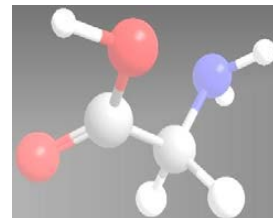


USAN^{INSIDER}



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International Nonproprietary Names and Payment

The USAN Council with the INN Programme, functions to ensure one non-proprietary name is used throughout the world for each marketed drug. As part of USAN services, USAN staff will file the INN application and submit additional materials on USAN applicants' behalf at no additional fee once USAN receives the \$12,000 INN application fee from the manufacturer. Important note: The INN review applications twice a year at their bi-annual meetings. If the manufacturers would like to have their application reviewed they must meet USAN's deadline before each INN meeting. For example, when the INN application is completed by USAN staff the manufacturer must submit their INN payment to USAN at that time. Also note that some banks charge a transaction fee for electronic processing of the INN payment. Please check with your bank and include this fee with the INN payment.

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.



Understanding INN Review

Before almost all names can be formally adopted as USAN, they are sent to the World Health Organization's (WHO's) [International Nonproprietary Names \(INN\) Programme](#). Review by the INN Experts ensures that the name will be accepted internationally. With the recent INN meeting, it seemed useful to address some common concerns about the INN review process.

The INN Experts meet twice a year, usually in April and October. Unlike the USAN Council, the INN Experts make decisions only at their meetings. After names are selected at each meeting, there is a period during which members of the group may make additional comments and suggestions on the selected names. This period usually lasts about 3-4 weeks, and USAN Program staff waits to notify manufacturers of INN decisions until after it has elapsed. 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 regarding the submission through the USAN Program Secretariat. Firms should not use a name accepted by the USANC until after the INN review process is complete and they have received an adoption statement. Once they receive this document, they may use the name as a USAN.

The name cannot be used as an INN until the INN Secretariat completes the publication process. Normally, names are published as a pINN about 6-12 months after the meeting. There is then a 4-month public comment period. If no objections are received, the name is published as a rINN. In the unlikely event that there is a public objection, USAN Program staff will notify the firm. 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 filling 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 USAN is requested before the INN, the USAN Program will not issue an adoption statement until the name is published as a pINN and the public comment period elapses.

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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

- ✓ 69th INN Fall Consultation – October 22-25th, 2019
- ✓ USAN Council Winter Meeting – December 5-6th, 2019



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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