**Procedure for USAN Name Selection**

The process of assigning a United States Adopted Name (USAN), referred to as a "negotiation," begins when a pharmaceutical firm or its representative files an application to name the substance. It ends with the statement of adoption a document that formally assigns a USAN to a specific substance. The sponsoring firm, the USAN Council and the International Nonproprietary Names (INN) Expert Group must agree on a single name for the substance before a statement of adoption is issued.

The USAN Council considers several criteria in evaluating potential names:

- Whether a name reflects the drug action and fits the naming scheme.
- How well a name translates into languages other than English.
- How easy a name is to pronounce and remember?

**When is a USAN Assigned?**

The USAN is assigned while a drug is undergoing clinical trials. Companies may apply during Phase 1 studies, but many wait until Phase 2 studies begin. Most want the USAN before Phase 3 large-scale studies are complete, so that it will be available for publications and, when needed, to develop packaging, labeling and promotional materials.

Because many more drugs enter clinical trials than are approved for market, many USAN are assigned to substances that are never sold in the U.S., but could be available in countries outside the U.S. Thus, review by INN ensures that there will be a single name accepted by all countries worldwide.

The USAN Council classifies drugs using the knowledge available when names are coined. Similarly, stems are defined according to the available knowledge at the time. If new indications are found for a stem class or drug, the name of the drug or the definition of the stem does not usually change. This means, for example, that the -prazole stem used to name lansoprazole (Prevacid™) was formally defined as "antiulcer
agents,” although these drugs are now more often used to manage GERD. Lansoprazole has indications for both heartburn and GERD. More knowledge may become available after a drug is named or a stem is coined, and nomenclature is an evolving art and science. Consequently, drugs have been named by different means over the last several decades. Early on, many drug names were coined by condensing the systematic chemical name. Later, the system was changed to the current prefix-infix-stem system to reduce confusion of drug names and to make the drug name more directly refer to the class or function. The USAN Program expects that nomenclature practices will continue to evolve as new substances are developed and marketed by the pharmaceutical industry.

Conjugated Monoclonal Antibody Naming Policy starting January 1, 2019 (New Policy)

✓ USAN Application Flowchart

Effective January 1, 2019 firms can only request a USAN modified for salts or esters of substance that have already received a USAN (or for which a USAN application has been submitted) and that do not have a peptide or nucleotide sequence. Substances that are not salts or esters but are related require additional work for chemical review and/or Council balloting. Consequently, related compounds that are not salts or esters are treated as single entities. Examples include stereoisomers or enantiomers isolated from a racemic mixture, antibody-drug conjugates, oligonucleotides or other substances where the chemical structure or sequence have changed and another name is required.

The USAN Program is often asked which form to fill out in specific situations.

- For a small molecule and its salt or ester, please use form A.
- For all substances for which there is a DNA, RNA or amino acid sequence, please use form F. When more than one name is requested, a separate form F should be filled out for each substance. Therefore, for example, an antisense oligonucleotide and its salt, or an antibody and an antibody-drug conjugate would require two applications using form F.
- Firms needing to revise the chemical, company, indication or other information associated with a substance should use form D.
- For a second name for the salt or ester of a substance that already has a USAN (or for which a USAN has been requested), form C should be used.
- For contact lens polymers, form E should be used.
- For all other substances, please use form B.
Upcoming Events

✓ USAN Council Winter Meeting – January 18th, 2019
✓ 68th INN Spring Consultation – April 2-5th, 2019
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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