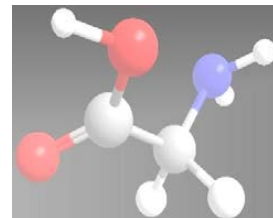


USAN_{INSIDER}



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USAN UPDATE

To all prospective 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).

Nomenclature Scheme for Cellular and Noncellular Therapeutic Products

The nomenclature scheme for cellular and noncellular therapeutic products, described in this report, was developed by the USAN working group for cell therapies. Under the scheme, the cell type/source and product manipulation or modification would be part of the cellular therapy product name, incorporated as infixes. The suffix -cel would be used for all cell therapies, and -imut for noncellular immunotherapeutic products. The USAN Council would review the prefixes suggested by the manufacturer for each name; the prefix would provide uniqueness for products in the same category.

Please note the following are not covered by the Cell and Gene therapies scheme: minimally manipulated hematopoietic elements including minimally manipulated umbilical cord blood and peripheral blood stem cells for transplant; combination products, which include combinations of cells with non-cellular pharmaceutical products (cell/device, cell/drug combination products); prophylactic vaccines; tissue engineered products; induced pluripotent stem (iPS) cells; embryonic-derived cell therapies; and veterinary cellular therapies.



2021 USAN Summer Meeting Minutes

The 2021 Summer Meeting of the United States Adopted Names (USAN) Council was held Friday, June 4th, 2021, 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

- 36 negotiations discussed: 3 revisions, 12 biologics, 12 multiple rounds, 8 new negotiations, and 1 INN's

WHO-INN Nomenclature and USAN-sponsored Applications

- USAN sponsored 16% of the new INN applications discussed (43 USAN-sponsored applications)
- Revisions were approved for 30 USAN Council names previously recommended

USAN Policy

- New stems: 8 approved by the Council
- Revised stem definitions: 2 approved by the Council

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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, 2020-April 31, 2021, and cumulative data since May 1, 2002, were discussed
- U.S. FAERS Medication Errors Report covering Nov 2020-April 2021

USP Updates

- USP representative provided information pertaining to USP activities

New Stems Approved

The new stems listed below were approved at the June 4th, 2021, USAN Council meeting:

Stem	Definition	Examples
-capavir	viral capsid inhibitors (check)	<i>lenacapavir</i>
-filam	filamin A binders	<i>simufilam</i>
-glipron	glucagon-like peptide receptor agonists	<i>danuglipron</i>
-melagon	melanocortin-1 receptor (MC1R) agonists	<i>dersimelagon</i>
-rasib	Kirsten rat sarcoma (KRAS) inhibitors	<i>sotorasib</i>
-stat -glenastat	glutamine antagonists	<i>sirpighenastat</i>
-terkib	Extracellular signal-regulated kinase (ERK) inhibitors	<i>temuterkib</i>



Revised definitions

Stem	Old Definition	Examples
-gli- (formerly gly-)	antihyperglycemics	antidiabetics
-tide -netide	neurologic indications	neuropeptide Y (NPY) receptors and analogues

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 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

- ✓ 73rd INN Fall Consultation – October 18-22nd, 2021
- ✓ USAN Council Winter Meeting – December 2021

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.

Edited by brad.wells@ama-assn.org