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:

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

Read more about USAN naming guidelines.

Who Assigns the USAN?

The USAN Program assigns names through the USAN Council, a group of 5 volunteers nominated to the USAN Council based on their extensive, relevant knowledge and experience.

The USAN Council comprises 5 members, 1 from each of the program sponsors: The American Medical Association (AMA), United States Pharmacopeia (USP), the American Pharmacists Association (APhA), Food and Drug Administration (FDA), as well as a member at large.

The AMA houses the offices of the USAN Program secretariat and administers the Program. The FDA reviews trade names separately. The USAN Program is not involved in brand/trade name development.

About the USAN Council

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.

What USAN Council Names

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
- Cell therapies and non-cellular immunotherapies
- 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:

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

*Unless it is clear and documented that assigning a name would promote safety and the USAN Council's principles.

Because of changes in U.S. salt nomenclature policies, firms are required to request a USAN for the active moiety (base, parent) of a compound and any salt form(s) that may be marketed when filing the initial USAN application. Please note that the USAN Program's definition of a salt includes counterions, coprecipitated acid molecules, and metal ion chelates. This is somewhat different than the usual chemical definition of a salt as a cation–anion pair. Esters also require a USAN and are usually carboxylic acid derivatives, but may have other forms, such as phosphate esters.

**How a Name Is Selected**

Before adoption, 3 parties—the sponsor, USAN Council and INN Expert Group—must accept the USAN. All negotiation is done by correspondence, electronic balloting or at biannual meetings. The meetings serve to review and set policy, review INN Expert Group decisions and discuss negotiations in process.

**Initial Application Processing**

After application submission, negotiations proceed generally this way:

1. Initial processing and review by USAN program staff.
2. After balloting is complete, USAN Council recommends and sponsor accepts a name.
4. USAN is adopted and published with information that identifies the substance.
After submission, the USAN Program secretariat verifies the application is complete, payment is received and the substance meets all application prerequisites.

The substance must have entered clinical trials and must have an IND number.

Each complete application is assigned a file number and a USAN staff member as the “negotiator” who will serve as the contact for all correspondence. The applicant then receives an acknowledgement letter, confirming receipt of application and fee and then includes the file number and negotiator’s name.

Supplement to the application, the USAN Council requests results of literature and chemical searches, verification that submitted names are conflict-free and rationale of the requested stem assignment. Adherence to the current Rules for Coining Names is crucial.

USAN applications are kept confidential throughout the process, only being shared among the USAN staff, the USAN Council and the INN Expert Group.

**Application and Initial Review**

- Firm gathers required supporting information, including documentation of a search to verify proposed names are free of trademark and generic name conflicts.
- Pharmaceutical manufacturer or sponsor submits a completed application.
- USAN Program staff verifies chemistry, searches databases for drug information.
- Staff determines how the drug may be classified using the nomenclature scheme and whether the proposed names appropriately reflect its action.
- Staff reviews names for conflicts with generic or proprietary names.
- Staff prepares a ballot with the firm’s proposed names and alternative suggestions, if any.
- Conflicts with generic or trade names are noted for the USAN Council.

**USAN Council Balloting**

- USAN Council members review names and make selections.
- Scientists and physicians on the USAN Council represent the AMA, APhA, USP and the FDA.
- Review criteria include absence of conflicts with trade or generic names, appropriate use of the nomenclature scheme and usefulness of the proposed names to the health care providers.
- Names too similar to existing generic or trade names are rejected.

URL: https://www.ama-assn.org/about/united-states-adopted-names/procedure-usan-name-selection

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FDA opinion on the proposed name(s) is sought through the FDA representative to the USAN Council.
When consensus is reached, staff forwards the name selection to the firm.

Review of the USAN Council's Suggestion by the Firm

- Firm reviews the USAN Council's selection and accepts or rejects it.
- Suggested name is posted for public comment online.
- If the firm accepts the name, the process will go through international review before adoption as a USAN.
- Firms rejecting a name must supply alternatives and the rationale for rejection, with supporting documentation.
- Rejection leads to another round of review by USAN Program staff and the USAN Council.

International Review and Clearance

- When the name is accepted, the sponsor sends the negotiator a check made out to WHO for the submission to WHO-INN Expert Group.
- USAN Program completes an INN application on behalf of the firm to ensure international harmonization.
- The INN experts then review and accept the proposed name or suggests an alternative.
- INN review criteria include conflicts with non-U.S. trademarks or generic names, connotations in languages other than English and conformity to international nomenclature schemes.
- INN Expert Group is composed of scientists and regulatory experts from around the world.

Review of the INN Decision by the Firm and USAN Council

- Firm and USAN Council notified of the INN Expert Group's decision by the USAN Program staff.
- Firm and USAN Council may accept or reject the INN Expert Group's alternative suggestions, if any.

Adoption and Publication
Occurs after the USAN Council, firm and INN experts reach a consensus.

Adopted USAN are published online and forwarded to Chemical Abstracts Service and the USP.

Internationally, names are published twice—as proposed INN and recommended INN.

INN Expert Group Review

After USAN Council review and name acceptance, staff completes an INN application.

Input from other countries prevents a USAN from having unacceptable connotations in other languages. The INN Expert Group follows procedures similar to the USAN Council. However, deliberations and selections are made at their biannual meetings, not through year-round balloting. Also, some things—such as contact lens polymers—are not named by the INN Expert Group.

Adoption of USAN

Following a successful INN review, adoptions occur the last Wednesday of each month. A formal adoption statement notifies the applicant that the process is completed and the USAN is assigned. A firm may then use the USAN immediately, and it is typically published 60 days later. It appears on the USAN website and is communicated to USP for inclusion in the *USP Dictionary of USAN and International Drug Names* and to CAS to be included in their database. (A firm may request a publication deferral of up to 6 months.)

Reasons to Change a USAN

- Official notification from pharmacovigilance system of medication errors involving the USAN in question.
- Proven previous trademark infringement with the USAN in question.
- Any other nomenclature issue deemed relevant by the USAN secretariat.

When to Request an Additional Round of Review

In recent years, requests from manufacturers and their representatives for additional balloting by the USAN Council have increased. Often these requests are sent without adequate data or substantial rationale. As the council’s mission is to provide simple, informative and unique nonproprietary names.
from logical naming classifications based on pharmacological and/or chemical relationships with minimal delay, the council offers the following clarifications.

**Policy Specifics**

- An additional round of balloting or reconsideration requests must be accompanied by a clear rationale based on *new* information (such as new research results or patient safety data) that was not sent to the USAN secretariat previously. Recapitulations or summaries of the initial data will not be accepted.
- A request for an alternative prefix to the USAN Council’s recommendation must be accompanied by the reason(s) the applicant has rejected the first recommendation. This rationale will be considered as the Council decides whether to assign an alternative prefix. Note that suggestions for alternative prefixes that imply a specific quality or attribute will not be considered.
- Citing past USAN designations as precedent, in the absence of new data, does not constitute adequate rationale for additional balloting.

Failure by the manufacturer or manufacturer’s representative to meet these policies will prevent the additional balloting round request from being forwarded to the USAN Council.

**Procedure for Changing a USAN**

Not to be confused with the USAN revised application procedure—which allows a firm to change supporting information of a USAN, not the actual USAN—this procedure is used to request a change of the USAN:

1. The USAN secretariat must be contacted with a written request for changing a USAN. Documentation must include official notice from pharmacovigilance systems, rationale, data and origin of request.
2. The USAN secretariat evaluates the request for merit and accuracy. More data may be requested of the petitioner.
3. If the request is warranted, the USAN Council, sponsor, USP, FDA, Institute for Safe Medication Practices (ISMP) and APhA are notified of the potential revision of the USAN in question.
4. The USAN secretariat prepares the background and alternative names relevant to the request. It is then discussed at either of the 2 biannual USAN Council meetings.
5. The USAN Council reviews the request and renders a decision. The name shall be retained if the council concludes there are no compelling reasons to revise or substitute a previously
adopted USAN.

6. The drug sponsor, USP, FDA, ISMP, APhA and the INN Program are notified of the USAN Council's decision if the USAN has been changed.

7. Once a consensus is reached among the USAN Council, USP and FDA, the information is posted on the USAN website, allowing time for public comment.

If the USAN has been formally changed, official notification is made by the sponsor, FDA, ISMP and USP.