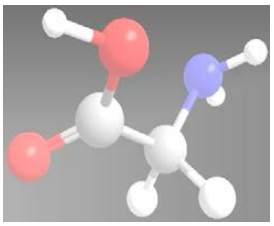
USAN INSIDER



Volume 10, Issue 1

In This Issue

USAN Website Links:

MAB Requirements for Monoclonal Antibodies

- A complete mature amino acid sequence in a Microsoft Word document (**Microsoft Word document**). **Please note: Your USAN application will not be considered for review without the supporting amino acid sequence MS Word documentation**
- Please ensure that the CAS Registry information includes the sequence, disulfide bridges and glycosylations
- A MS-Word document with single-letter codes for each amino acid, displayed in groups of 10 characters 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; >90% -umab, -zumab is typically >85%, <85% -ximab)
- CDR-Kabat (sequence and residue range)
- 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)
- If appropriate, the closest human V, J, and C genes and alleles (results obtained with IMGT/DomainGapAlign tool)
- For the V-domains, if the domains are nominally human (e.g. produced from human antibodies, EBV immortalization of human B-cells, human phage display libraries, transgenic mice with human V-domain genes, or similar), the closest human gene/allele should be given
- If the V-domains have been humanized by CDR-grafting onto a human framework, the closest human gene/allele to the parent human framework should be given
- Otherwise the closest germline (human or other species) should be given

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- If the terminal lysine is absent in the heavy chain amino acid
- sequence, a statement confirming that indeed there is no lysine codon in the nucleotide sequence (if not the lysine should be added in the amino acid sequence mentioning the posttranslational modification clipping)
- If relevant, amino acid differences with the native sequence (for a monoclonal antibody: constant region amino acid changes by comparison with the closer genomic C gene and allele)

2019 USAN Winter Meeting Minutes

The 2019 Winter Meeting of the United States Adopted Names (USAN) Council was held Friday, Jan. 18, 2019, at the PGA National Resort & Spa in Palm Beach Gardens, Florida. The topics discussed at this meeting included general USAN activities and policy, issues relating to drug nomenclature, and proposed USAN name reviews and recommendations.

All members of the USAN Council were in attendance as well as members of the USAN Program staff housed at the American Medical Association (AMA). Additional observers were present from the United States Pharmacopeia (USP), the American Pharmacists Association (APhA) and the World Health Organization (WHO) International Nonproprietary Names (INN) Program.

The following items were discussed:

USAN activities

- Negotiation stats showed a steady flow in adoptions with a slight increase in new submissions
- USAN Program activities discussed included statistical reports on active negotiations, cumulative adopted names and USAN participation in the INN Program

USAN negotiations

- 32 negotiations discussed: 13 revisions, 6 biologics, 9 multiple rounds, 4 new negotiations
- WHO-INN nomenclature and USAN-sponsored applications
- USAN sponsored 18% of the new INN applications discussed (26 USAN-sponsored applications)
- Revisions were approved for 17 USAN Council names previously recommended

USAN policy

- New stems: 9 approved by the Council
- Revised stems: 4 approved by the Council
- Radicals and Anions: 3 approved by the Council

USAN website

- Website statistics included average site views per month, year-to-date totals, average time viewed and demographic information of USAN website visitors

Medication error issues

- Institute for Safe Medication Practices (ISMP) Medication Errors Reporting Program covering May 1, 2018 to Oct. 31, 2018, and cumulative data since May 1, 2002, were discussed

USP updates

- USP representative provided information pertaining to USP activities

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

- ✓ 68th INN Spring Consultation – April 2-5th, 2019
- ✓ USAN Council Summer Meeting – June 20-21th, 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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