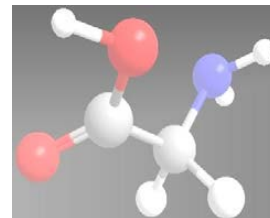


USAN_{INSIDER}



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USAN UPDATE

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.

Monoclonal Antibody Nomenclature

Recognizing the need for continued revisions because of crowding in the -mab stem class (over 800 monoclonal antibody names have been selected), the INN Experts have revised the nomenclature scheme for monoclonal antibodies. USAN Program staff, USAN Council members, and the FDA participated in developing the revisions to monoclonal antibody nomenclature published by INN.

The new antibody nomenclature scheme was implemented at the fall 2021 INN consultation in naming monoclonal antibodies, and firms with in-process USAN submissions for monoclonal antibodies may see revisions to their suggested names.

Although the USAN Council must formally review and accept the revised scheme for monoclonal antibody nomenclature before it can be published on the USAN Web site, we encourage firms to review the changes to monoclonal antibody nomenclature published by WHO. USAN submissions for monoclonal antibodies that were revised by the INN Experts at their fall 2021 consultation will also be discussed at the December meeting. Formal letters informing firms of any name changes because of the nomenclature scheme change will be sent after the December USANC meeting.

The new INN scheme for monoclonal antibody nomenclature is available at [new_mab_-nomenclature-_2021.pdf \(who.int\)](#).

Firms filing new submissions for monoclonal antibodies are STRONGLY ENCOURAGED to review this scheme before submitting a USAN application and may also base suggested names on the new suffixes for monoclonal antibody therapies.



Names that have already been adopted as USAN but have not been published on pINN or rINN lists are not expected to change at this time, nor will names that are already rINN names be changed to conform to the scheme.

If you have questions about a specific USAN negotiation that is a monoclonal antibody, please feel free to reach out to USAN staff and include your USAN file number in the correspondence.

[Contact Us](#)

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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).

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.

USAN Application Wire Transfers

We have recently received notification from our accounting department that some manufacturers are sending their USAN application fees to the wrong banking institution. Please use the following information in the hyperlink below when making a wire transfer to the USAN Program or contact AMA.treasury@ama-assn.org or mary.haynes@ama-assn.org for instructions.

- ✓ **USAN Program Wire Transfer and ACH Directions**

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 the INN comment period has expired.



Upcoming Events

- ✓ USAN Council Winter Meeting – December 2021
- ✓ 74th INN Spring Consultation – April 5-8th, 2022

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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