are cleared under one, and only one, of these sections. Section 409 deals with food additives. Section 507 provides for the certification of antibiotics. New drug applications are processed under section 505. This situation leads to inconsistent handling of animal drug clearances, along with delays, confusion, and frustration.

Let us look at the statutory procedure for clearing a human drug.

This chart (exhibit I) shows how an application for a new drug for human use moves toward approval. A new drug application is studied under section 505. If approved, the drug can be cleared for market within 180 days.

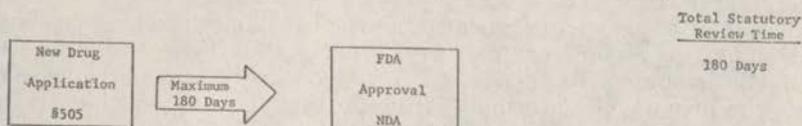
EXHIBIT I

 STATUTORY PROCEDURE
 FOR
 PRE-CLEARANCE OF HUMAN DRUGS


Now let us take a look at the maze of regulations that a drug manufacturer faces in getting clearance of animal drugs. This chart (exhibit II) shows the procedure for one of the simple ones, a new animal drug for a non-food-producing animal, such as a dog or household pet. A new drug application is filed and then is considered under section 505. The agency has 180 days in which to act from the date it considers the application filed.

 EXHIBIT II
 PRESENT REGULATORY CLEARANCE PROCEDURE

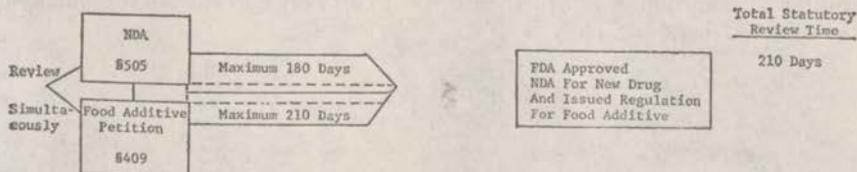
For

New Animal Drug - Nonfood-Producing Animal

A new animal drug for a food-producing animal usually requires action under both sections 505 and 409. The agency has 180 days to act under one section and 210 days under another. Total time under the statute is 210 days, and in practice it is much more. (See exhibit III.)

 EXHIBIT III
 PRESENT REGULATORY CLEARANCE PROCEDURE

For

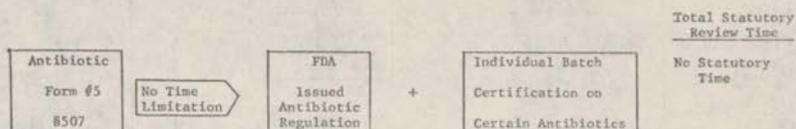
New Animal Drug - Food-Producing Animal

How about a certifiable animal antibiotic for a non-food-producing animal?

A certifiable antibiotic for a pet is handled under section 507. There is no specified time limit for approval. The antibiotic will also require subsequent individual batch certification. (See exhibit IV.)

EXHIBIT IV
PRESENT REGULATORY CLEARANCE PROCEDURE
For

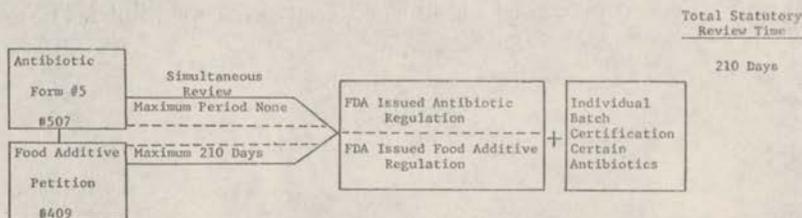
Certifiable Animal Antibiotic - Nonfood-Producing Animal



Let us look at a certifiable animal antibiotic for a food-producing animal. This is another situation requiring action under two sections, 507 and 409. There is no statutory time limitation under 507, while there is a 210-day limit under 409. In addition, this antibiotic may require individual batch certification. (See exhibit V.)

EXHIBIT V
PRESENT REGULATORY CLEARANCE PROCEDURE
For

Certifiable Animal Antibiotic - Food-Producing Animal



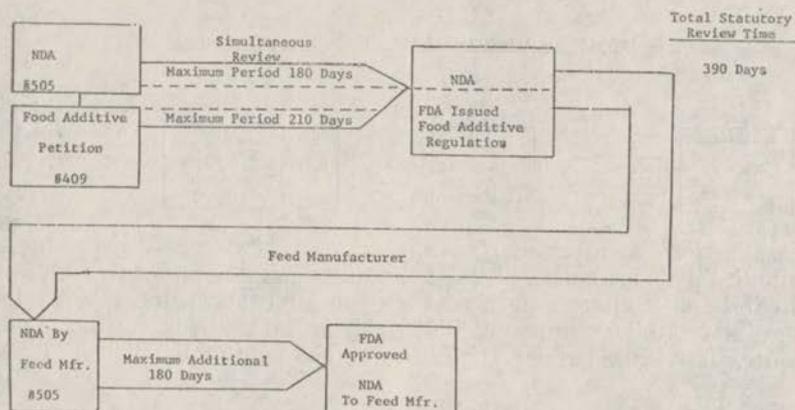
All right. What about new drugs for animal feeds?

The present statute is particularly complicated for new drugs intended for animal feeds. Both sections 505 and 409 apply on primary clearance. The agency has 180 days to act under section 505, and 210 days under section 409.

After safety and efficacy have been demonstrated, the new drug approved and a food additive regulation issued, each feed manufacturer must obtain a secondary clearance for each of his plants. This law allows the agency an additional 180 days for this. In the end, it can take 390 days total statutory time, more than a year before the animal

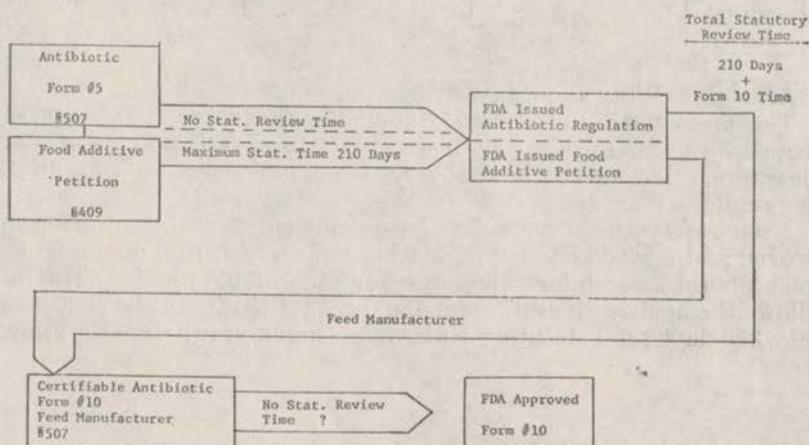
feed can be marketed. Our experience has been that the total elapsed time is frequently much greater. (See exhibit VI.)

EXHIBIT VI
PRESENT REGULATORY CLEARANCE PROCEDURE
For
New Animal Drug For Feed, Food-Producing Animal



Antibiotics for use in animal feeds have similar requirements. They are processed under two sections; 507 has no time limit, 409 has 210 days. There also is no time limit on the application of a feed manufacturer to get approval of his finished feed. (See exhibit VII.)

EXHIBIT VII
PRESENT REGULATORY CLEARANCE PROCEDURE
For
Certifiable Antibiotic For Animal Feed - Food-Producing Animal



Now let us put them all together—this collection of confusing and inconsistent statutory provisions is delaying the approval of new animal drugs that could save farmers and housewives millions of dollars every year. The requirements conflict in many areas and the time for approval often drags on for years. (See exhibit VIII.)

EXHIBIT VIII

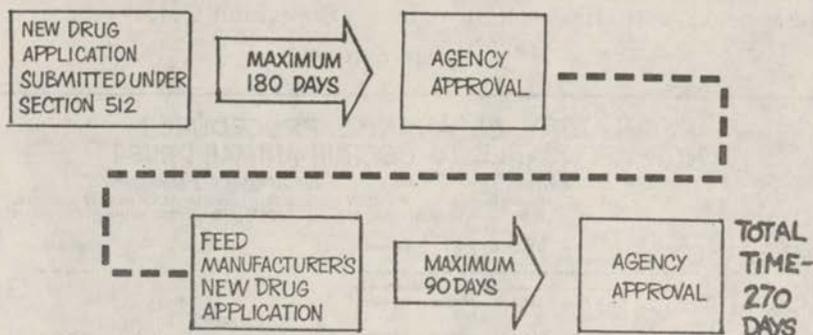
REGULATORY CLEARANCE PROCEDURES NOW APPLICABLE TO CERTAIN ANIMAL DRUGS										
PRIMARY CLEARANCE					SECONDARY CLEARANCES					
TYPE	DRUG USE	APPLI- CATION	CONSIDER- ATION	BASIC CLEARANCE TIME	STATUTORY TIME	APPLI- CATION	CONSIDER- ATION	CLEAR- ANCE	STATUTORY TIME	CUMULATIVE STATUTORY TIME
NEW ANIMAL DRUG	NON-FOOD PRODUCING ANIMAL	NEW DRUG APPLICATION	SEC. 505	APPROVED NDA	180 DAYS			NONE		180 DAYS
NEW ANIMAL DRUG	FOOD PRODUCING ANIMAL	NEW DRUG APPLICATION	SEC. 505	APPROVED NDA	180 DAYS			NONE		210 DAYS
		PETITION	SEC. 409	ISSUED REG.	210 DAYS					
CERTIFIABLE ANIMAL ANTIBIOTIC	NON-FOOD PRODUCING ANIMAL	ANTIBIOTIC FORM 5	SEC. 507	ISSUED REG.	NONE			MAY REQUIRE INDIVIDUAL BATCH CERTIFICATION		NONE
CERTIFIABLE ANIMAL ANTIBIOTIC	FOOD PRODUCING ANIMAL	ANTIBIOTIC FORM 5	SEC. 507	ISSUED REG.	NONE			MAY REQUIRE INDIVIDUAL BATCH CERTIFICATION		210 DAYS
		PETITION	SEC. 409	ISSUED REG.	210 DAYS					
NEW DRUG ANIMAL FEED	FOOD PRODUCING ANIMAL	NEW DRUG APPLICATION	SEC. 505	(NADA FILE)	180 DAYS	FEED MFR.	NEW DRUG APPLICATION	APPROVED NDA	180 DAYS 390 DAYS	
		PETITION	SEC. 409	ISSUED REG.	210 DAYS					
CERTIFIABLE ANIMAL FEED	FOOD PRODUCING ANIMAL	ANTIBIOTIC FORM 5	SEC. 507	ISSUED REG.	NONE	FEED MFR.	ANTIBIOTIC FORM 10	APPROVED NDA	NONE PLUS FORM 10 TIME	210 DAYS
		PETITION	SEC. 409	ISSUED REG.	210 DAYS					
FEDERAL FOOD, DRUG AND COSMETIC ACT			SEC. 505	---	SEC. 507	---	SEC. 409	---		

The proposed animal drug amendments would establish a single procedure for handling animal drugs under a new section of the act. Food additives, noncertifiable antibiotics and new drugs all would be processed under this section. The manufacturer would submit an application giving complete information about safety, effectiveness, components, controls, facilities, and labeling. He also would supply a practical analytical assay method. The agency would have 180 days to approve the new drug, to deny the application or call for additional information. If the product is not to be used in animal feeds, it could be marketed in 180 days.

Approval would include the publication of regulations specifying purposes and conditions of use, tolerances, withdrawal periods, and similar safety rules. If it is to be used in animal feed, mills would apply for approval prior to marketing. Since safety and effectiveness of the drug have been established, just 90 days is allowed to process the mill's application. The new feed additive could be on the market in 9 months instead of 14 months. (See exhibit IX.)

H.R. 7655 retains all of the standards of safety and effectiveness necessary for the protection of the public health. It does not in any manner shortcut the procedures now in the law. Instead it retains all of the safeguards.

PROPOSED ANIMAL DRUG CLEARANCE UNDER H.R. 7655



All applications must include:

1. Reports of investigations demonstrating safety and effectiveness.
2. List of articles used as components.
3. Statement of composition.
4. Description of methods and facilities for manufacturing, processing, and packaging.
5. A sample of the drug.

Labels must show how the drug is to be used by the feed manufacturer.

A sample label is required for each new drug or feed additive. The label must give the user all the information he needs for safe, effective use of the drug.

Under the bill it is necessary to describe practical methods for determining the quantity of the drug in food and any substance formed in or on food due to the drug. Another requirement is that proposed tolerances or withdrawal periods be cited if they are required.

For example, if safety requires that cattle be taken off a feed additive for a certain number of days before going to market, this time-span must be specified.

Each application will be subject to very careful review under the direction of the Secretary of Health, Education, and Welfare. Here are the points that will be studied:

1. Tests must prove that the drug is safe for use under the conditions prescribed.
2. Manufacturing and processing must preserve the identity, strength, quality, and purity.
3. There must be substantial evidence that the drug is effective.
4. Tolerances must not exceed those reasonably required to accomplish the intended effects.
5. Labeling must not be false or misleading in any particular.

6. Current safeguards to avoid cancer must be observed.

You will recognize that all existing criteria for evaluation have been carried over into the proposed new animal drug clearance section.

H.R. 7655 proposes shorter time for approval of feed additives in feed.

Under the proposed new section, the time permitted for approval of a feed manufacturer's new drug application for use of a new drug in feed is cut to 90 days. The reason for this is that the application is simply for the use in feed of a new drug that already has been approved. Since the safety and effectiveness have been previously established in the drug manufacturer's new drug application, all that remains to be approved are the feed manufacturer's ingredients, controls, facilities, and label. This 90-day period on a feed manufacturer's new drug application is a very generous period of time and could well be shortened. Clearance for new drugs remain at 6 months.

Let us sum up the benefits.

The enactment of H.R. 7655 will facilitate the development of animal drugs, and eliminate the delays caused by multiple clearances. Regulations can be developed specifically for animal drugs and approval will no longer be based on rules developed for human drugs.

The animal health professions and the industry will avoid the problems that have resulted from contradictory policies on animal drugs. And most important of all, the Congress will have established how premarketing clearance for new animal drugs must be handled.

Consolidation of all animal health activity into a single new section offers the opportunity to develop specialization within the agency. Responsibility in the hands of a single group should mean better control of these compounds.

This bill will encourage more animal health research.

Better designed approval procedures will free more scientists for basic research, and permit industry to explore many promising new fields. There are only limited product development dollars available. Let us spend them in research rather than in struggling through administrative redtape.

It could mean millions of dollars a year more income to farmers.

The \$2.8 billion loss to U.S. livestock and poultry producers can be substantially reduced through the development of new drugs. We will never completely eliminate losses—but it certainly is possible to cut them by millions of dollars a year. Look what this could mean to the farmer.

Fighting agricultural losses is a very worthwhile contribution to the future well-being of America. It means more income in farming, the country's largest single industry. And for consumers it means more food, and better food at lower prices.

The Animal Health Institute endorses and recommends the passage of H.R. 7655.

Thank you very much.

Mr. JARMAN. Does that complete your presentation?

Mr. BROWER. That completes our testimony.

Mr. JARMAN. You gentlemen heard Dr. Goddard's statement at the beginning of the committee's session in which he indicated that the bill would be acceptable to the Department if certain amendments are made to the bill.

Would you at this time care to make any comment on the suggested amendments?

Mr. BROWER. Mr. Chairman, we have not had the privilege of seeing these suggested amendments and so cannot comment at this time, but I assure you that such comments will be forwarded to your committee from the association.

Mr. JARMAN. It would be helpful to us.
(The information requested follows:)

ANIMAL HEALTH INSTITUTE,
Washington, D.C., June 28, 1966.

Re H.R. 7655, Animal Drug Amendments of 1965.

HON. JOHN JARMAN,
Chairman, Subcommittee on Public Health and Welfare,
House of Representatives, Washington, D.C.

MY DEAR MR. JARMAN: The following are the views of the Animal Health Institute on the amendments referred to by Commissioner Goddard in the course of his testimony before your Subcommittee on June 13, 1966, and set forth in the Report of the Department of Health, Education, and Welfare of the same date signed by the Honorable Wilbur J. Cohen, the accompanying Staff Memorandum and the Committee Print of the Bill dated June 14, 1966. Our recommendations on certain other amendments proposed during the hearing are also set out below.

We have carefully analyzed the amendments advanced by Under Secretary Cohen and Commissioner Goddard and are willing to accept many of them. Specifically these are:¹

Item 1: *Veterinary antibiotics.*

Item 2: *Residue of veterinary drugs in food for humans.*

Item 4: *Data to be submitted by manufacturer of medicated feed, and conditions of approval of his application.*

Item 5: *Effect of withdrawal of approval of a drug on the right to continue to use the drug in feed.*

NOTE.—With respect to Items 4 and 5, we are in basic agreement with the suggestions made except for the concept of approval of a new animal drug application by the issuance of a "regulation". Our recommendation in this respect is discussed in detail below.

Item 6: *Additional amendments (other than amendments to the transitional provisions).*

NOTE.—We are in disagreement with paragraphs (e) and (h) of Item 6, as explained below.

The amendments with which we are not in agreement are as follows:

ITEM 3

The new language appearing in lines 5 through 13 on page three of the Committee Print makes the drug manufacturer responsible for the use or misuse of his products by the feed manufacturer. This would arbitrarily impose on the drug manufacturer penalties of criminal liability, injunction and seizure for acts for which he is not responsible and cannot control. Such penalties are not imposed by present law. In no other situation under the Food, Drug, and Cosmetic Act is any manufacturer responsible for acts beyond his control, *i.e.*, the misuse of his products by a subsequent processor, manufacturer, or distributor.

H.R. 7655 would require specific approvals (as required by present law) for both the basic drug manufacturer and the manufacturer of an animal feed containing a new animal drug. Each manufacturer is responsible for handling the drug in accordance with the approval granted to him.

¹ These Item numbers and headings correspond to those in the Report and Staff Memorandum.

Under the present law and the Bill as introduced, the Food and Drug Administration has adequate authority to protect the public health without imposing arbitrary penalties on the drug manufacturer for acts beyond his control. Its present powers include

- (1) its capacity to approve and revoke the individual new drug applications of both basic drug manufacturers and manufacturers of medicated feeds;
- (2) its "establishment" registration and inspection procedures;
- (3) the good manufacturing practices regulations applicable both to drug manufacturers and to feed manufacturers; and
- (4) its powers of seizure, injunction and the imposition of criminal liability.

The amendment proposed in Item 3 would not afford any additional meaningful safeguard for the public health. The foregoing must be considered wholly apart from the questions of constitutional magnitude raised by this particular proposed extension of absolute criminal liability.

We therefore strongly urge the deletion of lines 5 through 13 on page 3 of the Committee Print.

ITEMS 4 AND 5

While we are in general agreement with the amendments set forth in these Items relating to publication of new animal drug approvals and their suspension or withdrawal subsequent to the effective date of the Bill, we note with concern the Department's position that publication of the approval "would be a regulation analogous to those published under the Food Additives Amendment." New drug applications are considered and approved on the basis of the data in the application or such other data as the Secretary may have before him. Once approval is granted there is no need for the issuance of a regulation with an invitation for comments, objections or hearing. The purposes of the Act are met and the public informed of the approved use of the drug simply by the publication of a "notice" in the Federal Register of the approved indications and conditions of use of the new animal drug.

The adoption of the "publication by regulation" concept as opposed to publication by notice could result in needless delays of the type which H.R. 7655 as introduced was intended to avoid.

We accordingly propose that the relevant portions of the Committee Print be modified in the following manner:

Page thirteen, line 20 through page fourteen, line 12 should be amended to read:

(i) When a new animal drug application filed pursuant to subsection (b) is approved, the Secretary shall publish by notice 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, 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."

NOTE.—The sentence beginning on page fourteen, line 7 has been deleted as surplusage for the Secretary already may and does announce by notice in the Federal Register the proposed withdrawal or suspension of approved new drug applications. He may continue to do so without any further grant of authority.

Page sixteen, line 21: Substitute for "regulation or regulations" the words "approval or approvals".

Page eighteen, line 7: Substitute for "a regulation" the words "an approval".

Page eighteen, line 12: Substitute for "regulation" the word "approval".

Page nineteen, lines 10 and 11: Substitute for "a regulation" the words "an approval".

ITEM 6E

The word "representative" should be inserted at the end of line 25 on page four. This will provide for the submission of feed samples which are typical of the intended uses of the drug but will avoid the submissions of all possible feed formulations in which the drug's concentration remains constant.

ITEM 6H

We propose that the word "material" be inserted at the end of line 3 on page eleven and at the end of line 25 on page nineteen of the Committee Print. The word "material" is used elsewhere in similar context in the basic Act and current regulations.

ITEM 7

The transitional provisions proposed in the Staff Memorandum reflect a commendable effort to shorten and simplify the ones appearing in the Bill as introduced. However, they fail to cover "master files" which, as of the effective date, may not have been converted administratively by the Food and Drug Administration to the status of approved new drug applications, as well as applications which had been submitted but not "filed" on the day preceding the effective date. Moreover, subsection (b) (3) of section 107, appearing at lines 12 through 24 on page thirty-six of the Committee Print, departs markedly from the comparable transitional provision (section 107 (c) (4)) of the Drug Amendments of 1962. The Drug Amendments of 1962 were applicable to drugs for animal use as well as drugs for human use. H.R. 7655 relates solely to drugs for animal use and the previously applicable transitional provisions affecting animal drugs should be preserved without modification. Any change in the transitional provisions of the 1962 Amendments would constitute a substantive change in the law and in the rights and protection afforded the animal health and nutrition industry and the veterinary medical profession. Accordingly the language shown as deleted in lines 5 through 12 on page thirty-three of the Committee Print should be retained, as set forth below, as subsection (b) (3) of the transitional provisions.

The sentence appearing on page thirty-six, lines 9 through 11 of the Committee Print, relevant to publication of prior new animal drug approvals, should be deleted. This requirement would be a carry-over from the period when H.R. 7247 was considered by the 88th Congress. Under that Bill feed manufacturers would not have been required to apply for new drug applications for feeds containing new animal drugs; they would simply have had to comply with published approvals. Inasmuch as such manufacturers have information on existing new animal drug approvals through a variety of sources, it is unnecessary for the staff of the Agency to assume the burden of mechanically collating and publishing such approvals for use by these manufacturers.

Accordingly, we propose that lines 3 through 24 on page thirty-six of the Committee Print be revised to read as follows:

"(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, as such terms are defined in the basic Act as amended by this Act, whether granted by approval of a new drug application, antibiotic regulation, food additive regulation, or master file, shall be deemed an approved application under section 511 of the basic Act as amended by this Act, 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) Any application or petition under section 409, 505 or 507 of the basic Act which has been submitted and is pending on the effective date shall be deemed, if it covers a new animal drug, or an animal feed bearing or containing a new animal drug, to be an application pending under the applicable provisions of section 511 of the basic Act as amended by this Act, and the filing date under such section 511 shall be deemed to be the date on which the petition or application was actually filed.

"(4) In the case of any drug (except a drug subject to section 511 (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 being 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 (v) as added by this Act shall not apply to such drug when intended solely for use under conditions prescribed, recommended, or suggested in labeling with respect to that drug on that day."

Paragraph (4) on line 25 should be renumbered "(5)".

TECHNICAL CORRECTIONS

We note in the Committee Print the following typographical errors and omissions which require correction:

- a) Page two, line 18: insert a comma after the word "drug".

b) Page twelve, line 5 and page twenty-nine, line 5: The numeral one should be changed to the letter (1) (as in the word "all").

c) Page seventeen, line 20 *et seq.*, should read: "*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—*".

d) Page twenty-six, lines 15 and 16: remove the comma after the word "feed" in line 15 and insert a comma after the word "feed" in line 16.

e) Page twenty-seven, line 9 should read: "or for a material time under such conditions; or".

During the hearing held June 13, 1966, Mr. Charles W. Klinger, a representative of the American Feed Manufacturers Association, recommended that H.R. 7655 be amended in two respects. He suggested that the 90-day statutory time for acting upon feed manufacturers' applications be reduced to 30 days (see page seventeen, line 6). He also proposed the deletion of the export limitation (see page twenty-nine, lines 9 through 16). We have appraised these recommendations and concur in their adoption. In the event the 30-day time limit referred to above is deemed too short, we strongly urge the adoption of a 60-day time limit for consideration of feed manufacturers' applications.

H.R. 7655 is intended to consolidate the clearance procedures applicable to new animal drugs under a new section in the Act without substantive modifications of existing law. We trust the foregoing comments are consistent with these objectives and constitute a constructive review of the recommendations made by representatives of the Department of Health, Education, and Welfare and others. We respectfully request that this letter be made a part of the record of the June 13, 1966, hearings on H.R. 7655.

Sincerely yours,

LEWIS E. HARRIS, *President.*

Mr. JARMAN. Mr. Mackay?

Mr. MACKAY. No, thank you.

Mr. JARMAN. Mr. Nelsen.

Mr. NELSEN. Thank you, Mr. Chairman.

I noted in the testimony it was suggested that the time that would be consumed in approving an application would be about 90 days, or could be, under the terms of this proposal.

In the event that the agency does not have adequate personnel there could be a problem in processing applications. This, of course, you could anticipate, could you not?

Mr. BROWER. Yes.

Mr. NELSEN. My feeling is that a bill of this kind generally will be criticized as being an attempt to cut corners without affording adequate protection to the public, but I gather from your statement and from the statement of the Department that there are no shortcuts taken in this legislation.

It actually is an attempt to bring about a more competent and efficient handling by eliminating the need for going through various different supervisory agencies for clearances.

Is that not true?

Mr. BROWER. That is very true.

Mr. NELSEN. You have had no opportunity to check the amendments that have been suggested, I understand?

Mr. BROWER. We have not seen them.

Mr. NELSEN. I would like, Mr. Chairman, to see that the industry has an opportunity to review the proposed amendments. They may be acceptable. I hope they are.

It would seem to me that we would then be in a much better position to bring this bill to the floor for what we hope to be final passage.

I thank the gentleman for his fine statement.

Mr. JARMAN. Thank you.

Mr. Gilligan?

Mr. GILLIGAN. Thank you. I have no questions, Mr. Chairman.

Mr. JARMAN. Dr. Carter?

Mr. CARTER. No questions.

Mr. JARMAN. Mr. Cunningham?

Mr. CUNNINGHAM. No questions.

Mr. JARMAN. Thank you very much, gentlemen.

Mr. BROWER. Thank you, sir.

Mr. JARMAN. At this time the Chair yields the microphone to our distinguished colleague from Nebraska, Mr. Cunningham, who will introduce our next witness.

Mr. CUNNINGHAM. Thank you, Mr. Chairman.

I am not a member of this fine subcommittee, but am a member of the full committee and I know of the good work that you are doing, and I appreciate very much the opportunity you have afforded me to introduce this witness.

He is Mr. Lewis E. Harris. He is a highly respected professional man from the State of Nebraska. He is president of Norden Laboratories of Lincoln, Nebr., manufacturers of pharmaceutical and biologicals for animal use.

Mr. Harris is also the president of the Animal Health Institute, so, Mr. Chairman and members of the committee, it is my great pleasure to present to you Mr. Harris.

STATEMENT OF LEWIS E. HARRIS, PRESIDENT, ANIMAL HEALTH INSTITUTE

Mr. HARRIS. Thank you, Congressman Cunningham.

Mr. JARMAN. The Chair appreciates your being with us this morning.

Mr. HARRIS. Thank you.

Mr. Chairman and members of the committee, my name is Lewis E. Harris. I am president of Norden Laboratories, Inc., of Lincoln, Nebr., a subsidiary of Smith Kline & French Laboratories, and I am also the president of the Animal Health Institute.

Norden is a small manufacturer of pharmaceuticals and biologicals for veterinary medical use. Our products are sold to veterinarians throughout the United States. We also export to 15 foreign countries.

The firm was founded in 1919 by Dr. Carl J. Norden and has enjoyed steady growth. We are now building new facilities for future expansion.

My testimony is in support of H.R. 7655.

The Federal Food, Drug, and Cosmetic Act, as amended, primarily regulates drugs for human use while animal drugs are covered by the act, they have always been given "stepchild" status. Since regulations under the act were primarily designed for human drugs, little attention has been given to specific problems related to animal drugs.

For many years, we in the animal drug industry have been handicapped and delayed by this burdensome procedure. Strange as it seems, it is sometimes more difficult to secure clearance for a new drug used to treat a farmer's hog than to clear a drug used to treat his child.

The present Food and Drug Act frequently results in multiple reviews of the same data submitted for a single new animal drug.

Instead of these reviews being made concurrently, in many instances one group within the Food and Drug Administration waits for the opinion of another before proceeding. Disagreements sometimes develop between divisions, based more on academic views than sound medical veterinary considerations. Correlation of these multiple reviews and viewpoints becomes difficult, if not impossible, and long periods of inactivity occur. Indeed, we have had some instances where new drug applications and supplemental data have been completely lost.

My company has been a victim of the present chaotic system of duplication and triplication of controls over animal drugs. Trying to obtain new animal drug clearances within the framework of the existing law has needlessly increased our development costs by an estimated 25 percent. Further, it has unnecessarily delayed the introduction of new and important animal drugs from 6 to 12 months.

Norden Laboratories strongly supports adequate and rigid laws to assure the safety and efficacy of drugs. H.R. 7655 offers an opportunity to eliminate the cumbersome and unnecessary multiple reviews of new animal drug applications. It streamlines the handling of clearances and reduces the workload for the Food and Drug Administration, but still retains all necessary restrictions for the protection of public health.

Proper recognition must be given to the cooperation and understanding which has been exhibited by the Food and Drug Administration personnel in trying to cope with the difficult situations created by the present act. They have been as frustrated and concerned about problems created by existing law as have industry representatives.

Some changes in forms have been made by the agency in an effort to improve procedures. The Division of Veterinary Medicine has been raised in status to that of a Bureau. An experienced and capable public servant, Dr. M. R. Clarkson, has been appointed to direct the Bureau. We heartily endorse these changes but they will not solve the problems created by the law in its present form.

It is my opinion that H.R. 7655 is clearly in the public interest and I respectfully request your favorable consideration of this measure.

Thank you, gentlemen.

Mr. MACKAY (presiding). Thank you, Mr. Harris.

Mr. Gilligan?

Mr. GILLIGAN. No questions, Mr. Chairman.

Mr. MACKAY. Mr. Nelsen?

Mr. NELSEN. I noted your statement regarding the reorganization with Dr. Clarkson being in charge of this particular activity. It would seem to me that since this reorganization has taken place, it is a recognition of the fact that there has been a problem which needs to be solved. I take it that you feel that this legislation is necessary to further develop a desirable efficiency in the processing of these applications.

Mr. HARRIS. Yes, sir; this is correct.

Mr. NELSEN. Over and beyond what has been done by reorganization within the Department?

Mr. HARRIS. Yes, sir.

Mr. NELSEN. Thank you.

Mr. MACKAY. Dr. Carter?

Mr. CARTER. No questions.

Mr. MACKAY. Mr. Cunningham?

Mr. CUNNINGHAM. No questions.

Mr. MACKAY. Thank you very much, Mr. Harris.

Mr. HARRIS. Thank you.

Mr. MACKAY. The next witness is Dr. John G. Salsbury.

STATEMENT OF JOHN G. SALSBUURY, MEMBER, BOARD OF DIRECTORS, ANIMAL HEALTH INSTITUTE, SALSBUURY LABORATORIES

Dr. SALSBUURY. Mr. Chairman and members of the subcommittee, I am John G. Salsbury, president of Salsbury Laboratories, Charles City, Iowa. I am also a member of the board of directors of the Animal Health Institute and wish to make a statement in support of H.R. 7655.

In operation since 1926, our company, founded by my father, Dr. J. E. Salsbury, is now a prime supplier of drugs, chemicals, pharmaceuticals, and biologics to the poultry industry. While we are small in size compared to some of the our competitors, our specialization in the poultry field has afforded us growth opportunities.

When we started in business, annual poultry production was approximately 250 million birds, most of which were dedicated to egg production. Today annual poultry production is 12 times that number of birds, including: 2,500 million broilers, 350 million layers, 100 million turkeys.

Our business has grown steadily over the years. Time was when most of our sales were in packaged pharmaceuticals used by several million small farmers. Today our main endeavor is in the area of feed additives, growth stimulants, coccidiostats, histomonastats, and biologics.

One of the main reasons for our growth has been specialized research. By concentrating on a small segment of agri-business, we have carved a niche in the animal health field. Of a total of 500 employees, we have approximately 80 in research and have committed an ever-increasing share of our sales dollar to new product development.

Even as a small company we have aspirations for growth and diversification, for in business as in other endeavors, you must grow. In recent years we have diversified into the cat and dog biological field and into the international sales field. We have enjoyed the good will of a large segment of the poultry business for many years. This good will, we believe, is based upon:

1. Good products;
2. Truthfully sold;
3. With quality guaranteed.

A small company such as ours finds the competitive climate increasingly keen. However, our philosophy has always been that business is an endeavor wherein one group of men establish an edge by making fewer mistakes than their competitors. We like to think that our group has distinguished themselves by working a little harder and a little longer than the other guy. We are pleased with the results of our labor.

The Food and Drug Act imposes the same stringent controls on both large and small companies alike. We, of course, are willing to

meet the formidable challenge of any requirements which are necessary for the protection of the public health. It is extremely difficult, however, for a small company to comprehend and cope with multiple controls based, not on reason and necessity, but on defective statutory structure.

We have a high regard for the public servants in the FDA. Our complaint against the Food and Drug Administration has not been in the ultimate judgments and decisions rendered, but only in the fact that it takes so long to get to the point of decision.

Multiplicity of paperwork, of review, of authority, and of decision-making caused by the present cumbersome law has made it difficult for even our most patient public servants to do justice to new drug clearances.

It is our belief that the present law has caused confusion and friction due to the unworkable nature of the overlapping responsibilities. In theory, the multiple reviews are to take place simultaneously, but in practice everyone is waiting for the other guy to act, lest needless effort be expended on an application.

With respect to protocols, or research test design, we have found that in some areas of food and drug, protocols are well established, well communicated, and predictable, while in other areas protocols are nonexistent, poorly communicated, and ever changing.

In other words, at times we had no measuring stick with which to gage our research effectiveness. At other times the measuring stick was established only to be changed by the Administration's whim before the results of our research could be evaluated.

At other times we have been caught in a crossfire of academic arguments raging within the various scientific disciplines of the Food and Drug Administration. Multiple reviews of new drug submissions have placed an undue stress on the law which, I am sure, was never the intent of Congress.

FDA does not have a monopoly on inefficiency. Industry, too, must share some part of the burden for the apparent slowness. We have not always communicated precisely, and at times have placed insufficient data at the disposal of the Food and Drug Administration.

I would like to commend the new aggressive and alert management that is manifesting itself at FDA. Certainly the changes and the apparent interest in cooperating with industry are like a breath of fresh air.

However, an opportunity now presents itself for the Congress to implement the positive moves of the past 6 months by streamlining the statutory procedure for clearing new animal drugs. I believe that by this move a great service will be done for the American people, the public health and animal health, if you will.

Speaking from the standpoint of small business, I believe that H.R. 7655 represents an opportunity to eliminate the unnecessarily cumbersome provisions of the present law without, in any manner, jeopardizing the public health.

Thank you, gentlemen.

Mr. JARMAN. Thank you, Doctor.

Are there any questions?

Mr. MACKAY. Thank you, Mr. Chairman.

Dr. Salsbury, I was interested in your statistics about the increase of poultry production. Were those for the Nation?

Dr. SALSBUARY. These are for the Nation, yes.

Mr. MACKAY. Secondly, I was interested in the mechanics of this approval. Is all of this done through the Washington office? Is it necessary for a representative of your company to come to Washington? Do you handle this by mail, or do you have people come to your plant?

Dr. SALSBUARY. We have Mr. Freeze, who was introduced here as our Washington representative, and he is probably spending about one-third of his time in Washington or traveling.

Mr. MACKAY. I was interested also in your mentioning the problem of small business against the large business.

Is it necessary for your individual business to send its own representative, or do you send it through an association representative?

Dr. SALSBUARY. No; we send our own representative. I don't think that the association representative does this type of work.

Mr. MACKAY. So the cost would be just as great to your company individually as it would be to a large company; is that right?

Dr. SALSBUARY. Probably to clear a product, yes.

Mr. MACKAY. But the main thrust of this bill is to coordinate the activity within the Department. It doesn't really cut out any other steps, does it?

Dr. SALSBUARY. No, it wouldn't. It is primarily to coordinate this work within the Food and Drug Administration.

Mr. MACKAY. Thank you very much.

No further questions.

Mr. JARMAN. Mr. Nelsen.

Mr. NELSEN. I wish to thank the gentleman for his fine statement. I, of course, realize, and I am sure he realizes, as we all do, that within the Food and Drug Administration they are required to act as the law provides, so some of the delays that may have existed are probably due to the guidelines set up by the law. As I understand the witnesses today, it is your hope, and it is certainly ours, that the laws may be streamlined to provide speedier handling as well as proper protection for the public. Is that not true?

Dr. SALSBUARY. This is true. This is what we hope in this proposed legislation.

Mr. NELSEN. One question perhaps not related to this bill, but knowing that your firm has long been in business, I recall that years ago on the farm we had one cure for everything. That was Dr. Hess' Stock Tonic. Whatever happened to it.

Dr. SALSBUARY. I am not sure whether that is on the market yet or not. You would have to ask Dr. Goddard.

Mr. JARMAN. Mr. Gilligan?

Mr. GILLIGAN. Doctor, you make reference in your statement to protocols, or research test design, and said that in some areas of Food and Drug protocols were well established, well communicated, and predictable, while in other areas protocols were nonexistent, poorly communicated, and everchanging.

Is there anything in the proposed legislation which would help to clear up that problem?

Dr. SALSBUURY. As I see it, it would bring all of the animal drugs under one section and then the protocols probably will be handled by one bureau, whereas in the past we have had, say, the efficacy of the product handled by one section and the toxicology handled by another, and there have been differences here.

Mr. GILLIGAN. But then what this really is is a fond hope that the legislation will indirectly bring about these benefits; is that right?

Dr. SALSBUURY. I think that is the intent, yes.

Mr. GILLIGAN. Thank you, sir.

No more questions.

Mr. JARMAN. Dr. Carter?

Mr. CARTER. No questions.

Mr. JARMAN. Dr. Salsbury, you in your statement refer to the fact that it takes a long time to get to the point of decision by the Food and Drug Administration.

The testimony we had this morning from Dr. Goddard was that a year ago the time consumed in handling all applications varied from 3 to 6 months.

By contrast, this year, he stated, that the time consumed in handling has been reduced to an average of 90 and 30 days, respectively.

Does your own company have any real difficulty now in terms of timelags on applications that you have?

Dr. SALSBUURY. I think probably the timelags are due to additional data or clarification of the data that they want from us, that they have asked us for.

Mr. JARMAN. Is the situation better than it was previously?

Dr. SALSBUURY. I would say it is definitely better than it was a year ago, yes.

Mr. JARMAN. Yet, as I understand it, under the more complicated procedure under which we now operate if an avalanche of applications came in we could again be faced with a serious timelag in processing applications. Am I correct?

Dr. SALSBUURY. I am not really familiar with what could happen if they did get a number of applications. Would you like to answer that?

Mr. JARMAN. That would be a comment on whether the personnel are adequate now to process any given number of applications that may come in. I do remember from the testimony before the subcommittee 2 years ago that a point was made that the application situation was getting more current, but that if a great many applications came in on a particular type drug, the situation could deteriorate. Does that situation exist?

Mr. THOMAS W. FREEZE (vice president, Salsbury Laboratories). Mr. Chairman, I would like to comment on the statement that Dr. Goddard made.

He indicated that action is being taken on these applications, but in many cases the action taken is rejecting the application, asking for more data.

If you will check the Federal Register you will see very few animal health drugs being approved in the last six months to a year, but I think it is going to take time for this team to get geared up and I know that the Bureau of Veterinary Medicine is adding many, many more veterinarians to their staff and we are hopeful that the new

bureau will be able to act much faster because they will have so many more areas of competency within their bureau that they will not have to be coordinating with some of the groups across the river in toxicology, pharmacology, and the rest of these scientific disciplines.

You see, in many of the scientific disciplines like toxicology and pharmacology we are dealing basically with Ph. D.'s, but in the Bureau of Veterinary Medicine we are dealing with veterinarians who are familiar with the animal health industry.

This makes it much easier to establish protocols with men who understand the problem.

Mr. JARMAN. Thank you very much.

I would like to say again to the gentlemen on behalf of the committee and to all who are interested in this legislation than an analysis and comments on the amendments that have been suggested or that may be suggested by industry witnesses submitted to the committee would be very helpful in our own analysis of this proposed legislation.

Our next witness is Charles R. Fulton, president of Delmarva Poultry Industry Association.

Mr. Fulton, we appreciate your being with us.

STATEMENT OF CHARLES R. FULTON, PRESIDENT, DELMARVA POULTRY INDUSTRY, INC.

Mr. FULTON. Mr. Chairman and members of the subcommittee, my name is Charles R. Fulton and I am here today as president of the Delmarva Poultry Industry Association.

Our organization represents poultrymen in the portions of three States located on the Delmarva Peninsula—all of Delaware, nine Eastern Shore counties of Maryland and two counties of Virginia—a major broiler-fryer and egg-production area. My personal connection with the poultry industry is primarily as vice president of Holly Farms in charge of the Delmarva division. We are a completely integrated broiler operation. This includes production of hatching eggs, hatchery facilities, feed manufacturing, processing, byproducts, and the growing of approximately 75 million birds annually.

The Delaware Poultry Industry is an organization of over 5,000 growers, hatcherymen, feed manufacturers, poultry processors, equipment dealers, and other associated business concerns, including a great number of civic-minded citizens who are deeply interested in the important poultry industry in our area because of the direct relationship it has to the economy of Delmarva.

On behalf of our organization, I wish to endorse and urge the passage of H.R. 7655 because we feel this bill would be of considerable aid to the poultry industry and to our millions of consumer customers.

Since shortly after World War I, the Delmarva Peninsula has been a pioneer in the growing of commercial broilers and fryers, and it is generally recognized as the birthplace of today's multimillion-dollar broiler-fryer industry.

In the recent past, Delmarva has begun to diversify with increased production of table eggs, and many of our members are now in this phase of poultry husbandry. Our region nevertheless continues as a major broiler growing region, and indeed Sussex County, Del., is the Nation's leading broiler growing county.

To give you an idea of how the poultry industry has grown, let me point out that, as recently as 1950, broiler production was about 630 million birds; last year it was well over 2 billion. This means that broiler production has more than trebled in the last 15 years. The average retail price of ready-to-cook broilers has, at the same time, decreased from 57 cents per pound in 1950 to approximately 39 cents in 1965, a decrease of about 32 percent. During this same 15-year period, the Bureau of Labor Statistics combined index of all food prices rose from 85.8 to 108.8—an increase of 26.8 percent. Today almost any family can eat a chicken dinner anytime—and does, thank goodness. Last year our average per capita consumption of broilers in the United States was 29.4 pounds, in contrast to only 8.7 pounds just 15 years ago. Currently broilers and fryers account for nearly 90 percent of all chicken meat consumed in our country, in contrast to 42 percent back in 1950.

The level of progress made in efficiencies of production in the poultry industry is greater than in any other branch of agriculture. There was a time when broilers had to eke out their own existence by eating green grass to combine with the cracked corn being provided, and to find insects and beetles to provide the protein necessary to balance their diet.

Broiler rations today provide all the essential amino acids, vitamins, minerals, and antibiotics combined in proper proportions and formulated by electronic computers. Poultry nutrition is at the highest peak in scientific advancement in the nutrition field.

Not too many years ago broiler producers had 15 to 20 percent of their chicks die before they reached maturity. Due to the great progress made in disease prevention, it is not unusual for broiler producers to raise 99 to 100 percent of the chicks started.

Better breeding and management practices are certainly important reasons, but even more significant in bringing about these dramatic changes are the development and introduction of a variety of feed additives and other types of nutritional and therapeutic agents. Such progress has been a team effort with nutritionists, geneticists, poultry pathologists of our land-grant colleges, and commercial companies cooperating toward increased efficiencies and an improved meat-type bird.

Among commercial efforts, I would like to single out those of the pharmaceutical and nutritional additive manufacturers. We have found that the addition of a variety of drugs and nutritional substances to feeds and water increases our birds' rate of gain, decreases the quantity of feed they must consume to reach market weight or maximum egg production, and helps prevent outbreaks of many of the dangerous diseases that would otherwise attack our flocks.

With the history of vast increases in knowledge and improvements of our feed and water additives in the past decade, we have every reason to hope that research will continue to furnish us even more knowledge and better therapeutic and nutritional agents.

We at Delmarva Poultry Industry sincerely hope that this research and the application of its results will not be hampered by unnecessary restrictions from any sources. Feed manufacturers in our organization have pointed out to me that one aspect of the present law has proved extremely burdensome. On Delmarva we make our own feeds,

using components furnished by different suppliers. The Food and Drug Administration requires the feed manufacturer to submit a medicated feed application, form 1800, before we can incorporate a new drug into any of our feeds. In one instance it took 271 days, in another it took 14 months for the agency to approve two of our members' use of new drugs, even though the drug companies had obtained approval for the drugs themselves many months before the feed manufacturers' applications.

We agree that our feed manufacturers should have to demonstrate that they utilize good manufacturing and control procedures in making up their feeds, but they have given proof of this on numerous occasions by their submissions on previous feeds containing drug products. It seems absurd that such an extended period of time would be necessary for FDA's review of virtually the identical information previously submitted by these feed manufacturers, when the only significant differences related to drugs already accepted by the Food and Drug Administration in the name of the basic manufacturer. Deprived of the benefit of these drugs in the production of poultry, these feed manufacturers had no operating economies to pass on as consumer benefits.

When these instances of delay are multiplied by the many times in a year that we assume such instances occur, the total impact of the present clearance procedures can be readily understood. H.R. 7655 protects the public as well as the statute in its present form, but without causing time-consuming delays. It is a sound improvement in the law. In this one area of feed manufacturers' clearance, I understand that the feed manufacturer would still have to submit an application containing information as under present law but FDA would be permitted only 90 days to process the mill's application. Even considering this single aspect of the bill, it will be of great value both to our industry and to the millions of consumers whom we serve.

Science is indeed in back of our great poultry industry and has made it the critical source of feed supply that it is today. We want to continue to set new records of achievement, and we believe that the passage of H.R. 7655 is one step that will help the people of our great broiler industry as we move forward in reaching new goals.

I thank you very much.

Mr. JARMAN. Thank you, Mr. Fulton.

Are there any questions?

Mr. MACKAY. No questions.

Mr. GILLIGAN. No questions.

Mr. JARMAN. Mr. Nelsen.

Mr. NELSEN. One question.

Have you had an opportunity to study the proposed amendments?

Mr. FULTON. I have not, sir.

Mr. JARMAN. Mr. Fulton, we appreciate your helping us make the record this morning.

Mr. FULTON. We thank you for an opportunity to appear, sir.

Mr. JARMAN. Our next witness is Mr. Earl L. Butz, dean of agriculture, Purdue University.

Mr. Butz.

STATEMENT OF EARL L. BUTZ, DEAN OF AGRICULTURE, PURDUE UNIVERSITY

Mr. BUTZ. Mr. Chairman and members of the committee, my name is Earl Butz. For the past 8 years I have been dean of agriculture at Purdue University. For 3 years prior to that I was Assistant Secretary of Agriculture in charge of Marketing and Foreign Agriculture in the USDA. I had the pleasure at that time of serving in the same department with your good colleague, Ancher Nelsen, who did a very distinguished job as Administrator of the Rural Electrification Administration.

Prior to that, for 8 years, I was head of the department of agricultural economics at Purdue University. My entire professional life has been spent in the area of food and population problems, both at home and abroad.

My interest in the so-called Animal Drug Amendments Act, H.R. 7655, stems primarily from the interest of an agricultural economist in the developing world population food crisis, which I think is much more imminent than many people in this country and abroad are aware.

My interest stems from the importance of making it possible to apply science in increasing proportions to the world population-food problem. The North American food industry is facing its greatest challenge of all time.

Unless we exercise every opportunity promptly to meet this challenge, I think the world shortly will face a crisis of such proportions that we in the Western Hemisphere can't escape the repercussions that will come from it.

One such opportunity, I am sure, presents itself in H.R. 7655, which will encourage the development of new animal drugs, and will make it possible to get more mileage out of the existing supply of agricultural scientists we have.

There are too few of us in America who are aware of the magnitude of this developing world problem. The world is on a collision course. There are two trend lines developing that are significant. One is the trend line of world food production which is going up rather slowly. It is increasing by an arithmetic factor. Under it comes the trend line of world population which is increasing in geometric proportions. When the fairly stable trend line of world food production meets the much more rapidly increasing trend line of world population, unless we do something to soften the impact of that collision we are going to have real problems in the world and in the United States. This prospect faces us within the decade.

This is the seventh year with one exception, that world population has increased more rapidly than world food production. We have actually been in a decline, worldwide, in the population-food ratio in the last several years.

The first claim of any society on its total production resources is to produce enough food to keep the population alive and to reproduce itself. This is so simple it is axiomatic.

In some parts of the world, especially in some of the Asiatic countries, it takes from 85 to 90 percent of their total population on the

land or in the food business to keep them alive, and they don't do it very well, even so.

In this country we do it with less than 6 percent of our total working force on the farms of America. This is a remarkable record. We actually could do it with about 3 percent of our total working force on our farms if we consider only commercial agriculture.

The only way we can do that is by the application of large amounts of science and scientifically trained personnel in our total food production business.

There is room for substantial expansion of food production, both in this country and abroad, through the continued infusion of science, and capital, and nonrestrictive governmental programs that would let farmers and agricultural institutions exercise the full amount of science available.

To come back for a moment to the world population problem, it is estimated that at the beginning of the Christian era we had about 250 million people in the world. It took us 15 centuries to double that number, up to the year 1600. In the next three centuries we tripled world population.

It came to about 1.5 billion people at the start of this century. Since that time, just in two-thirds of a century, we have doubled world population again. It is in excess of 3 billion people today.

Demographers at the United Nations in New York estimate that by the year 2000, which is only a third of a century away, we will have doubled again, having in excess of 6 billion people in the world.

Obviously we can't continue indefinitely to increase at that rate. It is estimated that if from the beginning of the Christian era we had increased population at about the same rate we are today, there would not be standing room for all of us on the earth's surface. Obviously, that would be impossible, but the implications of it are frightening.

From the beginning of history man has learned how to feed about 3 billion people on the earth, and two-thirds of them not very well fed. The job ahead of us means that if we feed these people by the year 2000 at the same level of caloric intake which they eat today (and that is not too exciting for much of the world's population), if we feed them at the same level, our job in the short term of a third of a century will be to learn how to feed as many more people as we have learned to feed since the dawn of history.

This is a frightening prospect. This has to be done at a time when we have no more virgin territories of the world to exploit. We have no more prairie sods to turn, no more virgin forests to clear.

As a matter of fact, we have to do it at a time when we are losing productive land to urbanization, to highways, to airports, to parks. Every time we run one of those dual-land highways through the country it takes up 30 acres a mile, and I think that is taken out pretty permanently.

Every time we put a cloverleaf in a dual-lane highway it takes up 25 to 40 acres, and I think that is out pretty permanently.

The point I want to make is that science is the only thing we have to infuse into the agriculture of the next one-third of a century to meet this tremendous challenge we face. It is research. It is the very kind of thing we are talking about here today.

In the long run we have to meet the world population-food problem by population control. In the short run, given the social and religious mores, and low levels of literacy and economic well-being in many parts of the world, we simply can't accomplish that in this generation. That means, therefore, in the short run—I am talking now about the next third of a century—our only alternative is to increase the level of agricultural output both per acre and per man.

This includes the accelerated application of fertilizers, of irrigation, of better seed varieties, of more herbicides, more insecticides, improved animal drugs and animal health items, and extensive research expenditures of all kinds.

The opportunity for increased food production on the North American Continent is tremendous. You have heard this morning about the terrific toll taken by disease, by parasites, and by insects, that cost the American farmers about \$3 billion a year. It costs the American consumers at least that much or more. This loss stands in the way of a very substantial additional contribution of American agriculture in meeting the world's No. 1 problem—the developing world population-food ratio crisis.

Our urgent need now is for new agents to fight these costly food losses and to add to the available food supply all around the world. We must encourage these yet-to-be-developed growth stimulants and feed additives that we are talking about here this morning.

The North American Continent has the world's largest contiguous area of good food producing land, where we have the combination of fertile soil, of climate, of growing season, the capital and know-how to do the job. This area will be called upon to do a massive job of meeting this population-food gap in the years ahead.

The U.S. public conscience, I am convinced, has made a firm commitment that we are not going to permit starvation anywhere in the world to the extent that we can prevent it. While that is not written specifically into law, it is nonetheless a very real commitment. That means those of us in agriculture must keep our total food industry as healthy as possible. We must maintain public confidence in it. We must prepare our people to use our scientists and American agriculture plant to the full extent that we can do it.

I am convinced that H.R. 7655 is a step in that direction.

Mahatma Gandhi once remarked "Even God dare not approach a hungry man except in the form of bread." That underscores the importance of food in the struggle we face in the years ahead.

American agriculture can do a great job of applying science to this whole process. I regard agriculture simply as a converter of energy. The source of energy for us on this globe is the radiant energy from the solar system. We are not very efficient in taking it directly from the sun. In agriculture, we convert the energy to a form we can use.

We use the plant as a vehicle for conversion. We then use the animal as a vehicle for further conversion. We capture only about three-tenths of 1 percent of the solar energy that hits the earth in our food production processes.

As we convert the energy from crops into meat, milk, and eggs, again there is a great loss in efficiency because of the toll of parasites, of disease, of insects, and the like.

There is a great opportunity to infuse more science into our food machine. Five years hence, when the world food problem becomes more acute than now, the trained agricultural scientist will be the same kind of glamour boy that the physicist and the engineer were in the immediate postsputnik years.

The tragic thing is that it takes 6 years to develop a trained agricultural scientist. You can't do it in 6 weeks. The same is true of these animal health products. That is the reason, gentlemen, that I as an agricultural, educational, and scientific professional person, am interested in the enactment of this legislation.

Thank you very much.

Mr. JARMAN. Thank you, Dean.

Are there questions?

Mr. MACKAY. Thank you, Mr. Chairman.

I would just like to thank you for this testimony. It came through loud and clear. Although this is not the Committee on Agriculture, I would be interested in any thoughts you might have regarding action that this committee might take within the scope of its jurisdiction.

I think that my constituents have only a vague notion of the gravity of the developing situation you presented, but you presented it in such a clear way that I am going to try to transmit it to them.

Mr. BUTZ. Thank you very much, Mr. Congressman.

During my 3 years as Assistant Secretary I learned that you never assign work to one committee through another congressional committee. In answer to your question, there is clear evidence that the people in the Department of Agriculture are aware of the magnitude of this problem.

They have increased the rice acreage allotments. They have increased the wheat acreage allotments. However, many people feel the adjustments have not been rapid enough or gone far enough.

Mr. JARMAN. Mr. Nelsen.

Mr. NELSEN. Thank you, Mr. Chairman.

I wish to thank Mr. Butz for his very fine and informative statement.

In the few pages that you have put together you have supplied us with a tremendous amount of information that I think we will all find very useful and certainly very persuasive arguments for the need of any legislation to speed up our production and to streamline the handling of any processing of applications which we deal with today.

I might mention, Mr. Chairman, that in the years that I did serve in the Department of Agriculture it certainly was a great pleasure to have been associated with Dr. Butz, and our country has been well served by his service there and also in the post that he now holds, and I thank the witness very kindly for his appearance.

Mr. BUTZ. Thank you.

Mr. JARMAN. That is a very fine tribute. It is good to have you with us this morning, Dean Butz.

Mr. BUTZ. I thank you, sir.

(The complete statement of Dean Butz follows:)

STATEMENT OF EARL L. BUTZ, PH. D., DEAN OF AGRICULTURE, PURDUE UNIVERSITY

My name is Earl L. Butz. For the past eight years I have been Dean of Agriculture at Purdue University. For three years prior to that, from 1954 to 1957, I served as Assistant Secretary of Agriculture in charge of Marketing and

Foreign Agriculture. Among other things, I was in charge of the Foreign Agricultural Service and traveled extensively in many parts of the world, studying food and agriculture conditions. For eight years previously, I was head of the Department of Agricultural Economics and Professor of Agricultural Economics at Purdue. My entire professional life has placed me in close proximity with food-population problems, both in this country and abroad.

My interest in H.R. 7655, the "Animal Drug Amendments," is the interest of an agricultural economist concerned with the world crisis which is developing in the population-food ratio. The North American food industry is facing its greatest challenge of all time, and we must exercise every opportunity to prepare to meet it. One such opportunity presents itself in H.R. 7655, which will encourage the development of new animal drugs.

The world is on a collision course. When the massive force of an exploding world population meets the much more stable trend line of world food production, something must give. Unless we give increased attention now to softening the effects of the impending collision, many parts of the world, within a decade, will be skirting a disaster of such proportion as to threaten the peace and stability of the Western world itself.

The man-food ratio around the world, never high enough to be very exciting to two-thirds of the world's population, has actually been in a decline the past half dozen years. Total food output has increased during those years, to be sure, but at a slower rate than population increase. In many of the world's underdeveloped areas, the man-food ratio is in a serious decline.

The first claim of any society on its total production resources is to produce enough food to keep the population alive and reproducing itself. Some Far Eastern nations require 80 to 90 percent of their population on the land to get the job done. In the United States we do it with less than 6 percent of our working population on our farms. There is room for substantial expansion of food production, both in the undeveloped and in the developed areas of the world, through continued application of science, infusion of capital, and nonrestrictive governmental programs.

At the beginning of the Christian era, world population was estimated to have numbered around 250 million. In the next fifteen centuries it doubled, reaching 500 million by 1600. Three centuries later, by 1900, world population had tripled and stood at about 1.5 billion. In the less than two-thirds of a century since 1900, world population has approximately doubled again and now exceeds 3 billion. Reliable estimates indicate that, in the little over one-third of a century remaining until the year 2000, it will double again and will stand at about 6.3 billion people.

If, from the beginning of the Christian era, we had multiplied at the present rate, there would now be over one million people per square foot of earth surface. Obviously, the rate of growth cannot persist indefinitely, because of the sheer limitation of space and food. However, its frightening implications are a threat we must face.

From the beginning of history, man has always been in a struggle to feed himself, with the possible exception of the Western world in the past two or three decades. From the beginning of the human race until now, man gradually developed the food production capacity required to sustain 3 billion people on the earth, although many many persons have a very meager available food supply per capita. If the 6 billion-plus people predicted by the year 2000 are to be sustained, with no improvement in diet whatever, man will need to develop the capacity to feed another 3 billion people—and *this must be done in the short term of one-third of a century*. This means that we must duplicate in the next generation the production record that man has achieved since the dawn of history. And we must do this at a time when nearly all of the virgin lands of the world have been brought into production and when we face increasing inroads on arable land by spreading suburban communities, highways, and the like.

There are only two possible answers to the problem I have posed here. One is a widespread and rapid increase in birth control practices, which, in the long run—say, by the close of this century—is the only solution. The second—and the immediate need confronting us—is to increase agricultural production worldwide.

We must do everything possible to accelerate the application of capital and technology to our agricultural and food systems in an effort substantially to increase output per acre and per man. This includes accelerated application and use of fertilizers, irrigation, better seed varieties, more pesticides, new and improved animal drugs and agricultural chemicals, and extensive research expendi-

tures, including research to improve the genetic capabilities of plants and animals.

The opportunity for increased food production on the North American continent is tremendous. In the United States alone, disease, parasites, and insects cost American farmers almost \$3 billion each year through loss of animal livestock and poultry. Urgently needed are new agents to fight these costly food losses and add to the available food supply. Also holding tremendous promise for increasing the food supply are yet-to-be developed growth stimulants and feed additives which will improve the efficiency of animal protein production.

The North American continent, and primarily the United States, will be called upon within the decade for a massive effort to meet the impending crisis in the world population-food ratio. It must be a major responsibility of all of us to keep our national food-producing machine healthy and efficient. We must strengthen public confidence in the capacity of our food industry to meet the great challenge ahead of it. To prepare for less than this will be to condemn a large part of the world to widespread famine and political instability on a scale unprecedented in history. Hence, there is no realistic alternative except for us to gear up to meet this challenge.

H.R. 7655 will have the beneficial effect of speeding up the introduction of new animal drugs useful in the overall effort to meet this challenge. I commend this measure as a constructive attempt to advance the interests of our farmers and the consuming public.

Mr. JARMAN. Our next witness is Dr. Frank Todd, who will present a statement by Dr. Don Spangler, the president of the American Veterinary Medical Association.

Dr. Todd.

**STATEMENT OF DR. DON H. SPANGLER, PRESIDENT, PRESENTED
BY DR. FRANK A. TODD, WASHINGTON REPRESENTATIVE, ON
BEHALF OF AMERICAN VETERINARY MEDICAL ASSOCIATION**

Dr. TODD. I am Dr. Frank A. Todd, Washington representative of the American Veterinary Medical Association.

Dr. Don Spangler, president of the American Veterinary Medical Association, has prepared and submitted a statement on behalf of the association pertaining to H.R. 7655. Dr. Spangler has asked that I present it to this committee. It is short and I would like to read it for the record of this hearing.

At a hearing of this Congressional committee held September 1963, the American Veterinary Medical Association (AVMA) opposed a bill dealing with the same subject. The Food and Drug Administration (FDA) also opposed the bill. Following this hearing, an extended series of conferences were held involving representatives of the FDA, the AVMA and individuals responsible for writing the bill. Extensive revisions have changed the general character as well as the specific details of the proposal so that we consider H.R. 7655 to be a constructive compromise.

The current version of H.R. 7655 with the separate section 512 appears to be a conscientious effort to guarantee the same degree of safety, stability, potency and effectiveness in drugs and medicated feeds as would have been provided by the existing statutes.

The proposed section 512 appears to be a faithful reproduction for animal preparations of the current Food, Drug, and Cosmetic statutes which are applied in common to drugs for man and animals.

In its present form, H.R. 7655 appears to serve the best interests of the public. The American Veterinary Medical Association supports passage of H.R. 7655 as a measure also beneficial to the animal drug and medicated feed industry and therefore to the veterinary profession.

Respectfully submitted.

Dr. DON H. SPANGLER,
President, American Veterinary Medical Association.

The American Veterinary Medical Association appreciates this opportunity to present its views on H.R. 7655 and wishes to thank you, Mr. Chairman and members of the committee.

Mr. JARMAN. Thank you very much, Dr. Todd.

Mr. Nelsen?

Mr. NELSEN. No questions, except to make the observation that the bill that we are now considering is quite similar to legislation that our former colleague, Mr. Roberts of Alabama, introduced in the 88th Congress. I note Mr. Chairman, that Ken is in the audience, and I want to thank him for the leadership that he gave to proposals of this kind in years past. I am also aware of his continued interest which we appreciate very much.

I thank the gentleman for his statement.

Mr. JARMAN. Thank you, sir.

I appreciate the gentleman making that a part of the record.

Mr. Roberts has made an outstanding contribution to legislation in this general field and we rely on him for counsel and advice and it is good to have him with us in the hearing this morning.

Our final witness in the hearing this morning is Mr. Charles W. Klinger of the American Feed Manufacturers Association.

STATEMENT OF CHARLES W. KLINGER; ACCOMPANIED BY LEE H. BOYD, AMERICAN FEED MANUFACTURERS ASSOCIATION

Mr. KLINGER. Mr. Chairman and Mr. Nelsen, I am Charles W. Klinger, product control manager for Central Soya Co., Fort Wayne, Ind. For the past 7 years I have had the general responsibility of insuring compliance for my company with the Federal Food, Drug, and Cosmetic Act.

I am here today on behalf of the American Feed Manufacturers Association, of which Central Soya is an active member. Accompanying me is Mr. Lee H. Boyd, director of feed control and nutrition of that association. We would both like to express our appreciation for the opportunity to present our views concerning the proposed legislation.

Central Soya is a company serving agriculture through feed manufacturing, grain merchandising and soybean processing. The feed division is a multiple-plant operation serving over 3,500 feed dealers in the eastern two-thirds of the United States.

The American Feed Manufacturers Association was founded in 1909 and is a nonprofit national trade association for the feed manufacturing industry. Membership, which also includes related industries, represents all areas of the United States.

The feed industry is a vital segment of U.S. agriculture. Feed is the largest input in the production of animal products—about two-thirds of the cost of producing meat, milk, and eggs. It is estimated that half of the feed tonnage contains animal drugs.

The annual dollar volume of the feed industry is approximately \$4 billion—placing it among the top 15 manufacturing industries of our country. It is the largest industry in the world providing goods and services exclusively for agriculture.

The feed industry's interest in animal drugs and feed additives centers on the contributions they make to wholesome and economical

animal products. These additives are generally incorporated into feed for the purpose of increased production, improved feed efficiency, or for the prevention of disease. It is generally agreed that modern methods of poultry and livestock production, and the accompanying lower costs of animal products, could not have been realized without the development and use of feed additives.

We, as feed manufacturers, are not normally involved in the development and manufacture of animal drugs. It is the responsibility of the drug manufacturer to obtain basic clearance from the Food and Drug Administration. Therefore, feed manufacturers use only additives which have been approved by the FDA as being safe and effective when used under specified conditions. Thus, feed becomes a vehicle by which the animal producer can conveniently avail himself of these important production tools.

It is important to note that animal drugs when used in feed constitute a minute portion of the finished feed—much less than 1 percent of the feed. Thus, the drug potency of the finished feed product is quite different from the product produced by the drug manufacturer.

Feed manufacturers who use animal drugs in feed must register each of their mills with FDA annually and are subject to periodic inspection. Medicated feeds are continually sampled and analyzed by the FDA as well as by State feed officials, to provide assurance that the correct amount of the feed additives are being used.

In addition to these safeguards, each feed manufacturer is required to submit a detailed application to obtain further approval for every medicated feed (which incorporates a new animal drug) produced in each plant. Once obtained, this clearance must be kept current to reflect changes in equipment, procedures, formulation, and labeling. For the most part, these clearances are highly repetitious.

A company such as mine must obtain and continuously amend several hundred individual approvals for normal operations. The consumption of time, both by feed company personnel and the FDA staff, is tremendous.

For example, if 1,000 feed mills want to use a newly developed drug after it has been approved by FDA and appropriate regulations issued, FDA is then faced with the job of processing 1,000 applications. The system obviously is time consuming and costly to the taxpayer as well as to the feed firms. By its nature, it holds the threat of delays. Processing of feed company clearance applications has often been a slow uncertain procedure as we testified at the hearings in 1963.

In the past, animal drugs have been subject to sometimes questionable control because these controls were inherited from legislation intended specifically for control of human drugs. We are encouraged, however, by recent administrative action taken by the Food and Drug Administration which promoted the Division of Veterinary Medicine to full "Bureau" status. We feel that this is a recognition of the desirability of considering the various aspects of animal drugs on their merits, exclusive of human drug considerations.

The American Feed Manufacturers Association, on behalf of its members, supports H.R. 7655 introduced by Congressman O'Brien, in that it gives further impetus to the specific recognition of animal drugs. We believe it will give the Bureau of Veterinary Medicine

authority and direction to implement practical regulations that embody safety and yet permit the maximum exercise of scientific judgment on the part of practicing veterinarians and the scientists in the feed industry.

The proposed legislation does not change the present requirements for medicated feed clearances which we consider to be unnecessary and costly. However, the bill is a significant step in the right direction and we thus encourage its passage.

We feel it necessary to request two amendments to H.R. 7655. The first involves the shortening of the 90-day processing limit for medicated feed applications (as specified in the proposed bill). It would appear that 30 days would be adequate time for FDA to make a decision on this type of application. In considering this proposal, please keep in mind that the FDA has already given basic approval to the use of these additives.

It is our hope that clearance requirements for feed manufacturers may eventually be greatly simplified by administrative action, or legislation if necessary, so that feed manufacturers who are registered and inspected by FDA can use new animal drugs as soon as basic clearance is granted to the drug company.

Secondly, we strongly urge modification of section 106 of the bill which deals with export. Section 106 would modify section 801 of the act to prohibit export of products not in conformance with the provisions of the act. There seems to be no reason to deny export if the product is in accord with the purchaser's specifications, meets with the destination country's laws, and is labeled for export. Other nations certainly have the right to set their own standards. When the standards of the recipient country have been met, we feel that U.S. manufacturers should have the opportunity to compete with other countries of the world for the export market.

In conclusion, I would like to emphasize there is a fundamental similarity in the objectives of FDA and feed manufacturers. Every feed manufacturer must have concern for the safety and efficiency of his feed product—surpassing that of FDA. A feed manufacturer's very existence depends upon the safety and quality of his product.

It should also be acknowledged at this time that we in the feed industry have been impressed with the leadership shown by Dr. Goddard and Dr. Clarkson of the Food and Drug Administration and are looking forward to working with them toward common goals. Further, their efforts to achieve administrative efficiency should not go unnoticed.

On behalf of the American Feed Manufacturers Association and Central Soya Co., may Mr. Boyd and I again express our appreciation for the privilege of appearing before the committee.

Mr. JARMAN. Thank you, Mr. Klinger, for your testimony.

With reference to your first recommended amendment, that is, that the 90-day processing limit for medicated feed applications as set out in the bill be reduced to 30 days, would you have any comment to make on the possibility of a 60-day limitation period?

Mr. KLINGER. Underlying our philosophy is the question of what degree of clearance should be required for feed manufacturers. We have pointed out that the basic review and approval of safety and efficacy have already been made by the Food and Drug Administra-

tion, but even after this it is now a requirement for feed manufacturers to further request clearance, and I think we must certainly look at the repetitious nature of these applications.

This requires an individual application for every individual feed that might use a particular drug. These applications are practically identical in nature. We would not see any reason for a 30-day processing period to be unrealistic.

Mr. JARMAN. Thank you.

Mr. NELSEN.

Mr. NELSEN. I note that you mention these additives have already been approved and are available for purchase.

For example, a farmer could go down to a supplier and buy certain additives that have been approved, could he not?

Mr. KLINGER. He would be in the same position in this case as a feed manufacturer if the additive has a new drug status. Any purchaser would have to have a clearance before he could mix it or use it.

Mr. NELSEN. I would point out that, for example, a farmer may bring a trailer load of ear corn and oats down the elevator to be ground into feed, and he may have purchased some of these additives which he himself adds to the feed and this he can do, can he not?

Mr. KLINGER. Not under the conditions you have expressed. I believe there are certain on-the-farm conditions where this would be true, but in the employment of a commercial mixer this would not be true.

Mr. NELSEN. The observation was made in the hearings 2 years ago that a responsible feed manufacturer really is under more close supervision than are many of the producers who may bring in their own load of feed and mix it up at home.

This they may do, and it seems a responsible manufacturer certainly would want to be very sure that in no way does he put together any combination that would hurt his future growth and acceptance with the general public. That was the point that I was attempting to make.

I wish to thank the gentleman for his statement.

Mr. JARMAN. Thank you.

Mr. KLINGER. Thank you.

Mr. JARMAN. The committee would like to express appreciation to all who have participated in and attended the hearing, aiding in making what we feel is a good basic record on this proposal.

The Chair might mention that the record will be kept open for 5 days to receive any additional statements.

The committee stands adjourned.

(The following material was submitted for the record:)

THE PROPRIETARY ASSOCIATION,
Washington, D.C., June 15, 1966.

HON. JOHN JARMAN,

Chairman, Subcommittee on Public Health and Welfare, Committee on Interstate and Foreign Commerce, House of Representatives, Washington, D.C.

DEAR MR. CHAIRMAN: This letter is in reference to H.R. 7655, identified as the "Animal Drug Amendments of 1965", and is submitted with the request that it be made a part of the record of hearings on the bill. This Association desires to be recorded in support of the proposed legislation. Its position was duly authorized by its Executive Committee—the governing body—at a regular meeting in Washington, D.C. on March 1, 1966.

The Proprietary Association has its offices at 1717 Pennsylvania Avenue, N.W., in the City of Washington. It was organized in 1881 and has been in continuous existence ever since. Its active members—ninety-six in number—are engaged in the manufacture and distribution of proprietary medicines—medicines which are completely compounded, packaged, labeled with directions for use and advertised directly to the public. They are over-the-counter items; items which are not restricted by law or practice to prescription sale.

While the greater volume of the medicines produced by members of this Association are for use in human medication, some of the members do make drugs for use in the medication of animals and are therefore interested in and would be affected by the purposes and provisions of the subject legislation.

The emphasis in food and drug legislation has understandably been on regulation of drugs for human use. Animal drugs have always been regulated under this law but they have been of secondary concern. H.R. 7655 would put in better balance the law's regulation applicable to human and animal drugs. It would simplify the regulation by coordinating controls currently imposed on animal drugs by several sections of the existing law. It would provide a single procedure for clearance of animal drugs. A single section for this purpose, inserted into the Federal Food, Drug and Cosmetic Act, would follow the pattern of regulation which pertains now to new drugs and antibiotic drugs for human consumption. The bill also applies to animal feeds which bear or contain new animal drugs.

An important purpose of the bill is to prevent delays in the introduction of new animal drugs and to facilitate the availability of them. It would thereby encourage development of new animal drugs which are needed to fight food losses which are presently at a high rate due to disease.

Therefore, this Association heartily subscribes to the purposes of H.R. 7655 and recommends the bill as capable of accomplishing them.

Respectfully submitted.

HOWARD A. PRENTICE,
Executive Vice President and Treasurer.

PHARMACEUTICAL MANUFACTURERS ASSOCIATION,
Washington, D.C., May 6, 1966.

Re H.R. 7655.

HON. HARLEY O. STAGGERS,

Chairman, House Interstate and Foreign Commerce Committee, U.S. House of Representatives, Washington, D.C.

DEAR MR. CHAIRMAN: This letter is submitted on behalf of the Pharmaceutical Manufacturers Association to evidence support for H.R. 7655, a bill entitled "The Animal Drug Amendments of 1965." The legislation is designed to improve public health protection by consolidating into a brand new section of the Federal Food Drug and Cosmetic Act current, diverse, overlapping, and often times contradictory sections of that Act, regulating the premarketing clearance of new animal drugs.

The Pharmaceutical Manufacturers Association, a national trade association, represents about 140 firms which manufacture approximately 95 per cent of the nation's output of prescription drugs. Our Association follows with great interest all proposed legislation relating to the public health, particularly those proposing amendment to the Federal Food Drug and Cosmetic Act.

The Pharmaceutical Manufacturers Association respectfully urges hearings on and the enactment of H.R. 7655. The procedural simplification which this bill would accomplish is desirable and in the public interest. By placing the premarketing clearance of new animal drugs under a single section of the Federal Food Drug and Cosmetic Act, long delays in their clearance will be eliminated, thus facilitating their availability to the producers of livestock and poultry. This result will be achieved without lessening any of the rigid controls necessary for the proper protection of the public health now imposed by existing law.

Three different regulatory divisions of the Food and Drug Administration have jurisdiction over animal drugs. Each employ separate statutory procedures for the clearance of the same uses of these drugs. Consequently, they sometimes adopt individual interpretations which produce inconsistencies in animal drug clearances. The enactment of H.R. 7655 will streamline and improve this approval procedure.

The regulation of new animal drugs should be based on procedures applicable solely to such drugs. They should not, as they now are, be handled under procedures applicable to human drugs. The efficient, economic and single procedure which this bill proposes for the clearance of animal drugs will reduce long recurring delays, will free more funds to be invested in basic research, and will ultimately benefit the health profession, the farmer, and the American consumer.

The need for a separate, single procedure for the clearance and regulation of new animal drugs is clear. Enactment of H.R. 7655 not only will retain all of the protection and objectives of the present law, but will also encourage and speed up the development and introduction of new drugs and thus reduce livestock and poultry disease. It should aid this country in increasing its productivity to meet the future demands for more meat, milk, and eggs which will come from our rapidly increasing population.

It would be appreciated if you would place this letter in your Committee's records on this legislation.

Sincerely,

C. JOSEPH STETLER.

NATIONAL AGRICULTURAL CHEMICALS ASSOCIATION,
Washington, D.C., June 10, 1966.

HON. JOHN JARMAN, M.C.
House Office Building,
Washington, D.C.

DEAR MR. JARMAN: I would like to support H.R. 7655 and ask that it be reported by your Subcommittee.

The principles and philosophies of this bill are those that are necessary in today's complex society.

While this Association has no responsibility in the field of veterinary drugs, we, like them, are a highly regulated industry and know the necessity for endeavoring in every way possible to provide for the simplification of procedures, provided the simplifications do not lessen the ability of the regulatory agency to properly protect the health and welfare of the public.

Thanking you for your consideration, I am

Sincerely yours,

PARKE C. BRINKLEY, *President.*

AMERICAN FARM BUREAU FEDERATION,
Washington, D.C., June 20, 1966.

HON. JOHN JARMAN,
Chairman, Subcommittee on Health and Welfare of the House Interstate and Foreign Commerce Committee, Washington, D.C.

DEAR CONGRESSMAN JARMAN: As the Nation's largest general farm organization with 1,677,820 farm families, Farm Bureau has a vital interest in any legislation concerning the use of animal drugs. We have many Farm Bureau members who produce and feed livestock, raise poultry and milk dairy cows. The use of animal drugs is very important in developing and maintaining a healthy livestock economy.

H.R. 7655, as we understand it, would amend the Federal Food, Drug and Cosmetic Act to provide for centering the control of new animal drugs (including medicated feeds) into one section of the law. This would establish a single procedure for the clearance of these new drugs.

The Farm Bureau Policies for 1966, adopted by the elected voting delegates from the member State Farm Bureaus, contain the following policy statement:

"The present procedure for pre-marketing clearances of new animal drugs may add unnecessarily to their cost and delay their use by farmers. Consideration should be given to eliminating these cumbersome procedures when public safety and health are not jeopardized."

As livestock producers and feeders, and therefore the ultimate users of such drugs, we are interested in the best and fastest procedure that can be established for the clearance of new animal drugs. At the same time, we also feel that the procedure should provide for the best possible protection for public health and welfare.

We had hoped that the problem of pre-marketing clearance for new animal drugs might be solved by administrative action by FDA. While there has been progress made, there apparently is need for legislation to definitely establish a single procedure for the clearance of new animal drugs separate from human drugs. H.R. 7655 would establish such a procedure and at the same time continue to provide adequate protection of the public welfare.

We would appreciate your making this letter a part of the hearing record.

Sincerely,

JOHN C. LYNN,
Legislative Director.

GRAIN & FEED DEALERS NATIONAL ASSOCIATION,
Washington, D.C., June 20 1966.

HON. JOHN JARMAN,
Chairman, Subcommittee on Health and Welfare, Interstate and Foreign Commerce Committee, House of Representatives, Washington, D.C.

DEAR MR. JARMAN: The Grain and Feed Dealers National Association has 1800 direct members ranging in size from the country elevator and feed mill to the largest grain and feed complexes. In addition, there are 53 state or regional associations which are affiliated with this National Association and which have about 17,000 members.

The Grain and Feed Dealers National Association would like to go on record as favoring the passage of HR 7655. We believe that the consolidation of laws pertaining to animal drugs would remove confusion from existing law. Furthermore, the simplification of clearances for animal drugs would benefit the grain and feed industry with no adverse effect on human consumers. We, therefore, urge the passage of HR 7655.

Sincerely yours,

ALVIN E. OLIVER, *Executive Vice President.*

STAUFFER CHEMICAL CO.,
Woburn, Mass., May 20, 1966.

HON. F. BRADFORD MORSE,
House of Representatives,
Washington, D.C.

DEAR CONGRESSMAN MORSE: Congressman L. W. O'Brien of New York has proposed H.R. 7655, a bill to provide a single, separate procedure for clearance of animal drugs. I would like to enlist your support of the bill, especially a request for hearings before the Subcommittee on Health and Welfare of the House Interstate and Foreign Commerce Committee.

A clear, Congressional intent for the handling of applications for clearance of feed additives, veterinary antibiotics, and new animal drug applications is necessary. The Federal Food, Drug, and Cosmetic Act of 1938 is primarily directed towards human drugs and, at best, animal drugs have received "stepchild" treatment. Delay and confusion ensue from the lack of a specific statutory basis for this specific group.

Animal feed additives are under Section 409, veterinary antibiotics under Section 507, and new animal drugs application under Section 505. This separation leads to individual interpretations of the Act by the agency administering these sections. But, the end product is always the health of the same cow. A realistic appraisal of the function of animal drugs is necessary.

Since animal drug clearance is an extrapolation from human drug law, it is subject to the vagaries of direction of such law. Clearance is tied to the emotional and explosive conditions of human drug law which is slated for even further regulation. To encourage development of new drugs, the clearance period must be shortened and the clearance path specified. This in turn will lead to a larger supply of food at a lower cost to the producer and consumer. At the same time no shortcut in procedures now in effect is required.

I request your careful study of this legislation and hope you will be able to support it.

Sincerely yours,

W. S. HOWARD, *Plant Manager.*

MERCK & Co., INC.,
Rahway, N.J., June 9, 1966.

HON. JOHN JARMAN,
Chairman, Subcommittee on Public Health and Welfare,
Interstate and Foreign Commerce Committee,
House Office Building, Washington, D.C.

DEAR CHAIRMAN JARMAN: We wish to thank you for scheduling hearings on H.R. 7655 before your Subcommittee on Monday, June 13. Merck & Co., Inc. endorses this Bill and urges your support in obtaining its enactment. This Company, as a leading manufacturer of animal health drugs used in veterinary products and animal feeds, believes that the Bill as introduced by Representative Leo W. O'Brien is necessary, and would simplify and clarify the clearance procedures of the Food and Drug Administration for approving the marketing of new animal drugs and animal feeds containing them. By so doing, we feel it will avoid unnecessary and time-consuming delays in the obtaining of approvals for these drugs and feeds. It is our considered opinion that under H.R. 7655 these approvals would be facilitated and expedited without sacrificing any of the safeguards enjoyed by the farmer or the public under existing law.

We very much appreciate your interest and understanding on this subject.

Sincerely yours,

FRED BARTENSTEIN, Jr.,
Administrative Vice President.

HOFFMAN-LA ROCHE, INC.,
ROCHE CHEMICAL DIVISION,
Nutley, N.J., June 9, 1966.

HON. JOHN JARMAN,
Chairman, Subcommittee on Public Health and Welfare,
Committee on Interstate and Foreign Commerce,
House Office Building, Washington, D.C.

DEAR CONGRESSMAN JARMAN: As a manufacturer of animal drugs, Hoffmann-La Roche Inc. is vitally concerned with the proposed H.R. Bill 7655 and the hearing with respect thereto to be held on Monday, June 13. We have studied this Bill carefully, and, through the Animal Health Institute, have worked with the representatives of the Government to make the Bill acceptable to all concerned. It is sincerely believed that the Bill as presently proposed would facilitate, both for Government and industry, the administration of the animal drug laws while maintaining the controls necessary to protect the public health.

We therefore respectfully urge that this Bill be favorably reported to the House of Representatives.

Very truly yours,

CLIFFORD A. SCOTT,
Director of Agricultural Sales.

THE UPJOHN CO.,
Kalamazoo, Mich., June 8, 1966.

HON. JOHN D. JARMAN,
Chairman, Subcommittee on Health and Welfare,
House Office Building, Washington, D.C.

DEAR MR. JARMAN: Information has been received that H.R. 7655 will be given hearing before your committee on Monday, June 13, 1966.

The Upjohn Company is extremely interested in the passage of this bill, as we feel it will assist the Commissioner of the Food and Drug Administration in making the agency a more effective and efficient instrument for the public good.

Your favorable consideration of this bill is urgently solicited.

Very truly yours,

D. A. PHILLIPSON, D.V.M.
Director of Agricultural Products Division.

INTERNATIONAL MINERALS & CHEMICAL CORP.,

Shokie, Ill., June 10, 1966.

Hon. JOHN JARMAN,
*Chairman, Subcommittee on Health and Welfare,
Committee on Interstate and Foreign Commerce,
House Office Building, Washington, D.C.*

DEAR MR. JARMAN: I am writing to express interest in H.R. 7655, a bill 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. I understand that your Committee has scheduled hearings on this bill for Monday, June 13, 1966.

As Chairman and Chief Executive Officer of International Minerals and Chemical Corporation, I wish to express my personal support, and the support of my company, for this bill. This proposed legislation would amend certain administrative procedures of the Federal Food and Drug Administration, which would facilitate the consideration and processing of applications to clear new products, useful in animal health and nutrition. In my opinion, enactment of the proposed changes would, in no way, weaken the provisions of the law which safeguards public welfare from the standpoint of safety.

On June 29th, 1965, I had the privilege of appearing before a Sub-Committee of the Senate Foreign Relations Committee to discuss the world population and food crisis, pointing up widespread hunger in the underdeveloped world, and urging that all practical steps be taken by both government and private organizations to promote increased food production.

In this context, I am convinced that the adoption of more workable procedures for the clearance of animal drugs would expedite the advance of animal production in this country. Improvements in U.S. technology for the production of animal products, meat, milk, poultry and eggs, lead to similar advances in the developing nations. Furthermore, every increase in the efficiency of animal production automatically enhances the feed grain supplies of the world. Consequently, I believe that enactment of the pending legislation would be a positive contribution to increasing world food production. The need for more animal protein is critical in many underdeveloped countries. Animal proteins supply components of the human diet which are essential in the maintenance of health and well being.

The changes in pre-marketing clearance procedures for animal drugs which would be effected by passage of H.R. 7655 have been carefully considered by competent legal and scientific personnel. As a result, the bill has gained wide support and endorsement from industrial and trade associations, technical and scientific societies, and responsible authorities, competent to judge its impact.

Our technical experts tell me that the difficulty in getting new animal drugs approved by the Food and Drug Administration is slowing the development of such drugs, primarily because pre-marketing clearance is now effected under a law principally directed toward human drugs. The long delays inherent in the current regulations add appreciably to the cost of any new compound. This tends to decrease research to develop new compounds. More importantly, it unnecessarily delays public receipt of the benefits which might be obtained, in this country and abroad, through earlier availability.

New and rapidly increasing world food needs call for new and more expeditious approaches to old problems.

I trust your Committee will give this bill your careful consideration, and make these views a matter of record in the proceedings of your Committee's deliberations.

Respectfully yours,

THOMAS M. WARE, *Chairman.*

WHITMOYER LABORATORIES, INC.,
Myerstown, Pa., June 9, 1966.

HON. JOHN JARMAN,
House of Representatives
Washington, D.C.

DEAR MR. JARMAN: It was gratifying to learn that the hearing on H.R. 7655, the animal drug amendments to the Food, Drug and Cosmetic Act, is scheduled for June 13, 1966.

As chairman of the Subcommittee on Health & Welfare of the House Interstate & Foreign Commerce Committee, I want to appeal to you to give this proposed legislation your thoughtful, and hopefully, your favorable consideration. A good case has already, I am sure, been made for the need for this legislation so that I will not dwell on details in this letter. I am sure that this legislation will prove beneficial to animal agriculture throughout the United States and that your constituents in the Fifth Congressional District of Oklahoma will be grateful to you for giving this your support.

In behalf of the animal agriculture industry and the veterinary pharmaceutical manufacturing industry, I do want to extend to you my thanks for giving the above-named proposed legislation your best attention.

Very truly yours,

C. W. WHITMOYER, *President.*

BINGMAN LABORATORIES, INC.,
Caldwell, Ohio, June 17, 1966.

HOUSE OF REPRESENTATIVES,
Committee on Interstate and Foreign Commerce,
Washington, D.C.
(Attention: W. E. Williamson, Clerk).

GENTLEMEN: We submit the following statement for the record in regard to certain bills before your committee to protect the public health by amending the Federal Food, Drug, and Cosmetic Act with respect to the safety and effectiveness of drugs used in animal feeds.

During the past several years there has been undue alarm created by certain government agencies pertaining to the danger of drugs in human and animal feeds and animal food products, and in this aura of fear and hysteria new feed additive amendments were passed by Congress amending the Federal Food, Drug, and Cosmetic Act. As a result of these amendments the Food and Drug Administration has established regulations regarding the use of practically all ingredients in animal feeds and medications. It seems apparent that this agency is taking upon itself authorities that go far beyond the contemplation and expectation of Congress when the law was passed.

I want to emphasize that *no hazard to public health has ever been demonstrated from residues of feed additives. No one has demonstrated that food animals are capable of harboring enough of any feed additive to adversely affect human consumers, or that there is sufficient residue to have any demonstrable effect on the second animal. There has never been proven one case of harm to any human as the result of drug residue in feeds, milk, meat, or any animal food product.* Yet based on myth, supposition, and imagination federal regulations regarding the use of practically all drug ingredients have been issued by the Food and Drug Administration. The agricultural industry, the nation, and the world would not now be enjoying the benefits of scientific nutritional advances and medications that we have today under such arbitrary controls and regulations as the Food and Drug Administration are presently establishing.

It is quite disconcerting to see public statements and news releases by the head of the Food and Drug Administration emphasizing only the danger and harm that have resulted from various medications and drugs that are being put on the market, and giving the impression that manufacturers are not concerned with the safety of their products. It appears that in many instances these statements are made primarily for the purpose of obtaining public support. While this support is sincere, it is unfortunate that most of this support is misinformed and misguided. It is clearly evident that the lives saved, improved health, and improved nutrition far overshadow any harmful effects. It is unreasonable to overemphasize the danger and minimize the benefits. There is no evidence that tissues of food animals or food byproducts of animals can hold enough of any feed additive to measurably affect consumers.

Because of the short notice of this hearing I have not had sufficient time to study in detail the current bills to amend the Federal Food, Drug, and Cosmetic Act with respect to the safety and effectiveness of drugs in animal feeds or medications. However, I have read them, and in my opinion these bills are not in the best interest of the consumer or our industry.

The Food and Drug Administration are in effect applying to animal feeds and medications laws and regulations that were primarily established for application to human food and medications. The application of human standards to animal feeds and medications is not reasonable. In considering the feed additives, drugs, etc., used for treating animal diseases it must be realized that there are many variable environmental conditions existing, and that it is not practical to attempt to diagnose and treat animal diseases in the same manner as humans. Because of this it is very important and essential that the Federal Food, Drug, and Cosmetic Act be amended so as to establish an entirely separate code of regulations pertaining to the safety and effectiveness of animal feeds and medications, and that in addition the concept of safety and effectiveness be clarified by specific laws and not left to the broad interpretation of the Food and Drug Administration. It has long been demonstrated that the safety to the consumer is implicit in the health of the animal; and in the best interest of the consumer and the agricultural industry the Federal Food, Drug, and Cosmetic Act should be amended so as to provide processes of law enforcement attuned to reality rather than imagination and supposition. Safety to the consumer is of utmost importance, and there should be controls and regulations to insure this safety. However, regulations based on supposition about some completely fanciful hazard associated with feed additive residues or drugs seems to be the order of the day. No one has yet shown that such hazards even exist. However, regulations are being established on the basis that they ought to exist or may exist. Current regulations being established by the Food and Drug Administration under the recent feed additives amendments and regulations which could be established under the new amendments being proposed are definitely not and would not be in the best interest of the consumer or the agricultural industry.

The Feed Additives Amendment to the Federal Food, Drug, and Cosmetic Act was passed with two purposes: (1) to protect the health of consumers by requiring manufacturers of food additives and food processors to pre-test any potentially unsafe ingredients which are to be added to food; (2) to advance food technology by permitting the use of food additives to safe levels. These purposes are desirable; however, under recent regulations by the Food and Drug Administration the second purpose of this law is not being fulfilled, and in reality is being enforced in such a manner that food technology will not continue to advance and the use of food additives at safe levels is being prohibited.

The enforcement of the feed additive laws so as to best provide for both purposes—safety for the user and advance food technology—requires judgment of the highest caliber. This judgment should not be left to the discretion of a regulatory agency such as the Food and Drug Administration; there must be specific laws and regulations, and there should be established a committee of qualified experts from universities and medical industries to pass on the status of food additives alone and in combinations. The broad interpretation by the Food and Drug Administration of the recent feed additive amendments are resulting in a case of runaway enforcement. They are establishing and enforcing regulations that are detrimental to the best interest of the consumer and our industry. Their approach to the question is unrealistic and unreasonable.

To attempt to go into complete detail in this statement for the record is not practical. I have tried in general to indicate the conditions that are existing. If The Committee is interested, I will be more than willing to appear in person to present further information and specific details regarding this subject.

I want to thank the committee for the opportunity to present this statement for the record, and will appreciate any consideration it is given.

W. D. SEMPLE, *President and General Manager.*

(Whereupon, at 12:07 p.m., the hearing was adjourned.)



