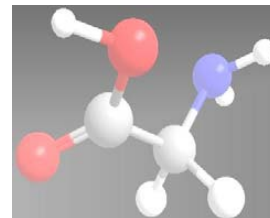


USAN_{INSIDER}



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*Firms waiting for the results of the upcoming December 2024 USAN Council meeting can expect to be notified the week of December 9. For your submission to be reviewed at the spring 2025 INN consultation, we will need acceptances and proof of payment (e.g., a PDF of the wire transfer confirmation) by **January 3, 2025**. If your firm has already received a balloting result from the USAN Council and is still considering whether to accept the name, we recommend letting USAN staff know in the next several weeks.*

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.

Rounding Molecular Weights

When applying for an USAN, the Molecular weight should be given according to current guidelines for standard atomic weights of the elements by the [IUPAC Commission on Atomic Weights and Isotopic Abundances](#). If no molecular weight can be calculated, this may be left blank, but approximate weights should be listed if they are known. For consistency, published USAN Adoption Statements illustrate molecular weights to tenths place only (not hundredths).

Stems in Trade Names

USAN naming guidelines include the following statement: “By definition, nonproprietary names are not subject to proprietary trademark rights but are entirely in the public domain. This distinguishes them from the trademarked names that have been registered for private use.” Essentially, don’t put your USAN stem or entire USAN within your trade name.

Creating a trade name with nonproprietary name information not only inhibits the USAN Council’s work, but also inhibits the work of the international naming body, the INN Program. The nonproprietary name should be **clearly** distinguished from the trade name. The nonproprietary stem is a clue in the name that relays information about the compound and acts as a grouping for all compounds that are similar either chemically,



in receptor affinity or by source if the substance is biologically derived. Now that database searches and Google hits are an important concern, nonproprietary stems within trade names can skew data and distort research.

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When the USAN Council is considering a name, research is done to verify that the potential name is free from trade name conflicts. If a stem or entire USAN has been incorporated into a trade name, this would be a potential conflict, disrupting the timely and efficient application of a name, delaying the INN process, the adoption of your name, the use of your name in your publications and other communications, and publication of your USAN and distribution for dictionary publication. If, after adoption takes place, the USAN Program discovers a trade name has been registered which conflicts with the adopted name, we will defer publication until we receive notice that the trade name has been abandoned.

Guiding Principle #4 under Naming Guidelines states: “A name should be free from conflict with other nonproprietary names and with established trademarks and should be neither confusing nor misleading.” Further expansion on this statement is the “Protection of USAN and INN Stems” document, also in the website’s Naming Guidelines section. This document states:

With the growing number of USAN/INN and brand names, the possibility of conflicts between nonproprietary names, between trademarks, and between trademarks and nonproprietary names has increased significantly. A frequent source of conflict in the latter category is the practice of piggybacking on the USAN/INN, which is the incorporation of the official nomenclature stems, or clearly recognizable parts of stems, in the trademark. If trademark registration is obtained for names containing an officially reserved stem, the freedom of the USAN and the INN programs to select further nonproprietary names in the same series of substances is seriously diminished.

If the USAN Council has applied a new stem to your compound, this means that there is a possibility this stem could be used again for another substance later. If the stem is conflicts with a trade name, it creates a fundamental problem for the USAN Council’s work.

You, as a sponsor, must take on the responsibility to refrain from infringing on official drug nomenclature stems by using them in trade names.

Publication Deferment Option

If you’ve come to adoption time and realized you are not ready for your statement to be published, there is an option. A publication deferment is a period of time after adoption takes place which will allow you further review time. You must request a publication deferment by the time your



initial post adoption sixty-day review period is completed. USAN Program policy allows for a publication deferment of up to six months from the time that your proposed adoption statement revisions and completed review confirmation form is due. This means that you have up to eight months total to review your statement and submit proposed revisions to the USAN Program before publication takes place. When the USAN Program is preparing to publish and there is no response from the sponsor when either the initial sixty-day period or the requested publication deferment period is up, the statement will be published as-is. If there are changes in the chemical information of your compound, or any other adoption statement items, which occur after you have approved the statement and the statement is published and distributed to the *USP Dictionary of USAN and International Drug Names*, the adoption statement must go through a USAN Revised application process (please see the Form D on the USAN website's [application page](#)). Please email brad.wells@ama-assn.org to request a publication deferment and you will receive a rescheduling confirmation.

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.



Upcoming Events

- ✓ USAN Council Winter Meeting – December 6, 2024
- ✓ 80th INN Spring Consultation – March 18-21, 2025

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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