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United States Adopted Names USAN Insider Newsletter



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USAN's **NEW** Application & Payment Submittal Portal Launched September 8, 2025

We are excited to announce that the launch of the USAN Application Portal is **now live!**

The new portal allows you to submit applications, including all supporting documentation, and pay application fees online. Methods of payment will remain the same (wire and ACH only). Our overall goal is to modernize and improve the application submission experience.

Effective September 8, we began accepting all new applications for naming consideration through the USAN Application Portal. Please feel free to bookmark this URL for easy access: apply-usan.ama-assn.org

If you have any questions as you begin to use the new portal or if you need an invite email, please do not hesitate to contact us at usanapp@ama-assn.org.



Brand name and generic name guidelines for active ingredients

Unlike generic names, brand names vary from company to company and from country to country. In rare instances, a brand name may be used for 2 different active ingredients in different countries. More commonly, a company uses different brand names in different countries for the same drug, or 2 countries may market the same substance under different brand names. Finally, as part of "brand extension" business strategies, companies use the same brand name to refer to 2 different active ingredients.

Brand: Cialis

Generic: tadalafil

Brand: Colemin, Lipex, Zocor and Vytorin

Generic: simvastatin

Brand: Gleevec, Glivec

Generic: imatinib mesylate



What compounds do the USAN Program name?

USAN will be provided for the following:

- Small-molecule drugs
- Biotechnology drugs including monoclonal antibodies, therapeutic vaccines, proteins and peptides, DNA, RNA, nucleoside and nucleotide therapies
- Gene therapies
- Cellular therapies
- Other biological substances deemed appropriate to be assigned a USAN by the USAN Council
- Contact lens materials
- Active ingredients in sunscreens
- Veterinary products intended to control diseases in animals
- The base, salt, ester or other chemical derivative of a substance that has received a USAN

USAN will not be provided for the following:

- Mixtures that do not have an IND number or do not require approval for human use by the FDA
- Bacterial strains
- Drug delivery mechanisms
- Excipients alone
- Prophylactic vaccines
- Product formulations* (emulsions, suspensions, etc.)
- Medical devices
- Manufacturing processes

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 are offered at no extra charge and are 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

- 81stINN Fall Consultation: **October 14-17, 2025**
- USAN Council Winter Meeting: **December 5, 2025**

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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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