SUPPLEMENTAL POLICIES

ESTABLISHED NAMES

Drugs are often times known by various names which may be code names, chemical names, acronyms, innovator's names, trivial names, official names, compendial names and United States Adopted Names (USAN). Because of the number of drugs available, it is important that we establish a name which is familiar to everyone so we can have a common denominator when discussing a drug. The need for designating a single name for each drug is specified in Section 508 of the Federal Food, Drug, and Cosmetic Act. 21 CFR Part 299 provides regulations that interpret Section 508 of the Act.

Use of an established name, if there is one for a drug, is required by Section 502(e)(1) of the Act as information of the identity of a drug which may be distributed in different dosage forms under different brand or proprietary names by manufacturers or distributors.

Physicians and veterinarians may use or prescribe drugs by an established name instead of a brand name.

1. Purpose:

   This guide provides information on the requirements, types and sources of names used for human and animal drug preparations.

2. Established Names - Types:

   a. Official Names

      Official names are designated pursuant to Section 508 of the Act. The Secretary may designate an official name for any drug if he determines that such action is necessary or desirable in the interest of usefulness and simplicity. Section 502(e)(3) recognizes an order of preference; i.e., if a name is established pursuant to Section 508, it must be used. If an official name has not been established under Section 508, a compendial name can be used. If there is no compendial name, then the common and usual name of the drug is to be used.

   b. Compendial Names

Compendial names are those used in official compendia. The Act recognizes the United States Pharmacopeia (USP), the National Formulary and the Homeopathic Pharmacopeia of the United States as official compendia. Where the compendia have different names for the same drug, the official USP title is to be adopted as prescribed in Section 502(e)(3)(c) of the Act.

The USP contains the following requirements regarding the use of official titles:

> "The word "official," as used in the U.S. Pharmacopeia is synonymous with "Pharmacopeial," with "USP," and with "Compendial."
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> The designation USP in conjunction with the official title on the label of an article is a reminder that the article purports to comply with USP standards;...The standards apply equally to articles bearing the official titles or names derived by transposition of the definitive words of official titles or transposition in the order of the names of two or more active ingredients in official titles, whether or not the added designation "USP" is used...
>
> Where an article differs from the standards of strength, quality, and purity, as determined by the application of the assays and tests, set forth in the Pharmacopeia, its difference shall be plainly stated on its label..."

c. Common or Usual Names

(1) The common or usual drug names are usually selected and adopted by the USAN Council, sponsored by the United States Pharmacopeia Commission, Inc. In general, as new drugs are discovered, the innovator may request a United States Adopted Name (USAN) for the new substance when it reaches the clinical investigation stage. The USAN is usually then accepted as the established name. Even though the Food and Drug Administration (FDA) has accepted all USAN names as established names in the past (and sees no reason to discontinue this practice), the FDA still has the final authority to accept or to reject any name proposed as an established name including USANs. The USAN Council has an FDA liaison member and his/her judgement should reflect that of FDA/CVM.

Pharmaceutical firms should be encouraged to utilize the experience of the USAN in developing systematic names for drugs.

(2) In case of drug adjuncts, nonchemical, nonproprietary names appearing in the Food Chemical Codex, the Index Medica, the Chemical Abstracts and the British Pharmacopeia may serve as common or usual names.

d. International Nonproprietary Names (INN)

The World Health Organization (WHO) may recommend international nonproprietary names for pharmaceutical substances to its member states under its charter. INN names are not recognized by FDA under Section 502(e)(3) of the Act. Names may be proposed to WHO by institutions, organizations and individuals. Names selected by WHO are first published as proposed names, allowing for comments and objections. After their resolution of objections, if any, the proposed names are published as recommended names which may then be recognized by member states as sole or preferred nonproprietary names. While the USAN does not directly recognize INN names as sole or preferred nonproprietary names, the USAN Council closely cooperates with WHO.

3. Chemical Names:

Chemical names appearing in a regulation and on the label(s) and package insert of a drug should preferably be those adopted by the Chemical Abstracts Service (CAS) of the American Chemical Society, or should be developed according to the CAS system of chemical nomenclature. The CAS should be petitioned by drug firms to designate a chemical name for a drug substance or adjunct. Other chemical names may also be acceptable, provided that the name is adequate to properly describe the compound and to permit the writing of its appropriate structure.

4. Multi-Component Pharmaceutical Preparations:

Established names are not required for pharmaceutical preparations containing multiple drug components (active ingredients). In such cases, the label must declare the established name of each component.