

Apply for a United States Adopted Name

Complete the application

Please remember it is the policy of the USAN Program that firms should apply for a nonproprietary drug name through their national nomenclature program first. In the United States of America, this national agency is the USAN Program.

Download the correct form. On the form, list the desired name(s), provide necessary chemical information, explanation and documentation of the drug's indications and action(s) and information about the company developing the therapy or drug.

Use the following as reference:

- Suggested Name: Propose 1–3 nonproprietary names. The name for the active moiety of the drug should be a single word. If you already have an INN, give that name.
- Chemical Name or Description: Usually 2 chemical names are given. The first used in all USAN publications is the CA index name. The second name should come from using the naming rules of the International Union of Pure and Applied Chemistry (IUPAC). That name is created by an independent chemical reviewer, so it may vary from those the firm lists on its application.
- CAS Registry Number: A Chemical Abstracts Service (CAS) number is required for all USAN submissions. This applies to the parent form and the salt or ester. Include a copy of CAS correspondence or the results of a database search. The CAS number will also be provided to the INN program. Submitting an application grants the USAN program permission to publish the chemical information.
- Structural Formula: The structural formula is required to determine if a USAN or INN already exists and to compare it with related compounds, Information must be complete, current and accurate, including information on stereochemistry, if known. If you are naming a protein, monoclonal antibody, peptide or biologic substance, this additional information is required:
 - ✍ All Proteins and Peptides: Complete mature amino acid sequence in MS Word document.
 - ✍ Single-letter codes for each amino acid, displayed in 10-character groups with 5 groups per line and a number indicating the position of the last amino acid at the end of each line.
 - ✍ Positions of all disulfide bridges and post-translational modifications listed

- after the sequences.
 - | Glycosylation patterns, including site and type of sugar, etc.
 - | For recombinant proteins, give the expression system and the comparison with native sequence.
- | Monoclonal Antibodies: Complete mature amino acid sequence in MS Word document.
 - | Single-letter codes for each amino acid, displayed in 10-character groups with 5 groups per line and a number indicating the position of the last amino acid at the end of each line.
 - | Glycosylation patterns, including site and type of sugar, etc.
 - | Precursor nucleotide sequence with spaces between codons and translation, with numbered lines.
 - | CDR-IMGT and sequence analysis of the variable regions showing percentage of human content (if -ximab, -zumab or -umab is requested)
 - | IG class and subclass, IG format
 - | Species or taxonomy related structure (chimeric, humanized, etc.)
 - | Name and/or structure of targeted antigen
 - | List of all disulfide bridges and their locations
 - | Expression system
 - | Clone name(s) and laboratory code name(s)
- | Nucleic Acids: Includes DNA vaccines, oligonucleotides and gene therapy products
 - | Full nucleotide sequence with pertinent regions delineated (e.g., coding regions, control regions)
 - | For gene therapies, schematic map of the product and an annotated sequence that delineates relevant sections
- | All Pegylated Substances: Details of pegylation—end group, polymer chain with average number of repeat units to 2 significant figures, details of the linker, point of attachment of the linker to the active moiety
- | Molecular Formula: Supply a 1-line molecular formula using accepted chemical practice, if possible. If the compound is a salt or ester, give the molecular formula information for both the salt or ester and the compound from which it is derived. For salts, the active and other species should be listed separately, e.g., C₈H₁₃N₅O₄·HCl. If no formula is available, such as for gene or cell therapies, this should be left blank.
- | Molecular Weight: Molecular weight should be given according to current guidelines for standard atomic weights of the elements by the IUPAC Commission on Atomic Weights and Isotopic Abundances. If no molecular weight can be calculated, this may be left blank, but approximate weights should be listed if they are known.
- | Code Designations: Any company code designation assigned to the compound should be entered, particularly if it has been published in scientific papers. The code must be specific to the chemical entity being developed. If the compound was licensed or acquired from

another firm, former codes should be listed.

Trademarks: Any trademark issued for the drug should be provided. Any known foreign trademarks along with the name of the country of registry should be included.

Trivial Names: Sometimes a compound acquires a trivial name used in scientific journals long before a nonproprietary or trademarked name is created. The USAN Council should be told of such names, though it discourages the creation of such names. Even if such names are entrenched in the literature, they are not assured of adoption and may only cause confusion. Many trivial names are not accepted as they do not conform to the USAN program's IND application on file. Exceptions are made for some veterinary drugs and contact lens polymers, which usually do not receive IND numbers.

Before you apply

Be sure to consult the USAN Naming Guidelines. But there are more rules for contact lens materials and new application requirements for biologics. Also, use the list of existing USAN Stems (XLSX) and the list of names for organic radical and anions for their salt and ester forms.

Before submission, review the Chemical Abstracts Service requirements and trademark screening.

Where to Send Applications

All application materials should be submitted to the USAN Program via email or an overnight delivery service.

Please send applications to the following:

United States Adopted Names (USAN) Program

American Medical Association Attn: Stephanie C. Shubat, director, USAN 330 N. Wabash Ave., Suite 39300 Chicago, Illinois 60611

Please send payments to the following:

American Medical Association Attn: Remittance 330 N. Wabash Ave., Chicago, Illinois 60611

Please reference that the payment is for a USAN application and list the sponsor's code designation on the check.

Electronic credit card payments cannot be accepted, but electronic fund transfers are possible. Please contact Mary Haynes at (312) 464-4046 for more information.

When to apply

It is USAN Council policy that U.S. pharmaceutical companies intending to market their products in the United States first apply for a nonproprietary name through the USAN Council. After a name is agreed upon, the USAN Council submits it to the INN Expert Group for consideration. If the name was previously approved by the INN, indicate the WHO request number and/or proposed/recommended INN list numbers on the USAN application.

Selection of a USAN should begin during clinical trials if a substance is regarded as an Investigational New Drug, so that the name will be adopted before the relevant New Drug Application (NDA) is filed. Firms usually apply for a USAN when the investigational therapy is in Phase I or Phase II trials. By then the sponsor's patents or intellectual property are in place and it is early enough that the risk of not having a name for the NDA is low.

Having handled hundreds of INN applications, USAN staff understand the details of the process including how to present the case for a specific name to which the USAN Council has agreed. The benefits of applying for a USAN first include:

- | Clearance by the USAN Council before the name is submitted to the INN experts
- | Experienced USAN staff who file the INN application on your behalf
- | Less time to an adopted USAN because USANs are adopted after the INN meeting and before the name appears on a proposed INN published list
- | Assistance from USAN staff in creating suitable prefixes and name alternatives
- | Accessibility and consultations with staff for applicants on stem choices
- | Continuous balloting throughout the year because USAN Council review is not limited to biannual meetings

Learn more about the drug name development timeline and the USAN Review Procedure.

Obtaining a CAS name

A Chemical Abstracts Service registry name and number are required for all applications, including gene therapy products. Cell therapies and noncellular immunotherapies are not included. This is needed for adoption and publication, plus the FDA encourages use of this terminology for labeling

purposes.

If marketing a salt or ester, a firm should supply a second CAS registry number and CA Index name for the parent substance. For contact lens materials and other synthetic polymers, CAS registry numbers should be supplied for each monomer and the entire polymer.

For CAS registry numbers and CA index names, contact CAS at:

Chemical Abstracts Service

P.O. Box 3012

Columbus, Ohio 43210

(800) 848-6538 (North America) (614) 447-3600 (worldwide) help@cas.org

Trade names and trademarks

USANs are, by definition, in the public domain. Sponsors are asked to exercise responsibility and judgment when creating trademarks for drugs. USANs, stems or other parts of a name should not be built into the trademark. The confusion created may ultimately compromise patient safety.

Putting a stem into a trade name interferes with the agencies' ability to systematically create new nonproprietary names for other members of the drug class. The USAN Council secretariat may lodge objections to proposed trademarks that conflict with USANs/INNs or included common stems.

Typically an internet search is performed before applying for a USAN. Additionally, Patent and Trademark Office searches may be made or—in Europe—the Office for Harmonization in the Internal Market (Trademarks and Designs) may be consulted.

Extensive, commissioned searches are not required, especially as the USAN Council often recommends changes to the originally submitted names.