

individual that is not a hospital within such health system.

**(2) Compliance with State rules**

Repackaging of a drug under this section shall be done in compliance with applicable State requirements of each State in which the drug is repackaged and received.

**(d) Termination**

This section shall not apply on or after the date on which the Secretary issues final guidance that clarifies the policy of the Food and Drug Administration regarding hospital pharmacies repackaging and safely transferring repackaged drugs to other hospitals within the same health system during a drug shortage.

(June 25, 1938, ch. 675, §506F, as added Pub. L. 112-144, title X, §1007, July 9, 2012, 126 Stat. 1106.)

**§ 357. Repealed. Pub. L. 105-115, title I, § 125(b)(1), Nov. 21, 1997, 111 Stat. 2325**

Section, act June 25, 1938, ch. 675, §507, as added July 6, 1945, ch. 281, §3, 59 Stat. 463; amended Mar. 10, 1947, ch. 16, §3, 61 Stat. 12; July 13, 1949, ch. 305, §2, 63 Stat. 409; Aug. 5, 1953, ch. 334, §2, 67 Stat. 389; Pub. L. 87-781, title I, §§105(a), (b), (d)-(f), 106(a), (b), Oct. 10, 1962, 76 Stat. 785, 786, 787; Pub. L. 90-399, §105(b), July 13, 1968, 82 Stat. 352; Pub. L. 102-300, §6(b)(2), June 16, 1992, 106 Stat. 240; Pub. L. 103-80, §3(p), Aug. 13, 1993, 107 Stat. 777, related to certification of drugs containing penicillin, streptomycin, chlortetracycline, chloramphenicol, bacitracin, or any other antibiotic drug.

**§ 358. Authority to designate official names**

**(a) Necessity or desirability; use in official compendiums; infringement of trademarks**

The Secretary may designate an official name for any drug or device 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 or device shall be the only official name of that drug or device used in any official compendium published after such name has been prescribed or for any other purpose of this chapter. In no event, however, shall the Secretary establish an official name so as to infringe a valid trademark.

**(b) Review of names in official compendiums**

Within a reasonable time after October 10, 1962, 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 Pharmacopoeia, the official Homoeopathic Pharmacopoeia of the United States, and the official National Formulary, and all supplements thereto, and at such times as he may deem necessary shall cause a review to be made of the official names by which devices are identified in any official compendium (and all supplements thereto) to determine whether revision of any of those names is necessary or desirable in the interest of usefulness and simplicity.

**(c) Determinations of complexity, usefulness, multiplicity, or lack of name; designation by Secretary**

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 device, 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 to two or more devices which are substantially equivalent in design and purpose or (3) no official name has been applied to a medically useful drug or device, he shall transmit in writing to the compiler of each official compendium in which that drug or drugs or device are identified and recognized his request for the recommendation of a single official name for such drug or drugs or device 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 or device. Whenever he determines that the name so recommended is useful, he shall designate that name as the official name of such drug or drugs or device. Such designation shall be made as a regulation upon public notice and in accordance with the procedure set forth in section 553 of title 5.

**(d) Revised official names; compilation, publication, and public distribution of listings**

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 or devices 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) Request by compiler of official compendium for designation of name**

Upon a request in writing by any compiler of an official compendium that the Secretary exercise the authority granted to him under subsection (a) of this section, he shall upon public notice and in accordance with the procedure set forth in section 553 of title 5 designate the official name of the drug or device for which the request is made.

(June 25, 1938, ch. 675, §508, as added Pub. L. 87-781, title I, §111(a), Oct. 10, 1962, 76 Stat. 789; amended Pub. L. 94-295, §5(b), May 28, 1976, 90 Stat. 581; Pub. L. 103-80, §3(q), Aug. 13, 1993, 107 Stat. 777.)

AMENDMENTS

1993—Subsecs. (c), (e). Pub. L. 103-80 substituted reference to section 553 of title 5 for “section 4 of the Administrative Procedure Act (5 U.S.C. 1003)”.

1976—Subsec. (a). Pub. L. 94-295 substituted “drug or device” for “drug” wherever appearing.

Subsec. (b). Pub. L. 94-295 substituted “National Formulary, and all supplements thereto, and at such times as he may deem necessary shall cause a review to be made of the official names by which devices are identified in any official compendium (and all supplements thereto)” for “National Formulary, and all supplements thereto.”

Subsec. (c)(2). Pub. L. 94-295 inserted “or device” after “single drug”, and “or to two or more devices which are substantially equivalent in design and purpose” after “purity”.

Subsec. (c)(3). Pub. L. 94-295 inserted “or device” after “useful drug” and after “drug or drugs” wherever appearing.

Subsec. (d). Pub. L. 94-295 inserted “or devices” after “drugs”.

Subsec. (e). Pub. L. 94-295 substituted “drug or device” for “drug”.

#### EFFECTIVE DATE

Pub. L. 87-781, title I, §111(b), Oct. 10, 1962, 76 Stat. 790, provided that: “This section [enacting this section] shall take effect on the date of its enactment [Oct. 10, 1962].”

### § 359. Nonapplicability of subchapter to cosmetics

This subchapter, 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.

(June 25, 1938, ch. 675, §509, as added Pub. L. 87-781, title I, §113, Oct. 10, 1962, 76 Stat. 791.)

#### REFERENCES IN TEXT

This subchapter, as amended by the Drug Amendments of 1962, referred to in text, means the amendment of this subchapter by Pub. L. 87-781 which enacted sections 358 to 360 of this title, amended sections 351 to 353, 355, and 357 of this title, and enacted provisions set out as notes under sections 352, 355, 358, and 360 of this title.

The Drug Amendments of 1962, referred to in text, is Pub. L. 87-781, Oct. 10, 1962, 76 Stat. 780, as amended. For complete classification of this Act to the Code, see Short Title of 1962 Amendment note set out under section 301 of this title and Tables.

### § 360. Registration of producers of drugs or devices

#### (a) Definitions

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 or device package in furtherance of the distribution of the drug or device from the original place of manufacture to the person who makes final delivery or sale to the ultimate consumer or user; and

(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) Annual registration

(1) During the period beginning on October 1 and ending on 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 the name of such person, places of business of such person, all such establishments, the unique facility identifier of each such establishment, and a point of contact e-mail address.

(2) During the period beginning on October 1 and ending on 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 device or devices shall register with the Secretary his name, places of business, and all such establishments.

(3) The Secretary shall specify the unique facility identifier system that shall be used by registrants under paragraph (1). The requirement to include a unique facility identifier in a registration under paragraph (1) shall not apply until the date that the identifier system is specified by the Secretary under the preceding sentence.

#### (c) New producers

Every person upon first engaging in the manufacture, preparation, propagation, compounding, or processing of a drug or drugs or a device or devices in any establishment which he owns or operates in any State shall immediately register with the Secretary—

(1) with respect to drugs, the information described under subsection (b)(1); and

(2) with respect to devices, the information described under subsection (b)(2).<sup>1</sup>

#### (d) Additional establishments

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 or a device or devices.

#### (e) Registration number; uniform system for identification of devices intended for human use

The Secretary may assign a registration number to any person or any establishment registered in accordance with this section. The Secretary may also assign a listing number to each drug or class of drugs listed under subsection (j) of this section. Any number assigned pursuant to the preceding sentence shall be the same as that assigned pursuant to the National Drug Code. The Secretary may by regulation prescribe a uniform system for the identification of devices intended for human use and may require that persons who are required to list such devices pursuant to subsection (j) of this section shall list such devices in accordance with such system.

#### (f) Availability of registrations for inspection

The Secretary shall make available for inspection, to any person so requesting, any registration filed pursuant to this section; except that any list submitted pursuant to paragraph (3) of subsection (j) of this section and the information accompanying any list or notice filed under paragraph (1) or (2) of that subsection shall be exempt from such inspection unless the Secretary finds that such an exemption would be inconsistent with protection of the public health.

#### (g) Exclusions from application of section

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

<sup>1</sup> So in original.