

shall finalize the taxonomy not later than 1 year after the close of the public comment period.”

### **§ 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 nec-

essary 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), 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.)

### **Editorial Notes**

#### **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”.

### **Statutory Notes and Related Subsidiaries**

#### **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.)

### **Editorial Notes**

#### **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