Understanding INN Review

Before almost all names can be formally adopted as USAN, they are sent to the World Health Organization's (WHO) International Nonproprietary Names (INN) Program.

Review by the INN Expert Group ensures that the name will be accepted internationally. The INN Expert Group meets twice a year, Spring (April or May) and Fall (October or November). Unlike the USAN Council, the INN Expert Group makes decisions only at their biannual meetings.

After names are selected at each meeting, there is a period during which members of the Expert Group may make additional comments and suggestions on the selected names. This period usually lasts about 3-4 weeks. USAN Program staff typically notifies sponsors of INN decisions after it has elapsed.

Deadlines for all materials to be submitted to the INN Expert Group 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 sponsor. Consequently, sponsors requesting an INN through the USAN Program should route correspondence regarding the INN submission through the USAN Program.

Sponsors should not use a name accepted by the USAN Council until after the INN review process is complete and the sponsor has received an adoption statement. Once a sponsor receives this document, the name may be used as necessary in publications and other communications.

The name cannot be used as an INN until the INN Program completes the publication process (i.e., it appears as a recommended INN (rINN)). Normally, names are published as a pINN about 8-12 months after the meeting. There is then a 4-month public comment period. If no objections are received, the name is published as a rINN. In the unlikely event that there is a public objection, USAN Program staff will notify the firm if the INN application was filed by USAN staff on behalf of the firm.
United States (US) sponsors that have begun US clinical trials should file for the USAN first. International sponsors may choose to request either the USAN or the INN first.

There is a misconception that filing for an INN first, to make deadlines for a specific INN meeting, may allow a firm to obtain a USAN/INN more quickly. This is not the case. If the USAN is requested before the INN, the USAN Program will not issue an adoption statement until the name is published as a pINN and the public comment period elapses.

What Is an IND?

An investigational new drug application (IND) is a submission to the US Food and Drug Administration (FDA) requesting permission to initiate a clinical study of new drug product in the United States. An IND is always required when you want to conduct a clinical trial of an unapproved drug in the United States. The IND application provides the FDA with the data necessary to decide whether the new drug and the proposed clinical trial pose a reasonable risk to the human subjects participating in the study. The safety of the clinical trial subjects is always the primary concern of the FDA when reviewing an IND, regardless of the phase of the clinical investigation. Drug manufacturers should consult with their regulatory affairs expert to assess if an IND is required. Conducting a clinical study without an IND when one is required can lead to the FDA taking regulatory action.

Orphan Drugs

Orphan drugs are intended to treat rare diseases that manufacturers are reluctant to develop under usual marketing trends. Orphan status is given to drugs and biologics defined as those intended for the safe and effective treatment, diagnosis or prevention of rare diseases/disorders that affect fewer than 200,000 people in the U.S., or that affect more than 200,000 persons but are not expected to recover the costs of developing and marketing a treatment drug.

The Orphan Drug Act was passed in 1983 to give drug companies incentives to develop treatments for rare diseases. The FDA Office of Orphan Products Development determines if a drug qualifies as an orphan product. Since 1983, there have been over 600 drugs and biologics developed by over 200 companies for rare diseases.
USAN Winter Meeting 2018 Highlights

The 2018 Winter Meeting of the United States Adopted Names (USAN) Council was held Friday, January 19, 2018 at the Royal Palm South Beach in Miami Beach, Florida. 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), the American Pharmacists Association (APhA), 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
37 negotiations discussed: 4 revisions, 4 biologics, 6 multiple round, 23 new negotiations

WHO-INN Nomenclature and USAN-sponsored Applications
USAN sponsored 25% of the new INN applications discussed (28 USAN-sponsored applications)

Revisions were approved for 18 USAN Council names previously recommended

USAN Policy
New stems: 8 approved by the Council

Revised stems: 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 May 1, 2017-October 31, 2017 and cumulative data since May 1, 2002 were discussed

USP Updates
USP representative provided information pertaining to USP activities

Upcoming Events
✓ 66th INN Spring Consultation – May 1-4th, 2018
✓ USAN Council Summer Meeting – July 13th, 2018
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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