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)**
- 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