[CHAPTER 280]

AN ACT

July 6, 1945
[H. R. 3118]
[Public Law 138]

To amend section 100 of Public Law Numbered 346, Seventy-eighth Congress, June 22, 1944, to grant certain priorities to the Veterans' Administration, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That section 100 of Public Law Numbered 346, Seventy-eighth Congress, June 22, 1944, is hereby amended to read as follows:

Servicemen's Readjustment Act of 1944, amendment.
58 Stat. 284.
38 U. S. C., Supp. IV, § 693.
Post, p. 623.

"SEC. 100. The Veterans' Administration is hereby declared to be an essential war agency and entitled to priority equal to the highest granted any department or agency of the Government in personnel, service, space, equipment, supplies, and material under any laws, Executive orders, and regulations pertaining to priorities. During the continuance of the present war and for six months after its termination, the Administrator is authorized, for the purpose of extending benefits to veterans and dependents, and to the extent he deems necessary, to procure the necessary space for administrative, clinical, medical, and outpatient treatment purposes by lease, purchase, or construction of buildings, or by condemnation or declaration of taking, pursuant to existing statutes."

Approved July 6, 1945.

[CHAPTER 281]

AN ACT

July 6, 1945
[H. R. 3266]
[Public Law 139]

To amend the Federal Food, Drug, and Cosmetic Act of June 25, 1938, as amended, by providing for the certification of batches of drugs composed wholly or partly of any kind of penicillin or any derivative thereof, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That section 301 (i) of the Federal Food, Drug, and Cosmetic Act of June 25, 1938 (21 U. S. C. 301 and the following), as amended, is amended by inserting "507" after "506,".

Penicillin; derivatives.
55 Stat. 851.
21 U. S. C. Supp. IV, §§ 331, 356.

SEC. 2. Section 502 of such Act, as amended, is amended by adding a new paragraph at the end thereof, as follows:

52 Stat. 1050.
21 U. S. C., § 352; Supp. IV, § 352 (k).

"(l) If it is, or purports to be, or is represented as a drug composed wholly or partly of any kind of penicillin or any derivative thereof, unless (1) it is from a batch with respect to which a certificate or release has been issued pursuant to section 507, and (2) such certificate or release is in effect with respect to such drug: *Provided*, That this paragraph shall not apply to any drug or class of drugs exempted by regulations promulgated under section 507 (c) or (d)."

When misbranded.

Infra.

Nonapplicability.

SEC. 3. Chapter V of such Act, as amended, is amended by adding a new section at the end thereof, as follows:

52 Stat. 1049.
21 U. S. C. §§ 351–355; Supp. IV, §§ 352(k), 356.
Supra.

"CERTIFICATION OF DRUGS CONTAINING PENICILLIN

"SEC. 507. (a) The Federal Security Administrator, pursuant to regulations promulgated by him, shall provide for the certification of batches of drugs composed wholly or partly of any kind of penicillin or any derivative thereof. A batch of any such drug shall be certified if such drug has such characteristics of identity and such batch has such characteristics of strength, quality, and purity, as the Administrator prescribes in such regulations as necessary to adequately insure safety and efficacy of use, but shall not otherwise be certified. Prior to the effective date of such regulations the Administrator, in lieu of certification, shall issue a release for any batch which, in his judgment, may be released without risk

Release in lieu of certification.

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.

Regulations for certifications.

"(b) Regulations providing for such certifications shall contain such provisions as are necessary to carry out the purposes of this section, including provisions prescribing (1) standards of identity and of strength, quality, and purity; (2) tests and methods of assay to determine compliance with such standards; (3) effective periods for certificates, and other conditions under which they shall cease to be effective as to certified batches and as to portions thereof; (4) administration and procedure; and (5) 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 section.

Exemptions; regulations.
Ante, p. 463.

"(c) Whenever in the judgment of the Administrator, the requirements of this section and of section 502 (l) with respect to any drug or class of drugs are not necessary to insure safety and efficacy of use, the Administrator shall promulgate regulations exempting such drug or class of drugs from such requirements.

"(d) The Administrator shall promulgate regulations exempting from any requirement of this section and of section 502 (l), (1) 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; (2) drugs which conform to applicable standards of identity, strength, quality, and purity prescribed by these regulations and are intended for use in manufacturing other drugs; and (3) drugs which are intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety and efficacy of drugs.

52 Stat. 1052.
21 U. S. C. § 355.
Ante, p. 463.
52 Stat. 1049, 1051.
21 U. S. C. §§ 351 (b), 352 (g).

"(e) No drug which is subject to section 507 shall be deemed to be subject to any provision of section 505. Compliance of any drug subject to section 502 (l) or 507 with sections 501 (b) and 502 (g) shall be determined by the application of the standards of strength, quality, and purity, the tests and methods of assay, and the requirements of packaging and labeling, respectively, prescribed by regulations promulgated under section 507.

Petition proposing issuance, etc., of regulations.

Notice.

Time limitation.

Hearing.

Order; basis.

"(f) Any interested person may file with the Administrator a petition proposing the issuance, amendment, or repeal of any regulation contemplated by this section. The petition shall set forth the proposal in general terms and shall state reasonable grounds therefor. The Administrator shall give public notice of the proposal and an opportunity for all interested persons to present their views thereon, orally or in writing, and as soon as practicable thereafter shall make public his action upon such proposal. At any time prior to the thirtieth day after such action is made public any interested person may file objections to such action, specifying with particularity the changes desired, stating reasonable grounds therefor, and requesting a public hearing upon such objections. The Administrator shall thereupon, after due notice, hold such public hearing. As soon as practicable after completion of the hearing, the Administrator shall by order make public his action on such objections. The Administrator shall base his order only on substantial evidence of record at the hearing and shall set forth as part of the order detailed findings of fact on which the order is based. The order shall be subject to the provisions of section 701 (f) and (g)."

52 Stat. 1055.
21 U. S. C. § 371 (f), (g).

Approved July 6, 1945.