**Form B**

**USAN Application for Single Entity Drug**

**Small molecules, short peptides, oligonucleotides, other drug substances**

**For biologics, please use form F**

UNITED STATES ADOPTED NAMES COUNCIL

AMERICAN MEDICAL ASSOCIATION

330 N. WABASH AVENUE SUITE 39300

CHICAGO, IL 60611

Email this form and all supporting documents to usan@ama-assn.org

|  |  |
| --- | --- |
| **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. Any other systematic names for the substance may also be listed)

|  |
| --- |
|  |

**STRUCTURAL FORMULA:**

(Provide stereochemistry)

|  |
| --- |
|  |

**MOLECULAR FORMULA (Not required if known. If calculated, please indicate the types of calculations used.):**

|  |
| --- |
|  |

**MOLECULAR WEIGHT (Please indicate whether this is theoretical/calculated or measured. If measured, please indicate the type of measurement(s) used, if calculated, please indicate the type(s) of calculations used. For polymers or substances with a variable weight, list a molecular weight range or average molecular weight with standard deviations):**

|  |
| --- |
|  |

**IS THIS A PRO-DRUG? YES\_\_\_\_ NO\_\_\_\_**

(A compound that, on administration, must undergo chemical conversion by metabolic processes before becoming an active pharmacological agent; a precursor of a drug)

**CHEMICAL ABSTRACTS SERVICE (CAS) REGISTRY NUMBER:**

**(CAS Registry number must be supplied. A copy of the CAS search results for your compound should be submitted as an MS-Word document with your application.)**

|  |
| --- |
|  |

**UNique Ingredient Identifier (UNII) NUMBER** (One will be assigned if a UNII is unknown or not available.)**:**

|  |
| --- |
|  |

**UNique Ingredient Identifier (UNII) NUMBER (SALT)** (One will be assigned if a UNII is unknown or not available)**:**

|  |
| --- |
|  |

**CODE DESIGNATION(S):**

|  |
| --- |
|  |

**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 targets to which the substance binds. If this substance binds to more than 1 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 explain why the INN submission was made first, and include the INN number and documentation showing the INN Experts selected this name.**

|  |
| --- |
|  |

**1. The process of selecting a USAN should be initiated after clinical studies have begun.**

 **Please indicate the date Phase 1 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 an International Union of Pure and Applied Chemistry (IUPAC) or other systematic name 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 assessed by the WHO is payable to the WHO via wire transfer; payment will be made when the name is forwarded to the 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 free and unrestricted nonproprietary names 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. Please wire $18,000.00 as the appropriate fee-for-service for names for a single entity drug and salt form. You can request USAN’s wire information by contacting** **AMA.treasury@ama-assn.org****.**

 ***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:**

|  |
| --- |
|  |

 **Name of Contact Person:**

|  |
| --- |
|  |

Optional: Please tell us your preferred pronouns or how you would like to be addressed in correspondence: [\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_]

 **Title:**

|  |
| --- |
|  |

 **Email Address:**

|  |
| --- |
|  |

 **Signature:**

|  |
| --- |
|  |

 **Date:**

|  |  |  |
| --- | --- | --- |
|  |  |  |

**USAN Application Checklist for Form B**

|  |
| --- |
| **Checklist of Required information. The following items must be supplied with the USAN application form when the firm files a request for a USAN.** |
| **\_\_ Cover letter (recommended)*** Explanation of the action and use of your substance
* Explanation of why the USAN stem suggested was chosen for your substance

**\_\_ Description and/or results of any trademark or generic name searches that were done to vet a name for conflicts with other names****\_\_ Editable ChemDraw File showing the structure(s) of the parent substance and its salt or ester****\_\_ CAS registry information (Acceptable forms of CAS information below, not required for cell therapies or non-cellular immunotherapies)*** Letter from CAS showing the CAS registry number
* Electronic document (MS-Word and/or PDF document preferred) showing results of a CAS search for the CAS registry number listed on the USAN application
* Sequence and structural information should be UNMASKED in the CAS database

**\_\_ Proof of payment*** PDF copy of the wire transfer confirmation, showing banking information

**\_\_ Sequence and Structural information, All Proteins and Peptides (MS-Word Document required)*** Complete mature amino acid sequence AS EDITABLE TEXT in a [Microsoft Word document: single letter codes for each amino acid, 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](https://www.ama-assn.org/sites/ama-assn.org/files/corp/media-browser/public/usan/sequence-request-format-other-proteins_0.doc)
* Complete precursor nucleotide sequence
* A list of any mutations/amino acid differences with the native sequence (for gene and allele) (e.g. mutations introduced to alter receptor binding or change the isoelectric point, to prevent C1q binding, enhance FcRn binding, etc.)
* 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

\_\_ **Pegylated Proteins and Peptides*** The details of pegylation: the end group and the polymer chain with the average number of repeat units (to 2 significant figures)
* The details of the linker (not the reagent used); where the linker is attached the moiety, and, ideally, if multiple sites are involved, in what proportion they are modified

**\_\_ Sequence and Structural Information, monoclonal antibodies, antibody fragments, multi-specific antibodies, antibody-drug conjugates (MS-Word document required)*** All information required for proteins and peptides
* [CDR-IMGT and sequence analysis of the variable regions showing percentage of human content](http://www.imgt.org/)
* CDR-Kabat (sequence and residue range)
* IG class and subclass, IG format
* Species or taxonomy related structure (chimeric, humanized, etc.)
* Name and/or structure of targeted antigen
* 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 terminal lysine is absent in the heavy chain amino acid sequence, a statement confirming that indeed there is no lysine codon in the nucleotide sequence (if not the lysine should be added in the amino acid sequence mentioning the posttranslational modification clipping)
* NEW! A list of all engineered mutations in the constant region, their locations, and their purpose

\_\_ **Antibody-drug conjugates*** All information required for monoclonal antibodies
* Editable ChemDraw file of the linker/payload combination, showing which parts of the molecule are the linker and which are the payload
* Sites of attachment of the linker to the monoclonal antibody included in the MS-Word sequence document

\_\_ **Sequence and Structural information, nucleic acid-based substances (MS-Word document required)*** 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 (Word or in the text of an email)
* The nucleotide sequence should be annotated to delineate relevant parts of the sequence (e.g., coding regions, control regions)
* A schematic map of the entire nucleic acid showing inserted/deleted gene(s) and relevant functional parts (not required for short oligonucleotides)

**\_\_ Gene Therapies (MS-Word Document Required)*** Required information for nucleic acid-based substances
* A schematic map of the entire vector and inserted gene(s)
* 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

**\_\_ Cell Therapies (MS-Word document required)*** 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
* Structural/manufacturing/properties and the non-clinical pharmacology sections of the IB

**\_\_ Verification of the Absence of conflicts (recommended)*** Trademark search results (WIPO database)
* Analysis of suggested names using the FDA’s POCA online tool
* Google search

**\_\_ Nucleic Acids salts (<30 base pairs, for other oligonucleotides, gene therapies and cell therapies please use form F or contact USAN staff for advice)*** Sequence as an MS-Word Document
* ChemDraw files showing the structures of the oligonucleotide and its salt

**Gene Therapy****\_\_ Additional information to support the choice of stem and document action of the compound (recommended)*** Pharmacokinetic data/binding constants showing strength of binding with intended target(s)
* Nonclinical pharmacology section or executive summary of the investigator’s brochure
* Publications related to the substance to be named

  |

***Please note:***

*This checklist lists USAN requirements for submission. INN has separate requirements, and failure to meet those requirements may delay INN review. If we will be filing an INN application on your behalf, requirements for the INN submission must also be included in the MS-Word document that includes structural information for the substance:*

* All Proteins <https://extranet.who.int/tools/inn_online_application/INN_online_application_files/20_481_Annex_INN_Form_Proteins_20200518.pdf>
* Nucleic acid-based substances

<https://extranet.who.int/tools/inn_online_application/INN_online_application_files/20_480_Annex_INN_Form_nucleic_20200518.pdf>

* Cell based therapies

<https://extranet.who.int/tools/inn_online_application/INN_online_application_files/20_478_Annex_INN_Form_cell_20200518.pdf>