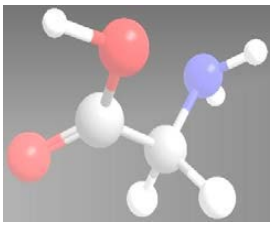
USAN INSIDER



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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.

What Does an USAN Name Mean?

Several decades ago when the USAN Program first began coining names (and even before its inception), condensing the systematic chemical name of a substance was a common way to coin drug names. This is no longer the case.

Now, new names consist of 3 parts: a prefix, an infix (sometimes) and a stem.

Prefix: Means nothing; differentiates drug from others in class

Infix: Used occasionally; further subclassifies

Stem: Indicates place in nomenclature scheme; drugs with the same stem are related

Stems are usually at the end of a name, with a few exceptions (e.g., cef-), and indicate the drug's place within the nomenclature scheme. Consequently, a new suffix often but not always suggests a new mechanism of action. Drugs with the same ending (stem) belong to the same pharmacologic family. Infixes, appearing in the middle of the word, are sometimes used to further classify the drug. Prefixes mean nothing. The sole purpose of a prefix is to differentiate a drug from other members of the class.

As an example, consider sildenafil (Viagra™), vardenafil (Levitra™), and tadalafil (Cialis™). The -afil stem is formally defined as for PDE5 (phosphodiesterase 5) inhibitors. The -den- infix indicates that sildenafil and vardenafil have similar chemical structures. The prefixes are sil-, var- and tadal-.

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Monoclonal Antibody Nomenclature Scheme (effective December 2021)

Suffix. To increase variation in the suffixes of monoclonal antibody names, antibodies were divided into four groups.

Group 1 -tug

Unmodified immunoglobulins. Monospecific full length and Fc unmodified immunoglobulins of any class, as they might occur in the immune system, including:

- IgG, IgA, IgM, IgD, IgE
- only allelic variants
- Glycoengineering without mutation
- C-terminal lysine deletion without any other mutation in the Fc region

Group 2 -bart

Engineered or “artificial” immunoglobulins. Monospecific full immunoglobulins with engineered constant domains (CH1/2/3), monospecific full-length immunoglobulins containing any point mutation introduced by engineering for any reason anywhere (hinge, new glycan attachment site, mixed allelic variants not occurring in nature, altered complement binding, altered FcRn binding, altered Fc-gamma receptor binding, etc.)

Group 3 -mig

Multi-immunoglobulins. Bi- and multi-specific immunoglobulins of any format, type or shape (full length, full length plus, fragments)

Group 4 -ment

Fragments. Monospecific domains and fragments of any kind, derived from an immunoglobulin variable domain (all monospecific constructs that do not contain an Fc domain)

Infix. Infixes to denote the action or target of monoclonal antibodies will still be used. The list of available infixes for naming new antibodies is shown below. Please note that some infixes, most notably the -li- for immunomodulatory antibodies, has been discontinued. Others, most notably -ki- have new definitions.

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.

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

- ✓ 74th INN Spring Consultation – April 5-8th, 2022
- ✓ USAN Council Summer Meeting – June 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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