⟨1121⟩ NOMENCLATURE

INTRODUCTION

The *USP* (or *NF*) titles for monograph articles are legally recognized under the Federal Food, Drug, and Cosmetic Act as the designations for use in labeling the articles to which they apply.

The value of designating each drug substance by one and only one nonproprietary[1] name is important in terms of achieving simplicity and uniformity in drug nomenclature. In support of the U.S. Adopted Names program (see *Mission and Preface* in *USP–NF*), of which the U.S. Pharmacopeial Convention is a co-sponsor, the USP Council of Experts gives consideration to the adoption of the U.S. Adopted Name, if any, as the official title for any compound that attains compendial recognition.

A compilation of the U.S. Adopted Names (USAN) published from the start of the USAN program in 1961, as well as other names for drugs, both current and retrospective, is provided in the *USP Dictionary of USAN and International Drug Names.* This publication serves as a book of names useful for identifying and distinguishing all kinds of names for drug substances, whether public, proprietary, chemical, or code-designated names.[2]

A nonproprietary name of a drug serves numerous and varied purposes. Its principal function is to identify the substance to which it applies by means of a designation that may be used by the professional and lay public free from the restrictions associated with registered trademarks. Teaching in the health sciences requires a common designation, especially for a drug that is available from several sources or is incorporated into a combination drug product; nonproprietary names facilitate communication among healthcare providers; nonproprietary names must be used as the titles of the articles recognized by official drug compendia; a nonproprietary name is essential to the pharmaceutical manufacturer as a means of protecting trademark rights in the brand name for the article concerned; and, finally, the manufacturer is obligated by federal law to include the established nonproprietary name in advertising and labeling.

Under the terms of the Drug Amendments of 1962 to the Federal Food, Drug, and Cosmetic Act, which became law October 10, 1962, the Secretary of Health and Human Services is authorized to designate an official name for any drug wherever deemed "necessary or desirable in the interest of usefulness and simplicity."[3]

The Commissioner of Food and Drugs and the Secretary of Health and Human Services published in the *Federal Register* regulations effective November 26, 1984, which state, in part:

> "**Sec. 299.4 Established names of drugs.**"
> "(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*."[4]

It will be noted that the monographs on the biologics, which are produced under licenses issued by the Secretary of the U.S. Department of Health and Human Services, represent a special case. Although efforts continue toward achieving uniformity, there may be a difference between the respective title required by federal law and the *USP* title. Such differences are fewer than in past revisions of the Pharmacopeia. The *USP* title, where different from the FDA Center for Biologics Evaluation and Research title, does not necessarily constitute a synonym for labeling purposes; the conditions of licensing the biologic concerned require that each such article be designated by the name appearing in the product license issued to the manufacturer. Where a *USP* title differs from the title in the federal regulations, the former has been adopted with a view to usefulness, simplicity, and conformity with the principles governing the selection of monograph titles generally.

MONOGRAPH NAMING POLICY FOR SALT DRUG SUBSTANCES IN DRUG PRODUCTS AND COMPOUNDED PREPARATIONS

The titles of *USP* monographs for drug products and compounded preparations formulated with a salt of an acid or base use the name of the active moiety, as defined below. The strength of the product or preparation is also expressed in terms of the active moiety.

An active moiety is the molecule or ion, excluding those appended portions of the molecule that cause the drug to be a salt (including a salt with hydrogen or coordination bonds), or other noncovalent derivative (such as a complex, chelate, or clathrate) of the molecule. The active moiety is responsible for the physiological or pharmacological action of the drug substance, without regard to the actual charged state of the molecule in vivo. For example, the active moiety of a hydrochloride salt of a base is the free base and not the protonated form of the base. The active moiety of a metal salt of an acid is the free acid.

This Policy is followed by USP in naming drug products and compounded preparations that are newly recognized in the *USP*. Revising existing monographs to conform to this Policy is not intended, except where the USP Council of Experts determines that, for reasons such as safety, a nomenclature change is warranted.

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[1] The term "generic" has been widely used in place of the more accurate and descriptive term "nonproprietary" with reference to drug nomenclature.
[2] *USP Dictionary of USAN and International Drug Names* is obtainable on order from U.S. Pharmacopeia, Customer Service Department, 12601 Twinbrook Parkway, Rockville, MD 20852.
[3] F.D.&C. Act, Sec. 508 [358].
[4] 53 Fed. Reg. 5369 (1988) amending 21 CFR § 299.4.

Labeling

The labeling clearly states the specific salt form of the active moiety that is present in the product or preparation because this information may be useful to practitioners and patients. The names and strengths of both the active moiety and specific salt form (when applicable) are provided in the labeling.

Exceptions

In rare cases in which the use of the specific salt form of the active moiety in the title provides vital information from a clinical perspective, an exception to this policy may be considered. In such cases, when the monograph title contains the specific salt form of the active moiety, the strength of the product or preparation also is expressed in terms of the specific salt form.

GENERAL NOMENCLATURE FORMS

List of the specific drug products with extensive examples can be found in the USP Nomenclature Guidelines (www.usp.org). USP also developed some general practices for drug product nomenclature:

- The [ROUTE OF ADMINISTRATION] is omitted for those dosage forms for which the route of administration is understood. The general form then becomes simply [DRUG] [DOSAGE FORM].
  - Thus, oral will not be included as the route of administration for orally administered capsules, tablets, and lozenges.
  - The route of administration is omitted for topically applied products—creams, ointments, lotions, and pastes. However, if some other route of administration is intended (e.g. ophthalmic), it will be included in the monograph title.
- In some instances, the drug is supplied in one dosage form for the preparation of the intended dosage form. In such cases, the dosage form provided in the container is named first and the word "for" appears, followed by the final dosage form that is suitable for administration. The general format becomes [DRUG] [DOSAGE FORM] for [ROUTE OF ADMINISTRATION] [DOSAGE FORM]., e.g. Aspirin Effervescent Tablets for Oral Solution.
- The term "for" is included in the names of solid preparations which must be dissolved or suspended in a suitable liquid to obtain a dosage form suitable for administration, and the general format becomes [DRUG] for [ROUTE OF ADMINISTRATION] [DOSAGE FORM]. e.g. Ampicillin for Oral Suspension, Cytarabine for Injection.
- The term "Vaginal Inserts", rather than "Vaginal Tablets", "Vaginal Capsules", or "Vaginal Suppositories" is used in the title of this type of vaginal preparation to decrease the potential for misadministration of these products.
- The term "Suppositories" is used in the titles of solid preparations that are intended for rectal administration.
- Solutions administered by injection are officially titled Injections (see *Injections and Implanted Drug Products* ⟨1⟩). The route of administration is omitted for drugs that are injected, because the route (e.g. intravenous, intramuscular, subcutaneous, etc.) must appear on the labels and in the labeling. USP defines seven types of injections:
  1. [DRUG] Injection—Liquid preparations that are drug substances or solutions thereof.
  2. [DRUG] for Injection—Dry solids that, upon the addition of suitable vehicles, yield solutions conforming in all respects to the requirements for Injections.
  3. [DRUG] Injectable Emulsion—Liquid preparations of drug substances dissolved or dispersed in a suitable emulsion medium.
  4. [DRUG] Injectable Suspension—Liquid preparations of solids suspended in a suitable liquid medium.
  5. [DRUG] for Injectable Suspension—Dry solids that, upon the addition of suitable vehicles, yield preparations conforming in all respects to the requirements for Injectable Suspensions.
  6. [DRUG] Extended-Release Injectable Suspension—Liquid preparations of solids suspended in a suitable liquid medium and formulated in a manner that allows the contained API to be available over an extended period of time.
  7. [DRUG] for Extended-Release Injectable Suspension—Dry solids that, upon the addition of suitable vehicles, yield preparations conforming in all respects to the requirements for Extended-Release Injectable Suspensions.

Injections intended to be administered through an intravenous secondary line ("piggyback") formulated in vehicles other than Water for Injection shall be named [DRUG] in [VEHICLE]. Examples of Vehicle formats which currently appear in *USP* monograph titles are:

1. [DRUG] in Dextrose Injection
2. [DRUG] in Dextrose and Sodium Chloride Injection
3. [DRUG] in Lactated Ringer's and Dextrose Injection
4. [DRUG] in Sodium Chloride Injection

POLICY FOR IMPLEMENTATION OF NOMENCLATURE REVISIONS

It is the practice of USP to set the official dates of nomenclature revisions (change of the established name or nomenclature aspects of the labeling sections in the monographs) to allow a reasonable time for product label changes to be made and to allow health practitioners and consumers time to become familiar with the new terminology. The assignment of an implementation schedule is handled by the USP Expert Committee. USP's implementation schedule, shown below, is automatic, unless an exception is sought.

18 Months

Implementation period of 18 months is usually applied when only one or a small number of products is affected.

30 Months

Implementation period of 30 months is usually applied when names or labeling of multisource products or multiproduct lines of a firm's preparations are being changed.

60 Months

Implementation period of 60 months is usually applied for title and labeling changes that affect excipients, because such changes would require relabeling of very large numbers of prescription-only and OTC preparations.

There may be exceptions to this schedule where a shorter time is needed in order to specify nomenclature and labeling changes in cases where public health and safety are a concern. Extensions to the implementation schedule are rarely made, and must have suitable justification as well as the approval of the USP Expert Committee. Any questions or concerns regarding this postponement schedule may be addressed to the USP staff liaison assigned to the Expert Committee.