United States Adopted Names naming guidelines

By definition, nonproprietary names are entirely in the public domain and are not subject to trademark rights. A United States Adopted Name (USAN) is a nonproprietary name selected by the USAN Council to ensure safety, consistency and logic in the choice of names. These principles take into account the existence of trademarks, international harmonization of drug nomenclature, new classes of drugs and the fact that the intended uses of substances for which names are being selected may change.

- How USAN works (PDF)
- INN process in relation to USAN process (PDF)
- How USAN publishes a name (PDF)

Brand name and generic name guidelines for active ingredients

Unlike generic names, brand names vary from company to company and from country to country. In rare instances, a brand name may be used for 2 different active ingredients in different countries. More commonly, a company uses different brand names in different countries for the same drug, or 2 countries may market the same substance under different brand names. Finally, as part of "brand extension" business strategies, companies use the same brand name to refer to 2 different active ingredients.

Brand: Cialis Generic: tadalafil

Brand: Colemin, Lipex, Zocor and Vytorin Generic: simvastatin

Brand: Gleevec, Glivec Generic: imatinib mesylate

Guiding principles

1. A nonproprietary name should be useful primarily to health care practitioners, especially physicians, pharmacists, nurses, educators, dentists and veterinarians.
    - The primary criterion for judging usefulness is suitability, including safety for use in

routine prescribing, ordering, dispensing and administering drugs in the U.S.
- The 2nd criterion is suitability for use in educational programs for medically oriented professions and for use in scientific and lay publications.
- The 3rd criterion is suitability for use internationally in drug identification, the exchange of information and translation into different languages.

2. Attributes that contribute to usefulness are simplicity (i.e., brevity and ease of pronunciation), euphony, ready recognition and recall.
   - The name for the active moiety of a drug should be a single word, preferably of no more than 4 syllables.
   - The name for the active moiety may be modified by a single term, preferably of no more than 4 syllables, to show a chemical modification, such as salt or ester formation (e.g., cortisone acetate, cefamandole sodium or erythromycin acistrate).
   - Only under compelling circumstances is a name with more than 1 modifying term acceptable. Compelling circumstances may include pharmaceuticals containing radioactive isotopes or the different classes of interferons.
   - Acronyms, initials and condensed words may be acceptable in otherwise appropriate terminology.

3. A name should reflect characteristics and relationships that will be of practical value to the users.
   - A common, simple word element (a "stem") should be incorporated in names of all members of a group of related drugs when pertinent, common characteristics can be identified (e.g., similarity of pharmacological action). However, when pharmacological similarity is found in drugs of distinctly different chemical nature, stems should differ.
   - Distinctive terminology should be used for specific drugs or groups (e.g., insulin I 131, dextran 40, interferon alfa-2a and interferon alfa-n1; licryfilcon A and licryfilcon B; epoetin alfa and epoetin beta).

4. A name should not conflict, mislead or be confused with other nonproprietary names and with established trademarks.
5. Names with established usage should be preferred, provided they conform to these guiding principles and do not conflict with existing nonproprietary names and trademarks.
6. Where possible, the USAN Council will assign substances to existing stems or nomenclature schemes that describe the substance, its action or its use. A new stem will be created only in unusual circumstances where existing stems and nomenclature schemes do not accurately represent a compound, its action, structure or use, and also when substantial preclinical and clinical data support the creation of a new stem.
7. Identical negotiations submitted by 2 or more manufacturers will be conducted in accordance with the Council's confidentiality practices. The applicants involved will not be notified of the

multiple sources of the submission. However, the name selected by the USAN Council will need to be accepted by each sponsor involved in the negotiation process.

8. A USAN request should be made after the drug sponsor has submitted an Investigational New Drug (IND) Application to the Food and Drug Administration to obtain permission to initiate studies on humans. An IND number is required before the USAN application review process can begin.
9. Negotiations may be placed on hold.
    - The USAN Council secretariat will put an ongoing negotiation on hold for 6 months, plus 1 additional 3-month extension, upon receipt of a written request from the manufacturer. If the USAN Council has selected a name candidate and recommended this name to the manufacturer, the maximum hold is a 6-month period.
    - The negotiation will be canceled after the maximum 9-month hold has lapsed.
    - If the negotiation is to be reopened at a later time, it will be treated as a new application and will be assigned a new USAN file number. The manufacturer will be expected to submit a new USAN application form, update the background information and submit the appropriate fee.

Who is USAN?

The USAN Council has been coining names since the early 1960s. The Code of Federal Regulations states that the USAN is an established name for a drug. Learn about the USAN Council.

What does the USAN program name?

USAN will be provided for the following:

- Small-molecule drugs
- Biotechnology drugs including monoclonal antibodies, therapeutic vaccines, proteins and peptides, DNA, RNA, nucleoside and nucleotide therapies
- Gene therapies
- Cellular therapies
- Other biological substances deemed appropriate to be assigned a USAN by the USAN Council
- Contact lens materials
- Active ingredients in sunscreens
- Veterinary products intended to control diseases in animals

- The base, salt, ester or other chemical derivative of a substance that has received a USAN

USAN will not be provided for the following:

- Mixtures that do not have an IND number or do not require approval for human use by the FDA
- Bacterial strains
- Drug delivery mechanisms
- Excipients alone
- Prophylactic vaccines
- Product formulations* (emulsions, suspensions, etc.)
- Medical devices
- Manufacturing processes
- Combination drug products

*The USAN Council will authorize an exception to the above only if there is a clear and well-documented need, such as that assignment of a name promotes safety and advances the USAN Council's nomenclature principles.

The number of names coined each year varies. In recent years, the USAN Program has coined over 150 new names annually.

What do the names mean?

Several decades ago when the USAN Program first began coining names (and even before its inception), condensing the systematic chemical name of a substance was a common way to coin drug names. This is no longer the case.

Now, new names consist of 3 parts: a prefix, an infix (sometimes) and a stem.

Prefix: Means nothing; differentiates drug from others in class

Infix: Used occasionally; further subclassifies

Stem: Indicates place in nomenclature scheme; drugs with the same stem are related

Stems are usually at the end of a name, with a few exceptions (e.g., cef-), and indicate the drug's place within the nomenclature scheme. Consequently, a new suffix often but not always suggests a new mechanism of action. Drugs with the same ending (stem) belong to the same pharmacologic family. Infixes, appearing in the middle of the word, are sometimes used to further classify the drug.

Prefixes mean nothing. The sole purpose of a prefix is to differentiate a drug from other members of the class.

As an example, consider sildenafil (Viagra™), vardenafil (Levitra™), and tadalafil (Cialis™). The -afil stem is formally defined as for PDE5 (phosphodiesterase 5) inhibitors. The -den- infix indicates that sildenafil and vardenafil have similar chemical structures. The prefixes are sil-, var- and tadal-.

Pharmacologic families of some commonly prescribed and top-selling branded drugs

The following are brand names, generic names and explanations of what the name means:

Stem: -stat Lipitor™ (atorvastatin calcium) meaning: enzyme inhibitors

Crestor™ (rosuvastatin) stem subgroup: -vastatin meaning: inhibitors of HMG-CoA, an enzyme involved in synthesizing cholesterol

Stem: -prazole Nexium™ (esomeprazole magnesium) meaning: esomeprazole is a stereoisomer of omeprazole

Prevacid™ (lansoprazole) meaning: agents to treat ulcer and/or heartburn that are chemically related to benzimidazole

Stem: -lukast Singulair™ (montelukast) meaning: antiallergics and antiasthmatics that are leukotriene receptor antagonists

Stem: -grel Plavix™ (clopidogrel sulfate) meaning: platelet aggregation inhibitors

Stem: - faxine Effexor XR™ (venlafaxine hydrochloride) meaning: antianxiety, antidepressant inhibitor of norepinephrine and dopamine reuptake

Stem: -oxetine Cymbalta™ (duloxetine hydrochloride) meaning: antidepressants with a chemical structure related to fluoxetine

Stem: -sartan Diovan™ (valsartan) meaning: angiotensin II receptor antagonists

Stem: -oxacin Levaquin™ (levofloxacin) Meaning: antibiotics that are chemical derivatives of quinolone

Stem: -vir Valtrex™ (valacyclovir) meaning: antiviral compounds stem subgroup: -cyclovir meaning:

chemical structure is related to acyclovir

Stem: -mab Avastin™ (bevacizumab) meaning: monoclonal antibodies stem subgroup: -zumab meaning: humanized infix: -ci- for circulatory system targets (e.g. inhibiting angiogenesis)

Remicade™ (infliximab) meaning: monoclonal antibodies stem subgroup: -ximab meaning: chimeric infix: -li- for immune system targets

Sources for prescribing/sales information are *Fierce Pharma*, Blue Cross/Blue Shield of Illinois and *Pharmacy Times*.

There are few prefixes and infixes with specific, defined meanings, some of which have been used to coin names for top-selling drugs. Ar-, es-, lev- and dex- are used to name stereoisomers of drugs that have already received a USAN. For example, esomeprazole is a stereoisomer of omeprazole. Peg- means that a biologic substance, such as peptide, is pegylated. -Io- has been used as an infix to suggest a high iodine content (amiodarone). When -fos- appears anywhere in a drug name, the element phosphorous is present, often as a phosphate ester.

Drugs with 2-word names are often salts, adducts with coprecipitated acid molecules, esters or prodrugs. The pharmacologically active portion is generally listed first in a 2-word name. The second word designates the pharmacologically inactive portion of the substance, or the part of the ester or prodrug that is cleaved *in vivo* to generate the pharmacologically active species.

Specific nomenclature rules

1. Prefixes that imply "better," "newer" or "more effective;" prefixes that evoke the name of the sponsor, dosage form, duration of action or rate of drug release should not be used (e.g., "dura," "forte," or "efex").
2. Prefixes that refer to a Latin or Greek number, unless meaningful to the compound, are not acceptable (e.g., "deci," "centi," "bi" or "di").
3. Prefixes with an anatomical connotation or referring to a medical condition are not acceptable.
4. Prefixes that indicate a chemical element or compound (Ca, Ni and Stannous) are not acceptable.
5. Because of the international exchange of drug information, specific guidelines have been formulated to ensure appropriate translation of nonproprietary names into other languages. These rules of preferred phonetic spelling should be used:
    - The letter "f" should be used instead of "ph"
    - The letter "t" should be used instead of "th"

- The letter "e" should be used instead of "ae" or "oe"
- The letter "i" should be used instead of "y"
- Avoid the letter "h"
- Avoid the letter "k"
- Avoid the letter "j"
- Avoid the letter "w"
- "ar," "rac," "lev," "dex" or "es" are reserved for stereochemical configurations

6. Additionally, these letter combinations are restricted until further notice:
    - Avoid the beginning letter combination of "me"
    - Avoid the beginning letter combination of "str"
    - Avoid chemical connotations such as "ben," "bu," "cat," "cel," "fen," "flu," "fo(s)" and "piro," unless chemically appropriate
    - Avoid chemical symbols unless present in the compound "al," "ba," "ca," "li" and "ni"
    - Avoid "z" or "x" as a beginning letter
    - Avoid blends of 2 consecutive vowels

7. Individual letters, numbers or hyphenations are restricted to those groups of substances for which usage fulfills a clearly demonstrable purpose (e.g., interferon alfa-2b, paflufocon A or technetium Tc 99m siboroxime).
8. Group relationships in a name preferably should be indicated by use of syllables or stems. Conversely, use of the stem for other than the appropriate group should be avoided. When multiple stems are available, the stem conveying the most information should be used.
9. Esters, salts, chelates, prodrugs and complexes ordinarily require a 2-word name to indicate the inactive as well as the active portion.
    - The preferred order for the name of an inorganic salt is cation-anion (e.g., sodium chloride), irrespective of the clinically significant portion. The same order is preferred for well-known salts of simple organic acids (e.g., sodium lactate, magnesium citrate, potassium acetate).
    - For more complex organic compounds, the pharmacologically active portion should be identified first (e.g., oxacillin sodium, dexibuprofen lysine).
    - A name for a salt or ester is generally derived from the name of the pharmacologically active moiety or corresponding acid (e.g., chloroprednisone acetate).
    - Ester prodrugs, which are cleaved *in vivo* to release the pharmacologically active species, ordinarily receive 2-word names (e.g., haloperidol decanoate, clindamycin palmitate). Other types of prodrugs may receive a 1- or 2-word name, as the USAN Council deems.
    - Exceptions to 2-word names may be appropriate when differences in pharmacologic activity for the ester form are clinically important (e.g., if only the ester but not the

parent is pharmacologically active). To receive a 1-word designation for an ester, sponsors must submit data to document the activity of the ester. The USAN Council may request such information if it is not provided.

10. As of January 2013, the name for the salt form of a pharmacologically active moiety will no longer specify the number of molecules used to react with the active moiety. Between January 1993 and December 2012, numerical prefixes were often used to specify the number of molecules used to react with the active moiety (e.g., basalazide disodium).
11. A name for a quaternary ammonium substance should designate the cation and anion separately (e.g., octonium bromide *not* octonine methylbromide). The name assigned to the cation must contain the *-ium* suffix stem. This rule is modified when a 2nd, more pertinent, stem is used. In such cases, the addition of the *-ium* suffix stem to solely designate a quaternary ammonium is not required.
12. A name for a complex of 2 or more components should list the name of the principal active ingredient followed by a coined designation for the second component ending with an "-ex" suffix to indicate "complex" (e.g., bisacodyl tannex, doxycycline fosfatex). Complexes formed from sulfonated diethenylbenzene-ethenylbenzene copolymers and an active ingredient should list the name of the principal active ingredient followed by "polistirex," such as in chlorpheniramine *polistirex* or codeine *polistirex.*
13. A name for a drug containing a radioactive atom should list, in the order given: (1) the name of the drug containing the radioactive atom, (2) the element symbol, (3) the isotope number and (4) the name of the carrier agent if any (e.g., rose bengal sodium I 131, cyanocobalamin Co 60, potassium bromide Br 82, technetium Tc 99m butilfenin, technetium Tc 99m medronate, indium In 111 oxyquinoline, indium In 111 satumomab pendetide).
14. A name for a substance generally should not indicate the state of hydration, the morphology or the mode of preparation. Reference to the water of hydration is retained in the chemical information (chemical names, formulas, weight) but is excluded from the nonproprietary name. The degree of hydration becomes a part of the chemical entity identified by the USAN.
15. Under the terms of the Orphan Drug Act of 1983, the development and marketing of drug products that are of limited commercial application but are potentially useful in relatively rare disease conditions are encouraged. The selection of a name for an orphan drug may be based on special considerations. Therefore, when the name for an orphan drug appears to follow a more chemically oriented terminology style than is customary for drug nomenclature, this is not a precedent for a future USAN.
16. A name coined for a new chemical entity routinely does not specify the stereoisomeric form of the molecule in the nonproprietary name. If the stereochemical configuration has been determined, this information is presented in the chemical name(s) and is reflected in the structural formula. A USAN can, therefore, identify the racemic mixture (e.g., carnitrine, ibuprofen, tetramisole) the levo isomer (e.g., remoxipride, quadazocine) or the dextro form (e.g.,

butopamine). Subsequently, if a name is needed for a different enantiomer or for the racemic form, the following prefixes should be added to the existing name:

- For the racemate, the rac-/race- prefix is used (e.g., racemethionine, racepinephrine, ractopamine).
- For the levorotatory form, the "(S)" isomer, the lev-/levo- prefix is used (e.g., levocarnitine, levamisole, levcromakalim and levdobutamine).
- For the levorotatory form, the "(R)" isomer, ["R(-)"-isomer], the "ar-" prefix is added to the base name.
- For the dextrorotatory form, the "(R)" isomer, the dex-/dextro- prefix is used (e.g., dexamisole, dexibuprofen, dextroamphetamine, dexverapamil, dexrazoxane, dexfosfoserine and dexniguldipine)
- For the dextrorotatory form, the "(S)" isomer ["S(+)"-isomer], the "es-" prefix is added to the base name.

17. Official names have been selected for a number of radicals and adducts used to form salts or esters of the pharmacologically active moiety. In a majority of cases, these names represent contractions of the chemical name assigned to the radical or adduct. In some cases, the official name identifies a multicomponent adduct.

Office of Orphan Products Development