

## 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

Section 111(b) of Pub. L. 87-781 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) On or before December 31 of each year every person who owns or operates any estab-

lishment 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.

(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.

**(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 his name, place of business, and such establishment.

**(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 and medicine and which are regularly engaged in dispensing prescription drugs or devices, upon prescriptions of practitioners licensed to