

## USAN Council

---

**Notice to all prospective applicants: USAN applications and USAN payments must be sent electronically. Please send all applications to [USAN@ama-assn.org](mailto:USAN@ama-assn.org). For electronic payment information please contact [AMA.treasury@ama-assn.org](mailto:AMA.treasury@ama-assn.org).**



The United States Adopted Names (USAN) Council is responsible for selecting simple, informative and unique nonproprietary (generic) drug names. The council and staff meet twice a year to discuss outstanding negotiations, new items of interest and policy issues.

The USAN Council establishes logical nomenclature classifications based on pharmacological and/or chemical relationships. In addition to one member-at-large and a Food and Drug Administration (FDA) liaison, the council consists of one representative from each of the following: The American Medical Association (AMA), United States Pharmacopeia (USP) and the American Pharmacists Association (APhA).

## Meeting minutes

The 2021 Summer Meeting of the USAN Council was held Friday, June 4, 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 AMA. Additional observers were present from the USP, the World Health Organization (WHO) International Nonproprietary Names (INN) Program, and the FDA.

The following items were discussed:

### **USAN activities**

- | Negotiation stats showed a slight increase 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 round, 8 new negotiations and 1 INN.

### **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: 11 approved by the Council.
- | Revised stem: 2 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 Nov. 1, 2020-April 31, 2021, and cumulative data since May 1, 2002 were discussed.
- | U.S. FAERS Medication Errors Report covering November 2020-April 2021.

## USP updates

- | USP representative provided information pertaining to USP activities.

## Additional recent updates

Effective Jan. 1, 2019, there are changes to the conjugated monoclonal antibody naming policy. Visit the monoclonal antibodies page for additional information.

USAN/INN Applicants: Please notify the USAN Program if you have received correspondence from the INN stating that there have been comments and/or objections to the proposed INN name. USAN will be able to eliminate the possibility of having two non-proprietary names for one compound.

New Policy: Effective for the July 2018 USAN Council meeting, only USAN applications for substances that are not proposed or recommended INNs will be reviewed at the USAN Council meetings.

USAN applications for names that have proposed or recommended INNs will be reviewed throughout the year via email by the USAN Council.

Meeting reviews will be reserved for:

- | New USAN applications for which no proposed or recommended INNs have been selected
- | Multiple round USAN negotiations
- | Open-ended (noncompleted) negotiations for which not all USAN Council ballots have been received

**New Policy:** The USAN Council discussed coining nonproprietary names with 2-letter stems (PDF) at the USANC summer meeting in July 2017. The USAN Council decided that moving forward the new USAN policy (PDF) will be not to coin nonproprietary names with 2-letter stems. The Council based its decision on the likelihood of 2-letter stems creating the potential for medication errors and the inconsistencies in accepting or rejecting proprietary names containing 2-letter stems.

**Policy Change:** Due to an increase in third-party (non-applicant) requests for stem determinations and the resulting increased demand of USAN staff time, the USAN Program will no longer provide potential stem reviews for third-party nonproprietary naming consultants who bill their clients for "USAN staff provided" information. USAN Program staff will continue to advise USAN applicants directly.

View the revised USAN stem list.

## **AMA headquarters address**

Please send all USAN applications, with checks to:

American Medical Association  
USAN Program  
330 North Wabash Ave., Suite 39300  
Chicago, Illinois 60611-5885

**Important Note to Manufacturers:** From the date of receiving the adoption notice, a manufacturer has 60 days to review the statement for accuracy, initial and return to the USAN office. After the 60 days expires, with or without an initialed adoption statement, the manufacturer's adopted USAN will be published on the USAN website after the first of the following month. Any changes, edits or modifications made on the manufacturer's behalf after the 60-day period will result in a revision/modification fee of \$5,000.

## **Information for USAN applicants**

The USAN Council primarily negotiates a USAN through rounds of balloting via correspondence. Plus, the council and staff meet twice a year to discuss outstanding negotiations, new items of interest and policy issues.

When nomenclature disputes between the USAN Council and applicants occur and normal procedures fail, the USAN Review Board is the final arbiter. Each sponsoring organization nominates

two members, with the boards of trustees of the other sponsoring organizations approving all nominees. Members have no term limits and all Review Board decisions are final and not subject to appeal.

## USAN program information

Please use the following contact information to ask general questions about the USAN process.

For questions regarding:

- | Cell therapy and gene therapy applications
- | Correct application of stems
- | Scope of USAN
- | INN review procedure
- | Name-selection process

Contact Stephanie C. Shubat, director at (312) 464-4045 or [stephanie.shubat@ama-assn.org](mailto:stephanie.shubat@ama-assn.org).

For questions regarding:

- | General information on stems
- | Monoclonal antibodies
- | Organic radicals and counterions
- | USAN modified applications

Contact Gail Karet, senior scientist at (312) 464-5352 or [gail.karet@ama-assn.org](mailto:gail.karet@ama-assn.org).

For questions regarding:

- | Contact lens applications
- | Publications
- | Publication deferments
- | USAN procedural inquiries
- | USAN revised applications
- | USAN website inquiries

Contact Brad Wells, operations manager at (312) 464-4906 or [brad.wells@ama-assn.org](mailto:brad.wells@ama-assn.org).

For questions regarding:

- | Electronic application submissions



- | Electronic fund transfers
- | General administrative inquiries
- | General status of applications
- | Payment and application address

Contact Mary Haynes, staff assistant at (312) 464-4046 or [mary.haynes@ama-assn.org](mailto:mary.haynes@ama-assn.org).

For general information on the USAN program, call (312) 464-4028 or email [USAN@ama-assn.org](mailto:USAN@ama-assn.org).

## **USAN newsletter**

Read the July 2021 USAN newsletter (PDF).