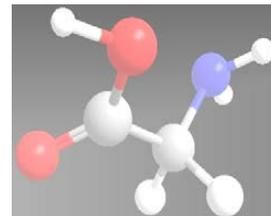


USAN^{INSIDER}



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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).

USAN Modified Designations for Monoclonal Antibodies

Sometimes the name of a monoclonal antibody requires additional clarifying words.

If the antibody is conjugated to a payload, such as radiolabel or toxin, this conjugate is identified by using a separate, second word or other acceptable chemical designation. For antibodies conjugated to a toxin, the "-tox" stem must be included as part of the name selected for the toxin (e.g., zolimomab aritox, in which aritox identifies ricin A-chain). In other cases (e.g., brentuximab vedotin), the payload may receive a name based on a stem or a chemical name.

For radiolabeled products, the word order is:

1. Name of the isotope
2. Element symbol
3. Isotope number

Name of the monoclonal antibody, as follows:

- technetium Tc 99m biciromab
- indium In 111 altumomab pentetate

The "peg-" prefix may be used for pegylated mAbs, but it should be avoided if it leads to an overly long name. Usually a 2-word name is preferable with the first word referring to the monoclonal antibody and "pegol" as the second word.



When firms apply to name an antibody conjugated to a payload, they should file separate USAN applications for the antibody and the payload, as well as the application for the conjugate. This allows the USAN Council to assign separate USAN designations to each component. The USAN Modified Application may be used for the additional names.

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What does the USAN program name?

USAN will be provided for the following:

- Small-molecule drugs
- Biotechnology drugs including monoclonal antibodies, therapeutic vaccines, proteins and peptides, DNA, RNA, nucleoside and nucleotide therapies
- Gene therapies
- Cellular therapies
- Other biological substances deemed appropriate to be assigned a USAN by the USAN Council
- Contact lens materials
- Active ingredients in sunscreens
- Veterinary products intended to control diseases in animals
- The base, salt, ester or other chemical derivative of a substance that has received a USAN

USAN will not be provided for the following:

- Mixtures that do not have an IND number or do not require approval for human use by the FDA
- Bacterial strains
- Drug delivery mechanisms
- Excipients alone
- Prophylactic vaccines
- Product formulations* (emulsions, suspensions, etc.)
- Medical devices
- Manufacturing processes
- Combination drug products

*The USAN Council will authorize an exception to the above only if there is a clear and well-documented need, such as that assignment of a name promotes safety and advances the USAN Council's nomenclature principles.



The number of names coined each year varies. In recent years, the USAN Program has coined over 150 new names annually.

Brand name and generic name guidelines for active ingredients

Unlike generic names, brand names vary from company to company and from country to country. In rare instances, a brand name may be used for 2 different active ingredients in different countries. More commonly, a company uses different brand names in different countries for the same drug, or 2 countries may market the same substance under different brand names. Finally, as part of "brand extension" business strategies, companies use the same brand name to refer to 2 different active ingredients.

Brand: Cialis

Generic: tadalafil

Brand: Colemin, Lipex, Zocor and Vytorin

Generic: simvastatin

Brand: Gleevec, Glivec

Generic: imatinib mesylate

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](#)

Can You File for a USAN and INN Simultaneously?

No!

USAN and INN applications **MUST** be filed sequentially. The reason why it's not feasible to file for a USAN and INN simultaneously, is due to both nomenclature institutions striving to have one non-proprietary name globally. By doing this, it helps promote nomenclature drug safety and lessen medication errors.

Medication errors make up a high proportion of all events related to patient safety, and are particularly common in intensive care, pediatrics/neonatology, care of the elderly, anesthetics, and obstetrics. Some medication errors will result in overdose, adverse drug reactions, or



under-treatment, and cause serious harm to patients. As more medications enter the market, with greater variation in routes of administration, this problem is becoming increasingly complex.

For example, a manufacturer files for an USAN and an INN at the same time. The manufacturer receives a proposed USAN and a proposed INN but they are two different names. This will only create confusion in the drug nomenclature industry which will affect physicians, pharmacists, and patients.



Upcoming Events

- ✓ 72nd INN Spring 2021 Consultation – April 12-16, 2021
- ✓ USAN Council Summer Meeting – June 4th, 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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