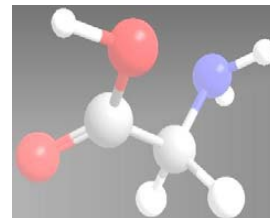


USAN_{INSIDER}



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USAN applications and USAN payments **MUST** be sent electronically. Please send all applications to USAN@ama-assn.org. For electronic payment information please contact AMA.treasury@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.

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.



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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.

Welcome New USAN's Staff Member

Miki Hewitt, B.F.A. is joining the American Medical Association (AMA) effective April 1 as the full-time Staff Assistant III for the United States Adopted Names Program (USAN). Miki received her undergraduate degree from the International Academy of Design and Technology. Prior to USAN, Miki contracted with the AMA's Human Resource department as a Human Resource consultant and Talent Coordinator. Miki brings her administrative assistant and support specialist skills to the USAN team. Join us in welcoming Miki to the AMA!

***New* - Adoption Statement Review Form**

When reviewing your USAN Adoption Statement for publication, you can now use the new Adoption Statement Review Confirmation and Publication Acknowledgement Form. Recipients of USAN Adoption Statements will now receive this form along with their adoption letter and statement.

(Adoption Statement Review Confirmation and Publication Acknowledgement Form)

USAN First Policy

Per USAN Program policy, firms should apply for a non-proprietary drug name through their national nomenclature program first. In the United States of America, this national agency is the USAN Program.

In addition to being policy, there are benefits associated with applying for a USAN before an INN.

Benefits of Applying for a USAN First:

- 1) The name (proposed USAN) that will be reviewed by the INN Committee is cleared by the USAN Council (USANC) with review from the FDA. The FDA can refer to detailed information about the drug substance through the IND number on file. Because of this vetting, names submitted to the INN Programme by USAN carry more weight and are more likely to be accepted by the INN Experts. Typically, less than 10% of USAN sponsored names submitted to the INN will need re-discussion at a future USANC meeting.
- 2) As part of USAN services, USAN staff will file the INN application and submit additional materials on USAN applicants' behalf at no additional fee. (The INN application fee is \$12,000).
- 3) Less time is required to officially become an adopted USAN; USAN are adopted after the INN Expert meeting comment period expires and before the name appears in a published INN list.
- 4) Assistance from USAN staff in identifying the proper stem, suitable prefixes
- 5) Free USAN staff assistance is available throughout the USAN and INN application process.
- 6) Continuous balloting by the USANC occurs throughout the year. Unlike INN review, USANC review is not limited to biannual meetings.

Tips for an INN Review

- ✓ Deadlines for all materials to be submitted to the INN Experts are about 2-3 months before the meeting. The INN deadlines are firm; they do not grant extensions.
- ✓ The USAN Program applies for an INN on behalf of the pharmaceutical firm. Consequently, firms requesting an INN through the USAN Program should route correspondence through the USAN program Secretariat.
- ✓ The name cannot be used as an INN until the INN Secretariat completes the publication process. After names are published as a pINN, there is a 4-month public comment period. If no objections are received, the name is published as a rINN. USAN Program staff will notify the firm of any pINN objections.





- ✓ US firms that have begun US clinical trials should file for the USAN first. International firms may choose to request either the USAN or the INN first.

There is a misconception that filing for an INN first to make the deadlines for a specific INN meeting may allow a firm to obtain a USAN/INN more quickly. **This is not the case.** If the INN is requested before the USAN, we will not issue an adoption statement until after the pINN public comment period elapses.

USAN Council 2024 Summer Meeting Minutes

The 2024 Summer Hybrid Meeting of the United States Adopted Names (USAN) Council was held Friday, June 14, 2024 at the US Pharmacopeia (USP) Headquarters in Rockville, Maryland. The topics discussed at this meeting included general USAN activities and policy, issues relating to drug nomenclature, and proposed USAN name reviews and recommendations.

Members of the USAN Council were in attendance, as well as members of the USAN Program staff housed at the American Medical Association (AMA). Additional observers were present from the United States Pharmacopeia (USP), the World Health Organization (WHO) International Nonproprietary Names (INN) Program, and The United States Food and Drug Administration (FDA).

The following items were discussed:

USAN Activities

- Negotiation stats showed a slight increase flow in adoptions with a slight increase in new submissions.
- USAN Program activities discussed included statistical reports on active negotiations, and USAN participation in the INN Program

USAN Negotiations

- 35 negotiations were discussed: 9 biologics, 2 multiple-round, 16 new negotiations, 6 open-ended negotiations and 2 INN actions

WHO-INN Nomenclature and USAN-sponsored Applications

- USAN sponsored 10% of the new INN applications discussed (26 USAN-sponsored applications)

- Revisions were approved for 12 USAN Council names previously recommended.

USAN Policy

- New stems: 17 approved by the Council.
- 1 new modifier for radicals and anions was approved by the Council.

USP Updates

- USP representative provided information pertaining to USP activities.

Upcoming Events



- ✓ 79th INN Fall Consultation – October 22-25, 2024
- ✓ USAN Council Winter Meeting – December 2024

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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