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(c) The Food and Drug Administration recognizes the skill and experience of the U.S. Adopted Names Council (USAN) in deriving names for drugs. The U.S. Adopted Names Council is a private organization sponsored by the American Medical Association, the United States Pharmacopeia, and the American Pharmaceutical Association, and has been engaged in the assignment of names to drugs since January 1964. The Council negotiates with manufacturing firms in the selection of nonproprietary names for drugs.

(d) The Food and Drug Administration cooperates with and is represented on the USAN Council. In addition, the Food and Drug Administration agrees with ''Guiding Principles for Coining U.S. Adopted Names for Drugs,'' published in *USAN and the USP Dictionary of Drug Names* (USAN 1985 ed., 1961–1984 cumulative list), which is incorporated by reference. Copies are available from: U.S. Pharmacopeial Convention, Inc., 12601 Twinbrook Parkway, Rockville, MD 20852, or are available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal__register/code__of__federal__regulations/ibr__locations.html*. All applicants for new-drug applications and sponsors for ''Investigational New Drug Applications'' (IND's) are encouraged to contact the USAN Council for assistance in selection of a simple and useful name for a new chemical entity. Approval of a new-drug application providing for the use of a new drug substance may be delayed if a simple and useful nonproprietary name does not exist for the substance and if one is not proposed in the application that meets the above-cited guidelines. Prior use of a name in the medical literature or otherwise will not commit the Food and Drug Administration to adopting such terminology as official.

(e) The Food and Drug Administration will not routinely designate official names under section 508 of the act. As a result, the established name under section 502(e) of the act will ordinarily be either the compendial name of the drug or, if there is no compendial name, the common and usual name of the drug. Interested persons, in the absence of the designation by the food and Drug Administration of an official name, may rely on as the established name for any drug the current compendial name or the USAN adopted name listed in *USAN and the USP Dictionary of Drug Names*. The Food and Drug Administration, however, will continue to publish official names under the provisions of section 508 of the act when the agency determines that:

(1) The USAN or other official or common or usual 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 that are identical in chemical structure and pharmacological action and that are substantially identical in strength, quality, and purity; or

(3) No USAN or other official or common or usual name has been applied to a medically useful drug. Any official name published under section 508 of the act will be the established name of the drug.

(f) A cumulative list of U.S. adopted names selected and released since June 15, 1961, is published yearly by the U.S. Pharmacopeial Convention, Inc., in *USAN and the USP Dictionary of Drug Names*. Copies may be purchased from the U.S. Pharmacopeial Convention, Inc., 12601 Twinbrook Parkway, Rockville, MD 20852.

[40 FR 14041, Mar. 27, 1975, as amended at 49 FR 37575, Sept. 25, 1984; 53 FR 5369, Feb. 24, 1988; 55 FR 11577, Mar. 29, 1990; 64 FR 401, Jan. 5, 1999; 69 FR 18803, Apr. 9, 2004]

§ 299.5 Drugs; compendial name.

(a) The name by which a drug is designated shall be clearly distinguishing and differentiating from any name recognized in an official compendium unless such drug complies in identity with the identity prescribed in an official compendium under such recognized name.

(b) The term *drug defined in an official compendium* means a drug having the identity prescribed for a drug in an official compendium.

(c) A statement that a drug defined in an official compendium differs in strength, quality, or purity from the standard of strength, quality, or purity set forth for such drug in an official compendium shall show all the respects in which such drug so differs, and the extent of each such difference.