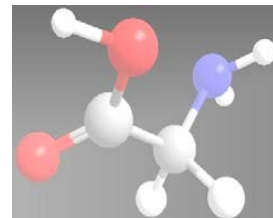


USAN_{INSIDER}



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In This Issue

USAN UPDATE

Procedure for USAN Name Selection

When is a USAN Assigned?

USAN Application Wire Transfers

Can You File for a USAN and INN Simultaneously? **No!**

Upcoming Events

About USAN

USAN Website Links:

How to Apply for a Name

Application Forms

Naming Guidelines

FAQs

USAN Council Nomination Inquiries

USAN UPDATE

The AMA office building is closed, and the USAN staff is working from home (WFH) effective March 17- until further notice. To all perspective applicants: USAN applications and USAN payments **must** be sent electronically. Please send all applications to USAN@ama-assn.org. For electronic payment information please contact Mary Haynes (mary.haynes@ama-assn.org) or Brad Wells (brad.wells@ama-assn.org).

Procedure for USAN Name Selection

The process of assigning a United States Adopted Name (USAN), referred to as a "negotiation," begins when a pharmaceutical firm or its representative files an application to name the substance. It ends with the statement of adoption a document that formally assigns a USAN to a specific substance. The sponsoring firm, the USAN Council and the International Nonproprietary Names (INN) Expert Group must agree on a single name for the substance before a statement of adoption is issued.

The USAN Council considers several criteria in evaluating potential names:

- Whether a name reflects the drug action and fits the naming scheme.
- How well a name translates into languages other than English.
- How easy a name is to pronounce and remember?

When is a USAN Assigned?

The USAN is assigned while a drug is undergoing clinical trials. Companies may apply during Phase 1 studies, but many wait until Phase 2 studies begin. Most want the USAN before Phase 3 large-scale studies are complete, so that it will be available for publications and, when needed, to develop packaging, labeling and promotional materials.



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Because many more drugs enter clinical trials than are approved for market, many USAN are assigned to substances that are never sold in the U.S., but could be available in countries outside the U.S. Thus, review by INN ensures that there will be a single name accepted by all countries worldwide.

The USAN Council classifies drugs using the knowledge available when names are coined. Similarly, stems are defined according to the available knowledge at the time. If new indications are found for a stem class or drug, the name of the drug or the definition of the stem does not usually change. This means, for example, that the -prazole stem used to name lansoprazole (Prevacid™) was formally defined as "antiulcer agents," although these drugs are now more often used to manage GERD. Lansoprazole has indications for both heartburn and GERD. More knowledge may become available after a drug is named or a stem is coined, and nomenclature is an evolving art and science.

Consequently, drugs have been named by different means over the last several decades. Early on, many drug names were coined by condensing the systematic chemical name. Later, the system was changed to the current prefix-infix-stem system to reduce confusion of drug names and to make the drug name more directly refer to the class or function. The USAN Program expects that nomenclature practices will continue to evolve as new substances are developed and marketed by the pharmaceutical industry.

USAN Application Wire Transfers

We have recently received notification from our accounting department that some manufacturers are sending their USAN application fees to the wrong banking institution. Please use the following information in the hyperlink below when making a wire transfer to the USAN Program or contact mary.haynes@ama-assn.org for instructions.

✓ **[USAN Program Wire Transfer and ACH Directions](#)**

Can You File for a USAN and INN Simultaneously? **No!**

USAN and INN applications **MUST** be filed sequentially. The reason why it's not feasible to file for a USAN and INN simultaneously, is due to both nomenclature institutions striving to have one non-proprietary name globally. By doing this, it helps promotes nomenclature drug safety and lessen medication errors.

Medication errors make up a high proportion of all events related to patient safety, and are particularly common in intensive care, pediatrics/neonatology, care of the elderly, anesthetics, and obstetrics. Some medication errors will result in overdose, adverse drug reactions, or



under-treatment, and cause serious harm to patients. As more medications enter the market, with greater variation in routes of administration, this problem is becoming increasingly complex.

For example, a manufacturer files for an USAN and an INN at the same time. The manufacturer receives a proposed USAN and a proposed INN but they are two different names. This will only create confusion in the drug nomenclature industry which will affect physicians, pharmacists, and patients.



Upcoming Events

- ✓ USAN Council Winter Meeting – December 4th, 2020
- ✓ 72nd INN Spring 2021 Consultation – April 12-16, 2021



About USAN

The purpose of the United States Adopted Names (USAN) Council is to serve the health professions of the United States by selecting simple, informative and unique nonproprietary names for drugs by establishing logical nomenclature classifications based on pharmacological and/or chemical relationships.

The USAN Council is tri-sponsored by the American Medical Association (AMA), the United States Pharmacopeial Convention (USP) and the American Pharmacists Association (APhA). The USAN Council aims for global standardization and unification of drug nomenclature and related rules to ensure that drug information is communicated accurately and unambiguously. It works closely with the International Nonproprietary Name (INN) Program of the World Health Organization (WHO) and various national nomenclature groups.

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