



## United States Adopted Names FAQ

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### **Does the USAN Council only review applications at its 2 yearly meetings?**

No, the USAN Council reviews USAN applications continually throughout the year.

### **What then is the purpose of USAN Council meetings and when do they occur?**

The purpose of these meetings—usually in Jan./Feb. and July—is primarily to review and set policy, review INN Expert Committee decisions, discuss multiple round negotiations and address open negotiations. Typically, fewer than 30 new negotiations are reviewed at each meeting. New negotiations are continually reviewed throughout the year.

### **What is required of trademark searches, conflict searches and linguistic analyses for suggested USAN at the time a USAN application is submitted? When, if ever, is the best time to perform this type of research?**

All we require is a preliminary, potential conflict review on the suggested USAN at the time the USAN application is submitted. What this entails is an Internet search through a search engine such as Google or Yahoo, a search on MedNet and a search on the USAN website and USP database. Additional searches can include the United States Patent and Trademark Office and the Office for Harmonization in the Internal Market (Trademarks and Designs) that provides information regarding the European Community. We do not require a lengthy, detailed, commissioned analysis or linguistic research activity of suggested names. If you as the applicant choose to perform a detailed, commissioned analysis or linguistic report of the suggested name, that step should be done after



notification of the USAN Council's recommended name. Please keep in mind that the USAN Council could—and often does—recommend changes to the suggested names initially submitted by an applicant.

## **Our company would like a new stem to describe our compound. How do we obtain a new stem?**

Lately, more and more new stem requests are received by USAN staff. However, with over 300 approved USAN stems and over 100 infixes, the chances are that a current stem or infix exists that would correctly and meaningfully describe your compound to health care practitioners. The goal of the USAN Program is to provide meaningful, informative designations for compounds to enhance correct prescribing practices and patient safety. The sponsor should be the one to convince the USAN Council that the compound warrants a new stem:

- Include information about why this compound is not similar to other compounds in an established stem class.
- Include information on the product's method of action, such as published research or an investigational brochure. It is preferable that the stem convey meaning to practitioners such as an abbreviation of the action or receptor to which the compound pertains.
- Explain the structural differences.
- Include a rationale supporting your new stem selection. Stem selections should not contain more than 2 syllables and should not conflict with existing stems. The same letter restrictions for USAN apply to USAN stem suggestions (no *w*, *k*, *h*, *ph*, *j* or *y*).

The USAN Council and the INN Expert Committee are very reluctant to approve new stems. Effort is made to identify stem classes that would describe the compound. Very often, a sponsor's stem selections, if a new stem is deemed necessary, are modified by the USAN Council and the INN Expert Committee because of conflicts with "working stems" yet to be published.

## **Why can't a stem be trademarked?**

USAN and INN stems are building blocks of nonproprietary names. Nonproprietary names, by their very nature, are in the public domain. Both USAN and INN cannot be owned by any individual company. These stems will be utilized in creating USAN and INN for compounds manufactured by several pharmaceutical companies and are not available for ownership. Failure to recognize this is an impediment to the work of the USAN Council is seriously diminished in establishing new USAN in a class of drugs and the freedom of both the USAN and INN programs in selecting further



nonproprietary names in the same series of substances.

## Where are USAN published?

USAN is published in the *USP Dictionary of USAN and International Drug Names* and monthly on the USAN website.

## What are the INN lists?

The International Nonproprietary Names (INN) Programme maintains both the proposed INN (pINN) and recommended INN (rINN) lists. Once an applicant has accepted a USAN Council recommendation and sent payment for the INN application, the name is sent to and deliberated by the INN Expert Committee at either the fall or spring meetings after which the applicant is informed of the decision.

The name is then published later in the year as a pINN in WHO Drug Information as well as on the INN website. A 4-month objection period follows. The period allows for comments and/or objections to the published names to be raised. Applicants are asked to not use the pINN until it has become a rINN to avoid confusion if the name is modified. Please note that objections to pINNs are rare but USAN cannot guarantee they will not occur. In the event there is an objection filed to a USAN/proposed INN, the USAN Council could rescind the name and rename the compound in order to harmonize with the INN.

Following the pINN's objection period, the final stage of the process is the rINN. According to INN Guidelines, once a name has been published as a rINN it will not normally be modified further and is ready for use in labeling and publications on drug information. Current INN lists can be viewed on the World Health Organization website.

## What is a USAN Modified (USANM)?

The USAN program assigns a USANM to a substance when another form of it has already received a USAN. If the parent substance does not have a USAN, the sponsor must apply for a new USAN. A fee of \$8,000 applies only to USANM submissions for salts of substances for which the parent (base) compound has a USAN.

## **Must all forms of a compound be named if plans are made to only market a salt or ester?**

Sponsors who plan to market a salt or ester must name the form that will be marketed. If you are planning to market a salt (e.g., chloride, hydrochloride, acetate), you must apply to name both the parent and the salt.

## **Can I apply for a USAN and USANM at the same time?**

To name a salt or ester and its parent, you may submit applications for a new USAN and a USANM concurrently. The new USAN is adopted after the usual negotiation process and the USANM is adopted usually 1-2 months later. Under the new USAN application policy, both names may be requested with a single form, Form A.

## **What do you mean by salt?**

The USAN Program's definition of a salt includes counterions, coprecipitated acid molecules and metal ion chelates. Esters are usually carboxylic acid derivatives, but may have other forms, such as phosphate esters.

## **What is a USAN Revised?**

A USAN Revised (USANR) is a USAN resulting from an application where the manufacturer requests revisions to USAN support information. A fee of \$5,000 applies to USANR applications.

## **In what cases should I apply for a USAN Revised?**

In the case of a USAN Revised (USANR), revisions in support information would necessitate an application for a USANR. Any one of the following revisions would require a USANR application:

- Changes in chemistry; wrong structure due to error or a revised structure due to changes in overall chemical information



- Change of internal code designations
- Therapeutic claim revision
- Addition of trade name
- Relicensing issues and/or change of sponsor (i.e., Has your company changed hands? Are there licensing issues with your parent company? Are you dealing with an international company?)
- CAS Issues (i.e., Have you changed/updated your CAS information?)

With each USANR application, please make sure to clearly note your requested revisions. Please also include the information you've sent to CAS regarding your requested revisions. When writing the introduction letter, please list each change needed along with the reason why. Also, if providing the change for sponsor name, please provide information documenting the "official" change of hands.

## **Why is standardized pronunciation important?**

Prescriptions are verbal communications, either oral or written, and should be spelled correctly and consistently. By the same token, an oral prescription should be pronounced correctly and consistently. With written prescriptions, and when considering proposed names, the USAN Council must take into account things such as name conflicts, correct stem usage, appropriate prefixes, etc., as well as differences in things such as handwriting and individual accents.

For this reason, the basic pronunciation should be definite, just as the spelling is definite. Prescriptions are transmitted orally from a physician to a patient or office aide or directly to a pharmacist or pharmacy technician in a hospital or store pharmacy, through a nurse or nurse's aide in a hospital, etc. The age of technology and voice recognition is upon us and the requirements of oral prescribing through computers and other electronic devices must be recognized.

## **Can I request a refund from USAN?**

Refunds are no longer possible once the USAN Council initiates the application review.