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New Policy Brings Clarity, Consistency to Drug Names

USP Monograph Naming Policy to Become Official May 1, 2013
Monograph Titles to Be Based on Clinically-Active Components of Drugs

Rockville, Md., November 19, 2012 — To provide greater clarity and consistency in naming practices for medicines, a new drug naming policy established by the United States Pharmacopeial Convention (USP) will become official on May 1, 2013. The policy will apply prospectively to drug product and compounded preparation monographs that appear in USP's compendia of public quality standards—the *United States Pharmacopeia* and *National Formulary* (*USP–NF*). USP has worked closely with the US Food and Drug Administration (FDA) and industry stakeholders over a number of years to develop the new policy.

According to the *Monograph Naming Policy for Salt Drug Substances in Drug Products and Compounded Preparations* (Monograph Naming Policy), a drug product or compounded preparation formulated with a salt of an acid or base will use the active moiety—the portion of the molecule responsible for clinical activity—in the title of a monograph. The Monograph Naming Policy also stipulates that the strength of the product or preparation will be expressed in terms of the active moiety. This means that the name of the drug and its strength should be based on the active moiety, not its salt form.

"The development of USP's Monograph Naming Policy is designed to provide concise and consistent names for drug products," said Roger L. Williams, M.D., chief executive officer of USP and chair of the Council of Experts. "This consistency in drug product names ultimately will benefit manufacturers, regulators, practitioners, and, most importantly, patients."

Under the Federal Food, Drug and Cosmetic Act, if there is a USP monograph for a drug product, the monograph title must be used as the nonproprietary name of that product. If a monograph does not exist at the time the product is approved, then FDA can designate an "Interim" name. USP monographs are typically developed years after the product approval, which has led to inconsistencies in naming, including mismatches of the name and strength of the drug product.

The Monograph Naming Policy was posted to USP's website in 2007 as a revision to General Chapter <1121> *Nomenclature* in *USP–NF*, so that stakeholders would have time to prepare for the May 2013 official date. The USP Nomenclature, Safety, and Labeling Expert Committee (NSL EC)—the USP Expert Committee responsible for monograph title approvals—will generally apply the following implementation principles:

- **For products with an existing USP monograph**, the policy will **not** be retroactively applied unless there is a justifiable need.
- **Prior to May 1, 2013**, FDA-approved products with no existing USP monographs will be considered on a case-by-case basis. USP generally will accept Interim drug names approved by FDA for USP dosage form monograph titles that are proposed or implemented before May 1, 2013. The NSL EC will work to avoid retrospective changes to approved product names, and will consider input from industry and other stakeholders regarding retrospective application of the policy.
- **After May 1, 2013**, the policy will apply to FDA-approved products with no existing USP monographs. Deviations from the policy may continue to occur, and will be considered on a case-by-case basis.
- **With regard to products not yet approved by the FDA**, applicants are encouraged to contact the FDA early in the application process to consider implications of the policy.

Exceptions to the policy will include:

- Cases in which the strength of the drug product is expressed for historical reasons in terms of the salt;
- When the inclusion of the specific salt form of the active moiety provides vital information from a clinical perspective (e.g., when the salt form affects the absorption, distribution, metabolism and/or excretion [ADME] of the drug in a manner that influences a clinician's product selection);
- Attempts to maintain consistency with other dosage form monographs in a particular "monograph family" (e.g., new approval for an additional dosage form of an existing product line).

"Because of the prospective nature of the policy," said Dr. Williams, "we do not anticipate many changes in the names of existing products, which would be confusing to patients and practitioners. Rather, the changes will occur prospectively over time."

A proposed revision to General Chapter <1121> describing the monograph naming policy appears in the November-December 2012 issue of *Pharmacopeial Forum*—the free-access, online vehicle through which USP proposes new and revised standards. To access additional information on USP's monograph naming policy, go to: http://uspgo.to/monograph-naming.

For additional information, contact mediarelations@usp.org.

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