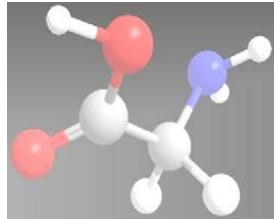


USAN INSIDER



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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.

Why is accurate and updated CAS information necessary for my USAN submission?

When 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. As an example, the first chemical name on the USAN Adoption statement should always match the CAS Registry Name. To check accuracy, the sponsor company should always verify that the CAS name detail matches the CAS Registry Number online. CAS numbers provide a way to properly identify and reduce ambiguity. They were created to function as unique identifiers to help eliminate confusion caused using 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,



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such as a partnered company, duplicates registration of a CAS number for the same substance.

What if I am applying for a contact lens material?

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.

2019 USAN Winter Meeting Minutes

The 2019 Winter Meeting of the United States Adopted Names (USAN) Council was held Friday, December 6, 2019 at the Diplomat Beach Resort in Hollywood, FL. The topics discussed at this meeting included general USAN activities and policy, issues relating to drug nomenclature, and proposed USAN name reviews and recommendations.

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 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

- 45 negotiations discussed: 14 revisions, 6 biologics, 6 multiple round, 15 new negotiations, and 4 INN's

WHO-INN Nomenclature and USAN-sponsored Applications

- USAN sponsored 25% of the new INN applications discussed (42 USAN-sponsored applications)
- Revisions were approved for 26 USAN Council names previously recommended

USAN Policy

- New stems: 3 approved by the Council
- Revised stem definitions: 3 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 May 1, 2019-October 31, 2019 and cumulative data since May 1, 2002 were discussed

USP Updates

- USP representative provided information pertaining to USP activities

New Stems Approved by USAN Council at December 6, 2019 Meeting

New Stems

Stem	Definition	Examples
-bep*	Bioengineered proteins*	<i>Taldefgrobep*</i>
-stat	1) kallikrein inhibitors or 2) serine protease inhibitors	<i>Avoralstat,</i>
-alstat		<i>berotralstat</i>

Revised stems (for harmonization with INN)

Old stem	New stem	Definition
None		

Revised definitions

Stem	Old Definition	New Definition
-cept ¹	Receptor molecules or membrane ligands, natural or modified	Receptor molecules or membrane ligands, natural or synthetic
-imod ² -tolimod	Immunomodulators, toll-like receptor	Immunomodulators, toll-like receptor agonists
-toran ²	Toll-like receptor 4 antagonists (TLR4)	Toll-like receptor antagonists

1. The nomenclature scheme for bioengineered proteins (-bep) will be used for synthetic receptor molecules.
2. Revision is suggested to avoid coining new stems for each TLR receptor subtype.

Harmonization of Definitions with INN

Stem	INN Definition	USAN Definition
None		

Radicals and Anions

Modifier	Chemical Name	Structure
None		

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

- ✓ 70th INN Spring Consultation – April 21-24th, 2020
- ✓ USAN Council Summer Meeting – June 5-6th or 11-12th, 2020



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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