Form F

USAN Application for Monoclonal Antibodies, Gene Therapies, Cellular and Non-Cellular Therapies

ONLY

UNITED STATES ADOPTED NAMES COUNCIL
AMERICAN MEDICAL ASSOCIATION
330 N. WABASH AVENUE SUITE 39300
CHICAGO, IL 60611
312-464-4046

REQUEST FOR A UNITED STATES ADOPTED NAME (USAN) FOR A SINGLE ENTITY DRUG

(for USAN staff use only)

File No. (Single Entity):	Acknowledged:
INN Status:	WHO No.:

SUGGESTED NAME(S) IN ORDER OF PREFERENCE:
(Please attach verification of the absence of conflicts with existing chemical names, insecticides, other nonproprietary names or trademarks)

1.
2.
3.
4.
5.

CHEMICAL NAME(S) OR DESCRIPTION:
(Chemical Abstracts Service Index Name must be supplied)

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

USAN Requirements for Biological Substances

All proteins and Peptides

- ✓ Complete mature amino acid sequence in a Microsoft 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
- ✓ If available, the three dimensional structure in Protein Data Bank format or the Protein Data Bank accession code
- ✓ For conjugated proteins: the ratio is the mean numbers of molecules of the conjugated part (indicated by range, thus integer numbers) per molecule of protein

Monoclonal Antibodies

- ✓ Complete mature amino acid sequence in a Microsoft 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 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
- ✓ 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)
- ✓ If the If the terminal lysine is absent in the heavy chain amino acid sequence, please confirm that there is no lysine codon in the nucleotide sequence. If there is a lysine codon, the terminal lysine should be included in the amino acid sequence, with the posttranslational modification (clipping) described
- ✓ 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)

Nucleic Acids

Includes DNA vaccines, oligonucleotides, gene therapy products

- ✓ The full nucleotide sequence of the substance in the following format: 50 nucleotides per line, in blocks of 10, with numbering at the end of each line
- ✓ 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
- ✓ Details of the linker (not the reagent used): where the liner is attached to the active moiety, and, ideally, if multiple sites are involved, in what proportion they are modified
- ✓ The pertinent regions (e.g. coding regions, control regions) should be delineated

USAN Requirements for Biological Substances

All Pegylated Substances

- ✓ Details of pegylation: end group, polymer chain with average number of repeat units to 2 significant figures, details of the linker, point of attachment of the linker to the active moiety

Cell Therapy

- ✓ 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

Gene Therapy

- ✓ A schematic map of the entire vector and inserted gene(s)
- ✓ The nucleotide annotated sequence that delineates relevant parts of the sequence
- ✓ For the therapeutic protein: the complete precursor nucleotide sequence with spaces between codons and translation (including the stop codon in 5'), with numbers per line, and in a format that can be copied for analysis (Word or in the text of an email)
- ✓ A CAS registry number is required

Sequence:
(Please attach as a word document.)

MOLECULAR FORMULA:

MOLECULAR WEIGHT:

CHEMICAL ABSTRACTS SERVICE (CAS) REGISTRY NUMBER:
(CAS Registry number must be supplied. Please attach a copy of the CAS search results to your compound. A CAS registry number is not required for cellular or non-cellular therapies.)

UNIQUE INGREDIENT IDENTIFIER (UNII) NUMBER:

CODE DESIGNATION(S):
(Please list all previous and current codes)

TRADEMARK(S):

TRIVIAL NAME(S):

MANUFACTURER(S):

PRINCIPAL THERAPEUTIC USE(S):

PHARMACOLOGIC ACTION:

DOES THE SUBSTANCE BIND TO A RECEPTOR, ENZYME, OR OTHER TARGET?
YES____ NO____
(If yes, please list all full names and abbreviations used to refer to the target to which the substance binds. If the drug binds to more one target, please provide binding constants or indicate the relative selectivity for each target, if known)

US firms that have a US IND number are expected to file for a USAN first, rather than requesting a nonproprietary name directly from the INN Programme. If you are requesting a name that is already an INN, please list the INN number, and explain why the INN submission was made first.

1. **The process of selecting a USAN should be initiated during that period of investigation when the compound is undergoing clinical studies.**

   Please indicate the date clinical trials began:

   IND Application Number(s):

2. **The undersigned confirms that the CAS registry numbers and Index names are correct. Permission is granted to USAN to utilize this information in USAN-generated publications.**

3. **Permission is granted for the USAN Council Secretariat to secure the International Union of Pure and Applied Chemistry (IUPAC) chemical names for the compounds submitted. Please note that names appearing on the statement of adoption may differ from those submitted by the firm.**
4. **Permission is granted for the USAN Council Secretariat to submit the negotiated nonproprietary name to the World Health Organization (WHO) Nomenclature Committee for consideration. A fee of $12,000.00 assessed by the WHO is payable by check to the WHO or via wire transfer; payment will be made when the name is forwarded to WHO for consideration and wire transfer instructions will be provided upon request. If the name is already an International Nonproprietary Name (INN), permission is granted to forward it to WHO as a matter of information.**

5. **This submission is made with the understanding that insofar as is known, none of the suggested names are trademarked or the subject of pending registration. It is further understood that the adopted USAN will remain a free and unrestricted nonproprietary name that will not be trademarked. Furthermore, USAN stems should not be incorporated into a trade name.**

6. **This submission is made with the understanding that names recommended by the USAN Council for this compound will be posted on the USAN Web site as "names under consideration."**

7. **The undersigned understands and acknowledges that because “names under consideration” as well as adoption statements are published on the USAN Web site, there is a possibility that unaffiliated third parties might register a name as an Internet domain without the prior knowledge of the USAN Program. The undersigned waives all liability of USAN if this is to occur.**

8. **The undersigned understands and acknowledges that all information included on the USAN application and provided by the applicant throughout the USAN negotiation process is kept confidential and is only shared with USAN staff, the USAN Council and the INN Expert Group.**

9. **The undersigned agrees not to publicly use USAN name suggestions before receiving a Statement of Adoption from the USAN Council.**

10. The appropriate fee-for-service is enclosed. Check one:

	Name for a new monoclonal antibody	**$15,000.00**
	USAN modified (name for a monoclonal antibody for which an adopted USAN already exists)	**$8,000.00**

11. Make check payable to American Medical Association/USAN. Please call 312-464-4046 to request information on an electronic fund transfer. If check is not enclosed or is to be sent separately, please send to the following address:

American Medical Association
Attn: Remittance Control-46th Floor
330 N. Wabash Avenue
Chicago, IL 60611-5885

Please make sure to note that payment is for a USAN application and include code designations or other relevant reference information.

Submitted by:

Applicant: **(Name of firm, sponsor or legal representative)**

Address:

Telephone:

Fax:

Name of Contact Person:

Title:

Email Address:

Signature:

Date:
