Naming Biologics

The USAN Council is involved in coining names for various biological products: insulins, interferons, interleukins, growth hormones, colony-stimulating factors, cytokines, monoclonal antibodies and coagulation factors. With increasing development of highly purified biological extracts and recombinant materials, the council has had a greater role in assigning names and developing nomenclature rules for these agents.

Please use the following MS Word document sequence templates to submit in a table format:

- Sequence template (DOC) required when submitting all proteins and peptides
- Sequence template (DOC) required when submitting monoclonal antibodies

USAN and INN requirements for biological substances include the following:

### All Proteins and Peptides

- Complete mature amino acid sequence (DOC) in a MS Word document
- 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
- Positions of all disulfide bridges and post-translational modifications should be listed after the sequence
- Glycosylation patterns (including site, type of sugar, etc.)
- For recombinant proteins: Expression system and comparison with native sequence

### Monoclonal Antibodies

- Complete mature amino acid sequence (DOC) in a MS Word document
- 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, type of sugar, etc.)
- Precursor nucleotide sequence with spaces between codons and translation, with numbered lines
- CDR-IMGT (DOC)

URL: https://www.ama-assn.org/about/united-states-adopted-names/naming-biologics
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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)

Cell Therapies

Name/code designation
Characterization/description
Cell source
List and description of manipulation (culture conditions included)
If genetic manipulation: the detailed description of the vector and insert should be provided

Nucleic Acids

Nucleic acids include DNA vaccines, oligonucleotides and gene therapy products.

Full nucleotide sequence with pertinent regions (e.g., coding regions, control regions) delineated
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 two significant figures), details of the linker, point of attachment of the linker to the active moiety

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