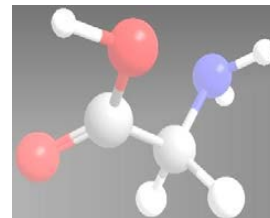


USAN_{INSIDER}



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USAN UPDATE

The AMA office building is closed, and the USAN staff is working from home (WFH) effective March 17- until further notice. To all perspective applicants: USAN applications and USAN payments **must** be sent electronically. Please send all applications to USAN@ama-assn.org. For electronic payment information please contact Mary Haynes (mary.haynes@ama-assn.org) or Brad Wells (brad.wells@ama-assn.org).

What is CAS and why is it important?

Worldwide, Chemical Abstracts Service (CAS) is regarded as a comprehensive source of chemical information. The CAS Chemical Registry System was introduced in 1965 and CAS Online was launched in 1980, initially used primarily by information specialists to search the database. Today the Registry contains more than 130 million organic and inorganic substances, with 67 million sequences. Each CAS registry number is a unique numeric identifier designating only one substance. The registry number is used throughout many fields spanning use in industry, education, scientific research, and commercial sales from chemical catalogs and online shopping. Federal regulations use CAS numbers heavily for identification purposes involving such things as importing and exporting, customs and merchandise, transportation, food additives, occupational safety and health standards, environmental pollutant codes, and substance identification in hazard evaluations. Registry numbers are often used to identify chemical substances in journal articles, handbooks, indexes, databases and inventories.

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



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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.

When submitting a USAN application for a contact lens material USAN needs to receive a CAS registration number for each monomer, and one for the entire polymer. If it is a hybrid material a CAS is required for each set of monomers plus both polymers.

2020 USAN Summer Meeting Minutes

The 2020 Summer Meeting of the United States Adopted Names (USAN) Council was held Friday, June 12, 2020 virtually via WebEx. The topics discussed at this meeting included general USAN activities and policy, issues relating to drug nomenclature, and proposed USAN name reviews and recommendations.

All members of the USAN Council were in attendance, as well as members of the USAN Program staff housed at the American Medical Association (AMA). Additional observers were present from the United States Pharmacopeia (USP), and the World Health Organization (WHO) International Nonproprietary Names (INN) Program.

The following items were discussed:

USAN Activities

- Negotiation stats showed a steady flow in adoptions with a slight increase in new submissions
- USAN Program activities discussed included statistical reports on active negotiations, cumulative adopted names and USAN participation in the INN Program

USAN Negotiations

- 41 negotiations discussed: 11 revisions, 12 biologics, 8 multiple round, 7 new negotiations, and 3 INN's

WHO-INN Nomenclature and USAN-sponsored Applications

- USAN sponsored 21% of the new INN applications discussed (41 USAN-sponsored applications)
- Revisions were approved for 30 USAN Council names previously recommended



USAN Policy

- New stems: 7 approved by the Council
- Revised stem definitions: 1 approved by the Council

USAN Website

- Website statistics included average site views per month, year-to-date totals, average time viewed and demographic information of USAN website visitors

Medication Error Issues

- Institute for Safe Medication Practices (ISMP) Medication Errors Reporting Program covering November 1, 2019-April 30, 2020 and cumulative data since May 1, 2002 were discussed
- U.S. FAERS Medication Errors Report covering November 2019-April 2020

USP Updates

- USP representative provided information pertaining to USP activities

New Stems Approved

The new stems listed below were approved at the June 12, 2020 USAN Council meeting:

Stem	Definition	Examples
-caprant	Kappa opioid receptor antagonists	Aticaprant
-fimloc	FimH (E. coli) blockers	Sibofimloc
-rsen -nersen	Antisense oligonucleotides Neurologic indications	Tominersen, Turanersen
-stat -polstat	DNA polymerase inhibitors	Ibezapolstat
-xestat	Autotaxin inhibitors	Ziritaxestat
-taront	Trace amine associated receptor (TAAR) agonists	Ralmitaront
-taront	Trace amine associated receptor (TAAR) agonists	Ralmitaront
-xian	Coagulation factor XIa inhibitors	Milvexian



Revised Definitions

Stem	Old Definition	Examples
-sulpiride	Sulpiride derivatives	Sulpiride derivatives and analogs ¹

1. INN is broadening their definition to include compounds that are related but not strictly derivatives of sulpiride.

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 in a proposed INN list and the 4-month public comment period has expired with no objections raised. 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

- ✓ INN Spring 2021 Consultation – April 20-23, 2021
- ✓ USAN Council Winter Meeting – TBD

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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