## When naming Monoclonal Antibodies the following items are <u>required</u> to be submitted with your application materials:

## **USAN Requirements for Monoclonal Antibodies**

- ✓ Complete mature amino acid sequence in a <u>Microsoft Word document</u>
- ✓ 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
- ✓ <u>CDR-IMGT and sequence analysis of the variable regions showing percentage of human content (if -ximab, -zumab, or -umab is requested; 85%+ -zumab or -umab, <85% -ximab)</u>
- ✓ 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)