

## USAN application forms

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**Notice: The AMA office building is closed, and the USAN staff is working from home (WFH) effective March 17 and will continue until further notice. To all perspective applicants: USAN applications and USAN payments must be sent electronically. Please send all applications to [USAN@ama-assn.org](mailto:USAN@ama-assn.org). For electronic payment information please contact [AMA.treasury@ama-assn.org](mailto:AMA.treasury@ama-assn.org).**

To streamline the application process and ensure compliance with current and future FDA and International Nonproprietary Names (INN) policies, USAN applications have been revised. There are now 6 separate application forms.

### For base and modified forms of a compound

Form A: Single entity drug and salt form (DOC) is used when requesting a USAN for the base substance and a USAN for the modified (salt) form of a new compound, (for which no USAN exists) to be marketed in the United States. Applicants will receive **two** separate USAN(s); one for the parent and one for the salt form.

Please note that in the past, because the USAN Program required naming only the form of the compound to be marketed in the United States, and the INN Program names only the parent (base) product, a USAN and INN were often different. To maintain consistency and avoid FDA approval delays if a related substance is later marketed, the USAN Program now requires filing Form A to obtain USAN(s) for the salt and base forms of the compound. The fee associated with this application is \$23,000.

### For a single entity

Form B: Single entity form (DOCX) is used to request a USAN for a single entity (active moiety, parent compound) for which no modified or salt form will be developed or marketed in the United States. The fee associated with this application is \$15,000.

## For a modified salt form

Form C: Modified compound form (DOC) is used to request a USAN for the modified (salt) form of a compound for which a USAN already exists. If a manufacturer finds that they have not requested a USAN for a salt to be marketed, or if they decide to market a different salt than what was named by the USAN Council, they are requested to pursue a USAN for the new salt form using Form C. The fee associated with this application is \$8,000.

| [Salt form information page](#)

## For a revision to an adopted USAN

Form D: Revise established USAN is used to request a revision to a published, adopted USAN. The fee associated with this application is \$5,000.

## For contact lens materials

Form E: Contact lens material form (DOC) is used to request a USAN for contact lens materials. The fee associated with USAN for new contact lens materials is \$15,000. The USANM and USANR fees are \$8,000. (Form E is also used to request both USANM and USANR for contact lenses.)

| [Contact lens material related links](#)  
| [Approved hydrophilic names](#)  
| [Approved hydrophobic names](#)

## For biologics

Form F: Biologics form (DOCX) is for proteins, peptides, monoclonal antibodies, nucleic acids, all pegylated substances, cell therapies, and gene therapies. Fee for a new monoclonal antibody is \$15,000. Fee for a monoclonal antibody for which an adopted USAN already exists is \$8,000.

Additional application requirements have been established for biologics. Please review these requirements and include with your application materials.

## Biologics information pages

- Biologics naming guidelines
- Monoclonal antibodies information
- Naming biologics information
- Gene therapy information
- Cellular and non-cellular therapies information
- Interferons information
- Interleukins information
- Colony stimulating factors information
- Erythropoietins information
- Somatotropins information

The USAN Program expects that this revised application procedure will simplify the process of obtaining the multiple USAN(s) required for salts and parent forms of compounds and better international harmonization of non-proprietary names.

(Once the USAN Council initiates the application review, refunds are no longer possible.)