

Public Law 87-781

AN ACT

October 10, 1962
[S. 1552]

To protect the public health by amending the Federal Food, Drug, and Cosmetic Act to assure the safety, effectiveness, and reliability of drugs, authorize standardization of drug names, and clarify and strengthen existing inspection authority; and for other purposes.

Drug Amend-
ments of 1962.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That this Act, divided into titles and sections according to the following table of contents, may be cited as the "Drug Amendments of 1962".

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TITLE I—DRUGS

PART A—AMENDMENTS TO ASSURE SAFETY, EFFECTIVENESS, AND RELIABILITY

REQUIREMENT OF ADEQUATE CONTROLS IN MANUFACTURE

SEC. 101. Clause (2) of section 501(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351(a)) is amended to read as follows: "(2) (A) if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health; or (B) if it is a drug and the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not

operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirements of this Act as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess;”.

EFFECTIVENESS AND SAFETY OF NEW DRUGS

SEC. 102. (a) (1) Section 201(p)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(p)(1)), defining the term “new drug”, is amended by (A) inserting therein, immediately after the words “to evaluate the safety”, the words “and effectiveness”, and (B) inserting therein, immediately after the words “as safe”, the words “and effective”.

52 Stat. 1041.

(2) Section 201(p)(2) of such Act (21 U.S.C. 321(p)(2)) is amended by inserting therein, immediately after the word “safety”, the words “and effectiveness”.

(b) Section 505(b) of such Act (21 U.S.C. 355(b)) is amended by inserting therein, immediately after the words “is safe for use”, the words “and whether such drug is effective in use”.

52 Stat. 1052.

(c) Section 505(d) of such Act (21 U.S.C. 355(d)) is amended to read as follows:

“(d) 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 (1) 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; (2) 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; (3) the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug are inadequate to preserve its identity, strength, quality, and purity; (4) 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; or (5) 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; or (6) 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 clauses (1) through (6) do not apply, he shall issue an order approving the application. As used in this subsection and subsection (e), the term ‘substantial evidence’ means evidence consisting of adequate and well-controlled investigations, including clinical investigations, 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.”

Grounds for refusing application.

Approval of application.

(d) Section 505(e) of such Act (21 U.S.C. 355(e)) is amended to read as follows:

52 Stat. 1052.

Suspension of approval.

“(e) The Secretary shall, after due notice and opportunity for hearing to the applicant, withdraw approval of an application with respect to any drug under this section if the Secretary finds (1) that clinical or other experience, tests, or other scientific data show that such drug is unsafe for use under the conditions of use upon the basis of which the application was approved; (2) that new evidence of clinical experience, 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 (3) 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 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 thereof; or (4) that the application contains any untrue statement of a material fact: *Provided*, That if the Secretary (or in his absence the officer acting as Secretary) finds that there is an imminent hazard to the public health, 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 proviso to suspend the approval of an application shall not be delegated. The Secretary may also, after due notice and opportunity for hearing to the applicant, withdraw the approval of an application with respect to any drug under this section if the Secretary finds (1) 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 (j), or the applicant has refused to permit access to, or copying or verification of, such records as required by paragraph (2) of such subsection; or (2) 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 (3) 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. Any order under this subsection shall state the findings upon which it is based.”

RECORDS AND REPORTS AS TO EXPERIENCE ON NEW DRUGS

52 Stat. 1052.

SEC. 103. (a) Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) is amended by adding at the end thereof the following new subsection:

“(j) (1) In the case of any drug for which an approval of an application filed pursuant to this section is in effect, the applicant shall establish and maintain such records, and make such reports to the Secretary, of data relating to clinical experience and other data or

information, received or otherwise obtained by such applicant with respect to 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) of this section: *Provided, however,* That regulations and orders issued under this subsection and under subsection (i) shall have due regard for the professional ethics of the medical profession and the interests of patients and shall provide, where the Secretary deems it to be appropriate, for the examination, upon request, by the persons to whom such regulations or orders are applicable, of similar information received or otherwise obtained by the Secretary.

“(2) Every person required under this section 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.” Access to records.

(b) Section 505(i) of such Act (21 U.S.C. 355(i)) is amended (1) by inserting “the foregoing subsections of” immediately after “operation of”; (2) by inserting “and effectiveness” immediately after “safety”; and (3) by adding at the end thereof the following new sentences: “Such regulations may, within the discretion of the Secretary, among other conditions relating to the protection of the public health, provide for conditioning such exemption upon—” 52 Stat. 1052.

“(1) the submission to the Secretary, before any clinical testing of a new drug is undertaken, of reports, by the manufacturer or the sponsor of the investigation of such drug, of preclinical tests (including tests on animals) of such drug adequate to justify the proposed clinical testing;

“(2) the manufacturer or the sponsor of the investigation of a new drug proposed to be distributed to investigators for clinical testing obtaining a signed agreement from each of such investigators that patients to whom the drug is administered will be under his personal supervision, or under the supervision of investigators responsible to him, and that he will not supply such drug to any other investigator, or to clinics, for administration to human beings; and

“(3) 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 drug, of data (including but not limited to analytical reports by investigators) obtained as the result of such investigational use of such drug, as the Secretary finds will enable him to evaluate the safety and effectiveness of such drug in the event of the filing of an application pursuant to subsection (b).” Regulations pertaining to exemption.

Such regulations shall provide that such exemption shall be conditioned upon the manufacturer, or the sponsor of the investigation, requiring that experts using such drugs for investigational purposes certify to such manufacturer or sponsor that they will inform any human beings to whom such drugs, or any controls used in connection therewith, are being administered, or their representatives, that such drugs are being used for investigational purposes and will obtain the consent of such human beings or their representatives, except where they deem it not feasible or, in their professional judgment, contrary to the best interests of such human beings. Nothing in this subsection shall be construed to require any clinical investigator to submit directly to the Secretary reports on the investigational use of drugs.”

52 Stat. 1042.

(c) Section 301(e) of such Act (21 U.S.C. 331(e)) is amended to read as follows:

21 USC 373.

21 USC 355.
Ante, p. 782.

“(e) The refusal to permit access to or copying of any record as required by section 703; or the failure to establish or maintain any record, or make any report, required under section 505 (i) or (j), or the refusal to permit access to or verification or copying of any such required record.”

52 Stat. 1043.

(d) Section 302(a) of such Act (21 U.S.C. 332(a)) is amended by striking out “(e).”

NEW DRUG CLEARANCE PROCEDURE

52 Stat. 1052.

SEC. 104. (a) Section 505(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(a)), is amended to read as follows:

“(a) No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) is effective with respect to such drug.”

(b) Section 505(c) of such Act (21 U.S.C. 355(c)) is amended to read as follows:

“(c) Within one hundred and eighty days after the filing of an application under this subsection, or such additional period as may be agreed upon by the Secretary and the applicant, the Secretary shall either—

“(1) approve 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 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.”

(c) Section 505(f) of such Act (21 U.S.C. 355(f)) is amended to read as follows:

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

Appeal.

52 Stat. 1052.

(d) (1) The first four sentences of section 505(h) of such Act (21 U.S.C. 355(h)) are amended to read as follows: “An appeal may be taken by the applicant from an order of the Secretary refusing or withdrawing approval of an application under this section. Such appeal shall be taken by filing in the United States court of appeals for the circuit wherein such applicant resides or has his principal place of business, or in the United States Court of Appeals for the District of Columbia Circuit, within sixty days after the entry of such order, a written petition praying that the order of the Secretary be set aside. A copy of such petition shall be forthwith transmitted by the clerk of the court to the Secretary, or any officer designated by him for that purpose, and thereupon the Secretary shall certify and file in the court the record upon which the order complained of was entered, as provided in section 2112 of title 28, United States Code. Upon the filing of such petition such court shall have exclusive jurisdiction to affirm or set aside such order, except that until the filing of the record the Secretary may modify or set aside his order.”

72 Stat. 941.

(2) The ninth sentence of such section 505(h) is amended to read as follows: "The judgment of the court affirming or setting aside any such order of the Secretary shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification as provided in section 1254 of title 28 of the United States Code."

21 USC 355.

(3) The amendments made by this subsection shall not apply to any appeal taken prior to the date of enactment of this Act.

62 Stat. 928.

(e) (1) Section 301(1) of such Act (21 U.S.C. 331(1)) is amended by (1) inserting "approval of" before "an application", and (2) striking out "effective" and inserting in lieu thereof "in effect".

52 Stat. 1042.

(2) Clause (C) of section 503(b) (1) of such Act (21 U.S.C. 353(b) (1)) is amended by striking out "effective" and inserting in lieu thereof "approved".

52 Stat. 1051.

(f) (1) Clause (A) of paragraph (3) of section 409(c) of such Act (21 U.S.C. 348(c)) is amended by inserting before the semicolon at the end thereof the following: ", except that this proviso shall not apply with respect to the use of a substance as an ingredient of feed for animals which are raised for food production, if the Secretary finds (i) that, under the conditions of use and feeding specified in proposed labeling and reasonably certain to be followed in practice, such additive will not adversely affect the animals for which such feed is intended, and (ii) that no residue of the additive will be found (by methods of examination prescribed or approved by the Secretary by regulations, which regulations shall not be subject to subsections (f) and (g) in any edible portion of such animal after slaughter or in any food yielded by or derived from the living animal".

72 Stat. 1785.

(2) Subparagraph (B) of paragraph (5) of section 706(b) of such Act (21 U.S.C. 376(b)) is amended by inserting before the period at the end of the subparagraph a colon and the following proviso: "*Provided*, That clause (i) of this subparagraph (B) shall not apply with respect to the use of a color additive as an ingredient of feed for animals which are raised for food production, if the Secretary finds that, under the conditions of use and feeding specified in proposed labeling and reasonably certain to be followed in practice, such additive will not adversely affect the animals for which such feed is intended, and that no residue of the additive will be found (by methods of examination prescribed or approved by the Secretary by regulations, which regulations shall not be subject to subsection (d) in any edible portion of such animals after slaughter or in any food yielded by or derived from the living animal".

74 Stat. 399.

CERTIFICATION OF ANTIBIOTICS

SEC. 105. (a) Section 507(a) of such Act (21 U.S.C. 357(a)) is amended by adding at the end thereof the following new sentence: "For purposes of this section and of section 502(1), the term 'antibiotic drug' means any drug intended for use by man containing any quantity of any chemical substance which is produced by a microorganism and which has the capacity to inhibit or destroy microorganisms in dilute solution (including the chemically synthesized equivalent of any such substance)."

59 Stat. 463.

(b) Section 507(a) of such Act (21 U.S.C. 357(a)) is further amended by striking the word "or" preceding the word "bacitracin" and by adding after the word "bacitracin" a comma and the following: "or any other antibiotic drug,".

(c) Section 502(1) of such Act (21 U.S.C. 352(1)) is amended by striking the word "or" preceding the word "bacitracin" and by adding immediately after "bacitracin," the following: "or any other antibiotic drug,".

59 Stat. 463.

59 Stat. 464.
Exemption; de-
terminations.

(d) Section 507(c) of such Act (21 U.S.C. 357(c)) is amended by adding at the end thereof the following: "In deciding whether an antibiotic drug, or class of antibiotic drugs, is to be exempted from the requirement of certification the Secretary shall give consideration, among other relevant factors, to—

"(1) whether such drug or class of drugs is manufactured by a person who has, or hereafter shall have, produced fifty consecutive batches of such drug or class of drugs in compliance with the regulations for the certification thereof within a period of not more than eighteen calendar months, upon the application by such person to the Secretary; or

"(2) whether such drug or class of drugs is manufactured by any person who has otherwise demonstrated such consistency in the production of such drug or class of drugs, in compliance with the regulations for the certification thereof, as in the judgment of the Secretary is adequate to insure the safety and efficacy of use thereof.

When an antibiotic drug or a drug manufacturer has been exempted from the requirement of certification, the manufacturer may still obtain certification of a batch or batches of that drug if he applies for and meets the requirements for certification. Nothing in this Act shall be deemed to prevent a manufacturer or distributor of an antibiotic drug from making a truthful statement in labeling or advertising of the product as to whether it has been certified or exempted from the requirement of certification."

59 Stat. 464.

21 USC 355.

(e) The first sentence of section 507(e) of such Act (21 U.S.C. 357(e)) is amended to read as follows: "No drug which is subject to section 507 shall be deemed to be subject to any provision of section 505 except a new drug exempted from the requirements of this section and of section 502(1) pursuant to regulations promulgated by the Secretary; *Provided*, That, for purposes of section 505, the initial request for certification, as thereafter duly amended, pursuant to section 507, of a new drug so exempted shall be considered a part of the application filed pursuant to section 505(b) with respect to the person filing such request and to such drug as of the date of the exemption."

59 Stat. 463;
Post, p. 787.

21 USC 355.

(f) Section 507 of such Act (21 U.S.C. 357) is further amended by adding at the end of such section the following new subsection:

"(h) In the case of a drug for which, on the day immediately preceding the effective date of this subsection, a prior approval of an application under section 505 had not been withdrawn under section 505(e), the initial issuance of regulations providing for certification or exemption of such drug under this section 507 shall, with respect to the conditions of use prescribed, recommended, or suggested in the labeling covered by such application, not be conditioned upon an affirmative finding of the efficacy of such drug. Any subsequent amendment or repeal of such regulations so as no longer to provide for such certification or exemption on the ground of a lack of efficacy of such drug for use under such conditions of use may be effected only on or after that effective date of clause (3) of the first sentence of section 505(e) which would be applicable to such drug under such conditions of use if such drug were subject to section 505(e), and then only if (1) such amendment or repeal is made in accordance with the procedure specified in subsection (f) of this section (except that such amendment or repeal may be initiated either by a proposal of the Secretary or by a petition of any interested person) and (2) the Secretary finds, on the basis of new information with respect to such drug evaluated together with the information before him when the application under section 505 became effective or was approved, that

there is a lack of substantial evidence (as defined in section 505(d)) that the drug has the effect it purports or is represented to have under such conditions of use."

RECORDS AND REPORTS AS TO EXPERIENCE ON ANTIBIOTICS

SEC. 106. (a) Section 507 of such Act (21 U.S.C. 357) is amended by adding at the end thereof the following new subsection:

59 Stat. 463.

"(g) (1) Every person engaged in manufacturing, compounding, or processing any drug within the purview of this section with respect to which a certificate or release has been issued pursuant to this section shall establish and maintain such records, and make such reports to the Secretary, of data relating to clinical experience and other data or information, received or otherwise obtained by such person with respect to such drug, as the Secretary may by general regulation, or by order with respect to such certification or release, prescribe on the basis of a finding that such records and reports are necessary in order to enable the Secretary to make, or to facilitate, a determination as to whether such certification or release should be rescinded or whether any regulation issued under this section should be amended or repealed: *Provided, however,* That regulations and orders issued under this subsection and under clause (3) of subsection (d) shall have due regard for the professional ethics of the medical profession and the interests of patients and shall provide, where the Secretary deems it to be appropriate, for the examination, upon request, by the persons to whom such regulations or orders are applicable, of similar information received or otherwise obtained by the Secretary.

"(2) Every person required under this section to maintain records, and every person having 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."

Access to records.

(b) Section 507(d) of such Act (21 U.S.C. 357(d)) is amended by adding at the end thereof the following new sentences: "Such regulations may, within the discretion of the Secretary, among other conditions relating to the protection of the public health, provide for conditioning the exemption under clause (3) upon—

59 Stat. 463.

Regulations pertaining to exemption.

"(1) the submission to the Secretary, before any clinical testing of a new drug is undertaken, of reports, by the manufacturer or the sponsor of the investigation of such drug, of preclinical tests (including tests on animals) of such drug adequate to justify the proposed clinical testing;

"(2) the manufacturer or the sponsor of the investigation of a new drug proposed to be distributed to investigators for clinical testing obtaining a signed agreement from each of such investigators that patients to whom the drug is administered will be under his personal supervision, or under the supervision of investigators responsible to him, and that he will not supply such drug to any other investigator, or to clinics, for administration to human beings; and

"(3) 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 drug, of data (including but not limited to analytical reports by investigators) obtained as the result of such investigational use of such drug, as the Secretary finds will enable him to evaluate the safety and effectiveness of such drug in the event of the filing of an application for certification or release pursuant to subsection (a).

Such regulations shall provide that such exemption shall be conditioned upon the manufacturer, or the sponsor of the investigation, requiring that experts using such drugs for investigational purposes certify to such manufacturer or sponsor that they will inform any human beings to whom such drugs, or any controls used in connection therewith, are being administered, or their representatives, that such drugs are being used for investigational purposes and will obtain the consent of such human beings or their representatives, except where they deem it not feasible or, in their professional judgment, contrary to the best interests of such human beings. Nothing in this subsection shall be construed to require any clinical investigator to submit directly to the Secretary reports on the investigational use of drugs."

(c) Section 301(e) of such Act (21 U.S.C. 331(e)), as amended by section 103(c) of this Act, is further amended by striking out "505 (i) or (j)" and inserting in lieu thereof "505 (i) or (j), or 507 (d) or (g)".

Ante, p. 784.
Ante, pp. 783,
782, 787.

EFFECTIVE DATES AND APPLICATION OF PART A

SEC. 107. (a) Except as otherwise provided in this section, the amendments made by the foregoing sections of this part A shall take effect on the date of enactment of this Act.

(b) The amendments made by sections 101, 103, 105, and 106 of this part A shall, with respect to any drug, take effect on the first day of the seventh calendar month following the month in which this Act is enacted.

(c) (1) As used in this subsection, the term "enactment date" means the date of enactment of this Act; and the term "basic Act" means the Federal Food, Drug, and Cosmetic Act.

(2) An application filed pursuant to section 505(b) of the basic Act which was "effective" within the meaning of that Act on the day immediately preceding the enactment date shall be deemed, as of the enactment date, to be an application "approved" by the Secretary within the meaning of the basic Act as amended by this Act.

(3) In the case of any drug with respect to which an application filed under section 505(b) of the basic Act is deemed to be an approved application on the enactment date by virtue of paragraph (2) of this subsection—

(A) the amendments made by this Act to section 201(p), and to subsections (b) and (d) of section 505, of the basic Act, insofar as such amendments relate to the effectiveness of drugs, shall not, so long as approval of such application is not withdrawn or suspended pursuant to section 505(e) of that Act, apply to such drug when intended solely for use under conditions prescribed, recommended, or suggested in labeling covered by such approved application, but shall apply to any changed use, or conditions of use, prescribed, recommended, or suggested in its labeling, including such conditions of use as are the subject of an amendment or supplement to such application pending on, or filed after, the enactment date; and

(B) clause (3) of the first sentence of section 505(e) of the basic Act, as amended by this Act, shall not apply to such drug when intended solely for use under conditions prescribed, recommended, or suggested in labeling covered by such approved application (except with respect to such use, or conditions of use, as are the subject of an amendment or supplement to such approved application, which amendment or supplement has been approved after the enactment date under section 505 of the basic Act as amended by this Act) until whichever of the following first

"Enactment
date,"
"Basic Act,"
52 Stat. 1040.
21 USC 301.

52 Stat. 1052.
21 USC 355.

Ante, p. 781.

Ante, p. 781.

Ante, p. 782.

occurs: (i) the expiration of the two-year period beginning with the enactment date; (ii) the effective date of an order under section 505 (e) of the basic Act, other than clause (3) of the first sentence of such section 505 (e), withdrawing or suspending the approval of such application.

Ante, p. 781.

(4) In the case of any drug which, on the day immediately preceding the enactment date, (A) was commercially used or sold in the United States, (B) was not a new drug as defined by section 201 (p) of the basic Act as then in force, and (C) was not covered by an effective application under section 505 of that Act, the amendments to section 201 (p) made 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 such drug on that day.

21 USC 321.

21 USC 355.

Ante, p. 781.

PART B—STANDARDIZATION OF DRUG NAMES

REVIEW AND DESIGNATION OF OFFICIAL NAMES

SEC. 111. (a) The Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.), as amended by this Act, is further amended by adding at the end of chapter V the following new section:

“AUTHORITY TO DESIGNATE OFFICIAL NAMES

“SEC. 508. (a) The Secretary may designate an official name for any drug if he determines that such action is necessary or desirable in the interest of usefulness and simplicity. Any official name designated under this section for any drug shall be the only official name of that drug used in any official compendium published after such name has been prescribed or for any other purpose of this Act. In no event, however, shall the Secretary establish an official name so as to infringe a valid trademark.

“(b) Within a reasonable time after the effective date of this section, and at such other times as he may deem necessary, the Secretary shall cause a review to be made of the official names by which drugs are identified in the official United States Pharmacopeia, the official Homoeopathic Pharmacopoeia of the United States, and the official National Formulary, and all supplements thereto, to determine whether revision of any of those names is necessary or desirable in the interest of usefulness and simplicity.

Review of
names.

“(c) Whenever he determines after any such review that (1) any such official name is unduly complex or is not useful for any other reason, (2) two or more official names have been applied to a single drug, or to two or more drugs which are identical in chemical structure and pharmacological action and which are substantially identical in strength, quality, and purity, or (3) no official name has been applied to a medically useful drug, he shall transmit in writing to the compiler of each official compendium in which that drug or drugs are identified and recognized his request for the recommendation of a single official name for such drug or drugs which will have usefulness and simplicity. Whenever such a single official name has not been recommended within one hundred and eighty days after such request, or the Secretary determines that any name so recommended is not useful for any reason, he shall designate a single official name for such drug or drugs. Whenever he determines that the name so recommended is useful, he shall designate that name as the official name of such drug or drugs. Such designation shall be made as a regulation upon public notice and in accordance with the procedure set forth in section 4 of the Administrative Procedure Act (5 U.S.C. 1003).

60 Stat. 238.

“(d) After each such review, and at such other times as the Secretary may determine to be necessary or desirable, the Secretary shall cause to be compiled, published, and publicly distributed a list which shall list all revised official names of drugs designated under this section and shall contain such descriptive and explanatory matter as the Secretary may determine to be required for the effective use of those names.

“(e) Upon a request in writing by any compiler of an official compendium that the Secretary exercise the authority granted to him under section 508(a), he shall upon public notice and in accordance with the procedure set forth in section 4 of the Administrative Procedure Act (5 U.S.C. 1003) designate the official name of the drug for which the request is made.”

(b) This section shall take effect on the date of its enactment.

NAME TO BE USED ON DRUG LABEL

SEC. 112. (a) Section 502(e) of such Act (21 U.S.C. 352(e)) is amended by—

(1) inserting the subparagraph designation “(1)” after “(e)”;

(2) striking out the words “If it is a drug and is not designated solely by a name recognized in an official compendium unless its label bears (1) the common or usual name of the drug, if such there be; and (2), in case it is fabricated from two or more ingredients, the common or usual name of each active ingredient”, and inserting in lieu thereof “If it is a drug, unless (A) its label bears, to the exclusion of any other nonproprietary name (except the applicable systematic chemical name or the chemical formula), (i) the established name (as defined in subparagraph (2)) of the drug, if such there be, and (ii), in case it is fabricated from two or more ingredients, the established name and quantity of each active ingredient”;

(3) striking out the words “the name” and inserting in lieu thereof the words “the established name”;

(4) inserting therein, immediately after the colon following the words “contained therein”, the following: “*Provided*, That the requirement for stating the quantity of the active ingredients, other than the quantity of those specifically named in this paragraph, shall apply only to prescription drugs; and (B) for any prescription drug the established name of such drug or ingredient, as the case may be, on such label (and on any labeling on which a name for such drug or ingredient is used) is printed prominently and in type at least half as large as that used thereon for any proprietary name or designation for such drug or ingredient.”;

(5) striking out the words “clause (2) of this paragraph” in the proviso to such paragraph and inserting in lieu thereof “clause (A) (ii) or clause (B) of this subparagraph”; and

(6) adding at the end of such paragraph the following new subparagraph:

“(2) As used in this paragraph (e), the term ‘established name’, with respect to a drug or ingredient thereof, means (A) the applicable official name designated pursuant to section 508, or (B), if there is no such name and such drug, or such ingredient, is an article recognized in an official compendium, then the official title thereof in such compendium, or (C) if neither clause (A) nor clause (B) of this subparagraph applies, then the common or usual name, if any, of such drug or of such ingredient: *Provided further*, That where clause (B) of this subparagraph applies to an article recognized in the United States

60 Stat. 238.

52 Stat. 1050.

Ante, p. 789.

Pharmacopeia and in the Homoeopathic Pharmacopoeia under different official titles, the official title used in the United States Pharmacopeia shall apply unless it is labeled and offered for sale as a homoeopathic drug, in which case the official title used in the Homoeopathic Pharmacopoeia shall apply."

(b) Section 502(g) of such Act (21 U.S.C. 352(g)) is amended by inserting immediately before the period at the end thereof a colon and the following proviso: "*Provided further*, That, in the event of inconsistency between the requirements of this paragraph and those of paragraph (e) as to the name by which the drug or its ingredients shall be designated, the requirements of paragraph (e) shall prevail".

52 Stat. 1050.

(c) This section shall take effect on the first day of the seventh calendar month following the month in which this Act is enacted.

EXCLUSION OF COSMETICS

SEC. 113. Chapter V of the Federal Food, Drug, and Cosmetic Act, as amended by section 111 of this Act, is further amended by adding at the end thereof the following:

Ante, p. 789.

"NONAPPLICABILITY TO COSMETICS

"SEC. 509. This chapter, as amended by the Drug Amendments of 1962, shall not apply to any cosmetic unless such cosmetic is also a drug or device or component thereof."

INFORMATION TO PHYSICIANS

SEC. 114. (a) Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331), as amended by this Act, is further amended by adding at the end thereof the following new paragraph:

52 Stat. 1042.

"(o) In the case of a prescription drug distributed or offered for sale in interstate commerce, the failure of the manufacturer, packer, or distributor thereof to maintain for transmittal, or to transmit, to any practitioner licensed by applicable State law to administer such drug who makes written request for information as to such drug, true and correct copies of all printed matter which is required to be included in any package in which that drug is distributed or sold, or such other printed matter as is approved by the Secretary. Nothing in this paragraph shall be construed to exempt any person from any labeling requirement imposed by or under other provisions of this Act."

(b) This section shall take effect on the first day of the seventh calendar month following the month in which this Act is enacted.

PART C—AMENDMENTS AS TO ADVERTISING

PRESCRIPTION DRUG ADVERTISEMENTS

SEC. 131. (a) Section 502 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352) is further amended by adding at the end thereof the following new paragraph:

52 Stat. 1050.

"(n) In the case of any prescription drug distributed or offered for sale in any State, unless the manufacturer, packer, or distributor thereof includes in all advertisements and other descriptive printed matter issued or caused to be issued by the manufacturer, packer, or distributor with respect to that drug a true statement of (1) the established name as defined in section 502(e), printed prominently and in type at least half as large as that used for any trade or brand name thereof, (2) the formula showing quantitatively each ingredient of such drug to the extent required for labels under section 502(e), and (3) such other information in brief summary relating to side effects,

Ante, p. 790.

70 Stat. 919.
21 USC 371.

contraindications, and effectiveness as shall be required in regulations which shall be issued by the Secretary in accordance with the procedure specified in section 701(e) of this Act: *Provided*, That (A) except in extraordinary circumstances, no regulation issued under this paragraph shall require prior approval by the Secretary of the content of any advertisement, and (B) no advertisement of a prescription drug, published after the effective date of regulations issued under this paragraph applicable to advertisements of prescription drugs, shall, with respect to the matters specified in this paragraph or covered by such regulations, be subject to the provisions of sections 12 through 17 of the Federal Trade Commission Act, as amended (15 U.S.C. 52-57). This paragraph (n) shall not be applicable to any printed matter which the Secretary determines to be labeling as defined in section 201(m) of this Act."

52 Stat. 114.

52 Stat. 1041.
21 USC 321.

(b) No drug which was being commercially distributed prior to the date of enactment of this Act shall be deemed to be misbranded under paragraph (n) of section 502 of the Federal Food, Drug, and Cosmetic Act, as added by this section, until the earlier of the following dates: (1) the first day of the seventh month following the month in which this Act is enacted; or (2) the effective date of regulations first issued under clause (3) of such paragraph (n) in accordance with the procedure specified in section 701(e) of the Federal Food, Drug, and Cosmetic Act.

TITLE II—FACTORY INSPECTION AND EFFECT ON STATE LAWS

FACTORY INSPECTION

67 Stat. 477.

SEC. 201. (a) Section 704(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 374(a)) is amended to read as follows:

"(a) For purposes of enforcement of this Act, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are authorized (1) to enter, at reasonable times, any factory, warehouse, or establishment in which food, drugs, devices, or cosmetics are manufactured, processed, packed, or held, for introduction into interstate commerce or after such introduction, or to enter any vehicle being used to transport or hold such food, drugs, devices, or cosmetics in interstate commerce; and (2) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, such factory, warehouse, establishment, or vehicle and all pertinent equipment, finished and unfinished materials; containers, and labeling therein. In the case of any factory, warehouse, establishment, or consulting laboratory in which prescription drugs are manufactured, processed, packed, or held, the inspection shall extend to all things therein (including records, files, papers, processes, controls, and facilities) bearing on whether prescription drugs which are adulterated or misbranded within the meaning of this Act, or which may not be manufactured, introduced into interstate commerce, or sold, or offered for sale by reason of any provision of this Act, have been or are being manufactured, processed, packed, transported, or held in any such place, or otherwise bearing on violation of this Act. No inspection authorized for prescription drugs by the preceding sentence shall extend to (A) financial data, (B) sales data other than shipment data, (C) pricing data, (D) personnel data (other than data as to qualifications of technical and professional personnel performing functions subject to this Act), and (E) research data (other than data, relating to new drugs and antibiotic drugs, subject to reporting

and inspection under regulations lawfully issued pursuant to section 505 (i) or (j) or section 507 (d) or (g) of this Act, and data, relating to other drugs, which in the case of a new drug would be subject to reporting or inspection under lawful regulations issued pursuant to section 505(j) of this Act). A separate notice shall be given for each such inspection, but a notice shall not be required for each entry made during the period covered by the inspection. Each such inspection shall be commenced and completed with reasonable promptness. The provisions of the second sentence of this subsection shall not apply to—

Ante, pp. 783,
782, 787.

“(1) pharmacies which maintain establishments in conformance with any applicable local laws regulating the practice of pharmacy and medicine and which are regularly engaged in dispensing prescription drugs, upon prescriptions of practitioners licensed to administer such drugs to patients under the care of such practitioners in the course of their professional practice, and which do not, either through a subsidiary or otherwise, manufacture, prepare, propagate, compound, or process drugs for sale other than in the regular course of their business of dispensing or selling drugs at retail;

“(2) practitioners licensed by law to prescribe or administer drugs and who manufacture, prepare, propagate, compound, or process drugs solely for use in the course of their professional practice;

“(3) persons who manufacture, prepare, propagate, compound, or process drugs solely for use in research, teaching, or chemical analysis and not for sale;

“(4) such other classes of persons as the Secretary may by regulation exempt from the application of this section upon a finding that inspection as applied to such classes of persons in accordance with this section is not necessary for the protection of the public health.”

(b) Section 704(b) of such Act (21 U.S.C. 374(b)) is amended by inserting after “warehouse,” the words “consulting laboratory,”

67 Stat. 477.

(c) Section 302(a) of such Act (21 U.S.C. 332(a)) is amended by striking out “(f),”

52 Stat. 1043.

(d) Nothing in the amendments made by subsections (a) and (b) of this section shall be construed to negate or derogate from any authority of the Secretary existing prior to the enactment of this Act.

EFFECT ON STATE LAWS

SEC. 202. Nothing in the amendments made by this Act to the Federal Food, Drug, and Cosmetic Act shall be construed as invalidating any provision of State law which would be valid in the absence of such amendments unless there is a direct and positive conflict between such amendments and such provision of State law.

52 Stat. 1040.
21 USC 301.

EFFECTIVE DATE

SEC. 203. The amendments made by this title shall take effect on the date of enactment of this Act.

TITLE III—REGISTRATION OF DRUG ESTABLISHMENTS AND PATENT INFORMATION

FINDINGS AND DECLARATION

SEC. 301. The Congress hereby finds and declares that in order to make regulation of interstate commerce in drugs effective, it is necessary to provide for registration and inspection of all establishments in which drugs are manufactured, prepared, propagated, compounded,

or processed; that the products of all such establishments are likely to enter the channels of interstate commerce and directly affect such commerce; and that the regulation of interstate commerce in drugs without provision for registration and inspection of establishments that may be engaged only in intrastate commerce in such drugs would discriminate against and depress interstate commerce in such drugs, and adversely burden, obstruct, and affect such interstate commerce.

REGISTRATION OF PRODUCERS OF DRUGS

SEC. 302. Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by adding at the end thereof the following section:

“REGISTRATION OF PRODUCERS OF DRUGS

“SEC. 510. (a) As used in this section—

“(1) the term ‘manufacture, preparation, propagation, compounding, or processing’ shall include repackaging or otherwise changing the container, wrapper, or labeling of any drug package in furtherance of the distribution of the drug from the original place of manufacture to the person who makes final delivery or sale to the ultimate consumer;

“(2) the term ‘name’ shall include in the case of a partnership the name of each partner and, in the case of a corporation, the name of each corporate officer and director, and the State of incorporation.

“(b) On or before December 31 of each year every person who owns or operates any establishment in any State engaged in the manufacture, preparation, propagation, compounding, or processing of a drug or drugs shall register with the Secretary his name, places of business, and all such establishments.

“(c) Every person upon first engaging in the manufacture, preparation, propagation, compounding, or processing of a drug or drugs in any establishment which he owns or operates in any State shall immediately register with the Secretary his name, place of business, and such establishment.

“(d) Every person duly registered in accordance with the foregoing subsections of this section shall immediately register with the Secretary any additional establishment which he owns or operates in any State and in which he begins the manufacture, preparation, propagation, compounding, or processing of a drug or drugs.

“(e) The Secretary may assign a registration number to any person or any establishment registered in accordance with this section.

“(f) The Secretary shall make available for inspection, to any person so requesting, any registration filed pursuant to this section.

“(g) The foregoing subsections of this section shall not apply to—

“(1) pharmacies which maintain establishments in conformance with any applicable local laws regulating the practice of pharmacy and medicine and which are regularly engaged in dispensing prescription drugs, upon prescriptions of practitioners licensed to administer such drugs to patients under the care of such practitioners in the course of their professional practice, and which do not manufacture, prepare, propagate, compound, or process drugs for sale other than in the regular course of their business of dispensing or selling drugs at retail;

“(2) practitioners licensed by law to prescribe or administer drugs and who manufacture, prepare, propagate, compound, or process drugs solely for use in the course of their professional practice;

“(3) persons who manufacture, prepare, propagate, compound, or process drugs solely for use in research, teaching, or chemical analysis and not for sale;

“(4) such other classes of persons as the Secretary may by regulation exempt from the application of this section upon a finding that registration by such classes of persons in accordance with this section is not necessary for the protection of the public health.

“(h) Every establishment in any State registered with the Secretary pursuant to this section shall be subject to inspection pursuant to section 704 and shall be so inspected by one or more officers or employees duly designated by the Secretary at least once in the two-year period beginning with the date of registration of such establishment pursuant to this section and at least once in every successive two-year period thereafter.

“(i) Any establishment within any foreign country engaged in the manufacture, preparation, propagation, compounding, or processing of a drug or drugs shall be permitted to register under this section pursuant to regulations promulgated by the Secretary. Such regulations shall include provisions for registration of any such establishment upon condition that adequate and effective means are available, by arrangement with the government of such foreign country or otherwise, to enable the Secretary to determine from time to time whether drugs manufactured, prepared, propagated, compounded, or processed in such establishment, if imported or offered for import into the United States, shall be refused admission on any of the grounds set forth in section 801 (a) of this Act.”

67 Stat. 477;
Ante, p. 792.
21 USC 374.

Post, p. 796.

TRANSITIONAL PROVISIONS

SEC. 303. Any person who, on the day immediately preceding the date of enactment of this Act, owned or operated any establishment in any State (as defined in section 201 of the Federal Food, Drug, and Cosmetic Act as amended by this Act) engaged in the manufacture, preparation, propagation, compounding, or processing of a drug or drugs, shall, if he first registers in accordance with subsection (b) of section 510 of that Act (as added thereto by this Act) prior to the first day of the seventh calendar month following the month in which this Act is enacted, be deemed to have complied with that subsection for the calendar year 1962. Such registration, if made within such period and effected in 1963, shall also be deemed to be in compliance with such subsection for that calendar year.

Post, p. 796.

Ante, p. 794.

FAILURE TO REGISTER

SEC. 304. Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amended by adding at the end thereof the following new paragraph:

Ante, p. 791.

“(p) The failure to register as required by section 510.”

DRUGS FROM NONREGISTERED ESTABLISHMENTS MISBRANDED

SEC. 305. Section 502 of such Act (21 U.S.C. 352) is amended by adding at the end thereof the following new paragraph:

Ante, p. 791.

“(o) If it is a drug and was manufactured, prepared, propagated, compounded, or processed in an establishment in any State not duly registered under section 510.”

SAMPLES OF IMPORTED DRUGS

52 Stat. 1058.

SEC. 306. Section 801(a) of such Act (21 U.S.C. 381(a)) is amended by inserting, after the first sentence thereof, the following new sentence: "The Secretary of Health, Education, and Welfare shall furnish to the Secretary of the Treasury a list of establishments registered pursuant to subsection (i) of section 510 and shall request that if any drugs manufactured, prepared, propagated, compounded, or processed in an establishment not so registered are imported or offered for import into the United States, samples of such drugs be delivered to the Secretary of Health, Education, and Welfare, with notice of such delivery to the owner or consignee, who may appear before the Secretary of Health, Education, and Welfare and have the right to introduce testimony."

Ante, p. 795.

DEFINITIONS

52 Stat. 1041.

SEC. 307. (a) Section 201(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(a)) is amended to read as follows:

"(a) (1) The term 'State', except as used in the last sentence of section 702(a), means any State or Territory of the United States, the District of Columbia, and the Commonwealth of Puerto Rico.

"(2) The term 'Territory' means any Territory or possession of the United States, including the District of Columbia, and excluding the Commonwealth of Puerto Rico and the Canal Zone."

(b) The second sentence of section 702(a) of such Act (21 U.S.C. 372(a)) is amended by inserting before the words "a Territory" the words "the Commonwealth of Puerto Rico or".

INFORMATION ON PATENTS FOR DRUGS

52 Stat. 1056.

SEC. 308. Section 702 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 372) is amended by adding at the end thereof the following new subsection:

"(d) The Secretary is authorized and directed, upon request from the Commissioner of Patents, to furnish full and complete information with respect to such questions relating to drugs as the Commissioner may submit concerning any patent application. The Secretary is further authorized, upon receipt of any such request, to conduct or cause to be conducted, such research as may be required."

Approved October 10, 1962.

Public Law 87-782

AN ACT

October 10, 1962
[S. 3396]

To amend section 511(h) of the Merchant Marine Act, 1936, as amended, in order to extend the time for commitment of construction reserve funds.

Merchant Marine
Act, 1936, amend-
ment.
Construction re-
serve funds.
75 Stat. 661.
46 USC 1161.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That the proviso at the end of section 511(h) of the Merchant Marine Act, 1936, as amended, is amended to read as follows: "Provided, That until January 1, 1963, in addition to the extensions hereinbefore permitted, further extensions may be granted ending not later than December 31, 1963."

Effective date.

SEC. 2. The amendment made by the first section of this Act shall take effect December 31, 1962, or on the date of enactment of this Act, whichever date first occurs.

Approved October 10, 1962.