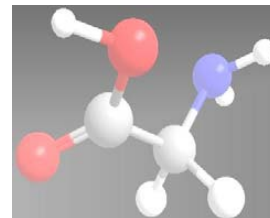


# USAN<sup>INSIDER</sup>



## Volume 12, Issue 4

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USAN applications and USAN payments must be sent electronically. Please send all applications to [USAN@ama-assn.org](mailto:USAN@ama-assn.org). For electronic payment information please contact [AMA.treasury@ama-assn.org](mailto:AMA.treasury@ama-assn.org).

## USAN Fee-for-Service Changes

Starting January 2, 2024 the fee-for-service for obtaining a United States Adopted Name (USAN) will increase. Listed below is the new fee schedule:

- Naming a new single-entity drug, including a compound that has been assigned an International Nonproprietary Name (INN), pharmaceutical aid, or suture material.....**\$18,000.00**
- USAN modified (name for a salt, ester, or enantiomer/racemate of a drug for which a USAN already exists).....**\$ 10,000.00**
- USAN revised (revision of support information used to define a USAN or USAN modified) .....**\$ 5,000.00**
- Name for a new contact lens polymer.....**\$18,000.00**
- USAN modified (name for a contact lens polymer for which an adopted USAN already exists or USAN revised (revision of supporting information used to define a USAN or USAN modified)....**\$ 10,000.00**

## Why Is Accurate and Updated CAS Information Necessary for My USAN Submission?

Whether you, as the applicant, are submitting USAN applications for a parent compound, salt or submitting a USAN Revised application, it is important to update your information with CAS. The USAN Program relies on this accuracy to allow for chemical review and subsequent publication of the adoption statement. CAS numbers provide a way to properly identify and reduce ambiguity. They were created to function as unique identifiers to help eliminate confusion caused by the use of synonyms applied to the same chemical. This is so important because a particular substance with a common name may have different chemical names and different CAS assignments.



Again, updated information is very important with your USAN application. Sometimes there are cases of deleted or replaced registry numbers which can create confusion. It is possible that a different source of registration, such as a partnered company, duplicates registration of a CAS number for the same substance.

## 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).

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## 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 and name alternatives is offered at no extra charge and is included in the USAN application fee.

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.

## How is My Name Being Registered as an Internet Domain?

USAN and INN are in the public domain and cannot be owned. However, the same rule does not apply to Internet domain names. There are certain parties that will register USAN and any names under consideration without prior knowledge of the USAN Program or the applicant. Then, for a company to obtain the proper domain name later following the selection and adoption of USAN and INN, substantial fees are charged by the



domain name owners. To combat this, USAN has started issuing notices in our correspondence to applicants and has posted the USAN Council's statement on domain names on the USAN web site, however it is still not illegal for USAN or names under consideration to be registered by unaffiliated third parties.

The USAN Program strongly recommends parking your "names under consideration" and USAN Council recommendations before they go to the INN. Internet sites such as godaddy.com or register.com will allow you to either park your name or determine if your name has been taken.



## Upcoming Events

- ✓ USAN Council Winter Meeting – December 2023
- ✓ 78<sup>th</sup> INN Spring Consultation – March 19-22, 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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