In This Issue

What the Revised Monoclonal Antibody Scheme Means to You

As you may already know, the USAN Program and INN Experts have revised the monoclonal antibody nomenclature scheme and eliminated the “source infix,” which included information in the name about the origins of monoclonal antibody chains. Thus, the USAN/INN name for a monoclonal antibody will no longer include a syllable to indicate whether an antibody is fully human, humanized, chimeric or from another source.

There were several reasons why the USAN Program felt it was necessary to make this change.

First and most importantly, there is a need to introduce greater variation in the suffixes of monoclonal antibody names. Over 350 monoclonal antibodies have been named, and dozens have been marketed. This has increased the odds that two monoclonal antibody names will look alike, and one of the most important considerations in naming substances is avoiding look-alike, sound-alike medication errors that might compromise patient safety. Greater variation in the names is therefore needed. Removing the source infix reduces the number of syllables at the end of the name that are “predetermined” by the monoclonal antibody nomenclature scheme. In general, shorter stems and suffixes reduce the odds that names of members of the same class will look or sound alike.

Second, there have been numerous disagreements about how source infixes should be defined or assigned involving firms, the USAN Program and the INN Experts. Arguments over whether an antibody should be classified as humanized or chimeric, for example, have caused significant delays—in some cases a year or more—in the process of name assignment.

Finally, the USAN Program, after consultations with the FDA, concluded that including the source information in the antibody name might imply that one antibody is better than another, when this is not necessarily the case. Antibody sequence is not the only factor that determines immunogenicity, and the fact that an antibody is humanized (rather than chimeric) does not necessarily mean that there will be fewer adverse events when it is marketed. The USAN Program discourages firms from
engineering antibodies solely to receive a certain classification (e.g., humanized or human); firms should focus on developing the best and most useful product.

Although the USAN Program and INN Experts are no longer including the source infix in the name, they are currently publishing information about the source of the antibody chains (humanized, vs. human, vs. chimeric) in the chemical descriptions that appear with the names. Firms are therefore still required to send sequence information and the results of IMGT analysis when they apply. There is no change in the information that is required for a monoclonal antibody submission.

Additionally, names that have already been assigned to a monoclonal antibody will not be affected. The USAN Council has no plans to retroactively change names already coined. To retroactively change names of monoclonal antibodies would introduce additional confusion, especially for marketed products. As a general rule, the USAN Program does not revise names already assigned when nomenclature rules change. If you have received a name for a monoclonal antibody, please continue to use the existing name with no revisions. The new nomenclature scheme applies only to monoclonal antibodies for which a USAN has not been adopted.

Additionally, the USAN Program plans to continue accepting monoclonal antibody names that have been published on a proposed INN list, but that may not conform to the current scheme. Consequently, firms that received an INN for a monoclonal antibody under previous nomenclature schemes should list that name on the USAN application, rather than a different name based on the new nomenclature scheme.

Firms should note that nomenclature practices are continually evolving. Consequently, further updates may occur any time the Council believes change is necessary.

The New Nomenclature Scheme

A full description of the monoclonal antibody scheme is published on the USAN Program web site (https://www.ama-assn.org/about/monoclonal-antibodies). This is a brief summary.

The key elements of a monoclonal antibody name appear in the following order:

1. Prefix
2. Infix representing the target
3. Stem used as a suffix (e.g., -mab)
To create a unique name, a distinct, compatible syllable or syllables should be selected as the prefix. Suggested prefixes should comply with the USAN Program's rules for coining names. In addition, we ask that manufacturers avoid potential conflicts with names of other monoclonal antibodies.

The target infix places information about the action or use of the antibody in the name. The USAN Council has approved specific syllables to denote diseases or targets. Additional target infixes may be added to the scheme if the USAN Council believes there is sufficient rationale to do so. For a current list, please visit our web site.

Sometimes the name of a monoclonal antibody requires additional clarifying words. Typically, a second word is used when naming an antibody-drug conjugate.

**Nomenclature Rules for Coining Names for Contact Lens Materials**

For nomenclature purposes, contact lens materials are divided into hydrophilic and hydrophobic groups depending on their water content. The hydrophilic lens materials with water content equal to or more than ten percent (10%) by weight at ambient temperature (23± 2º C) are assigned “filcon” names; “focon” names are given to hydrophobic lens materials with content less than ten percent (10%).

In addition to water content, nomenclature for contact lens materials depends primarily on the polymeric composition, i.e., the repeating monomer units comprising the lens material. Initiators, catalysts, fillers, and chemically bound or physically entrapped color additives or ultraviolet absorbers are excluded in establishing the polymeric composition of the contact lens material for nomenclature purposes.

The first member of a series is assigned a unique nonproprietary name containing the proper –filcon or –focon suffix stem. A separate capital letter “A” is added after each parent designation. Subsequent designations for polymers consisting of identical monomers receive the same parent name but a different appended letter (B,C,D, etc.). These letters are needed to differentiate between polymers of identical monomeric units but with different ratios of units that have different physiochemical properties, as determined by water content, oxygen permeability (Dk) value, refractive index, wetting angle, elasticity, and toughness of the lens. The addition of a surface treatment of an existing lens material that has been assigned a USAN does not require a new USAN.
Publication Deferment Option

If you’ve come to adoption time and realized you are not ready for your statement to be published, there is an option. A publication deferment is a period of time after adoption takes place, which will allow you further review time. You must request a publication deferment by the time your initial post-adoption sixty-day review period is completed. USAN Program policy allows for a publication deferment of up to six months from the time that your proposed adoption statement revisions and completed review confirmation form is due. When the USAN Program is preparing to publish and there is no response from the sponsor when either the initial sixty-day period or the requested publication deferment period is up, the statement will be published as-is. If there are changes in the chemical information of your compound, or any other adoption statement items, which occur after you have approved the statement and the statement is published and distributed to the USP Dictionary of USAN and International Drug Names, the adoption statement must go through a USAN Revised application process (please see the Form D on the USAN website’s application page). Please email brad.wells@ama-assn.org to request a publication deferment and you will receive a rescheduling confirmation.

Quick USAN Application Tips

- If you are submitting a biologics application, please make sure to submit your amino acid sequences in an editable MS Word document. Email them to gail.karet@ama-assn.org or mary.haynes@ama-assn.org.
- If you are submitting a contact lens application, please let us know if anything has been added to the lens material to alter the properties.
- Include the investigator’s brochure in your application materials.
- It is the applicant’s responsibility to register Internet domain names; the cost is minimal.
- Remember your assigned negotiator and file number when emailing or calling.

Upcoming Events

- INN 65th Consultation Meeting – October 17-20, 2017
- USAN Council Winter Meeting – January 18-19, 2018
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.

Edited by brad.wells@ama-assn.org