Generic Naming in the US

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What is USAN?

- USAN stands for **United States Adopted Names**
- Organized U.S. effort to coin nonproprietary names for drugs and related agents
- Co-sponsored by AMA, United States Pharmacopeia (USP), American Pharmacists Association (APhA)
- USAN Program has been in existence since 1961, USAN has been accepted by the FDA as the established name since 1984
USAN Council Members

- 5 members
- AMA, USP, and APhA represented
- Liaison member from the FDA
- One member at-large
Anatomy of a Statement of Adoption

- Planned use
- Assigned USAN
- Pronunciation
- CAS name
- Chemical structure
- IUPAC name
- Name of sponsoring company
- Molecular formula and weight
- Code designations, trademarks
- Molecular formula
- Molecular weight
- Code
- Trademark
- Manufacturer
- CAS registry number
# Things we Name

<table>
<thead>
<tr>
<th>Category</th>
<th>Example</th>
</tr>
</thead>
<tbody>
<tr>
<td>Small molecules</td>
<td>basimglurant, briclib, bradanicline</td>
</tr>
<tr>
<td>Salts or esters</td>
<td>bradanicline hydrochloride</td>
</tr>
<tr>
<td>Contact lens plastics</td>
<td>riofilcon A</td>
</tr>
<tr>
<td>Surgical materials</td>
<td></td>
</tr>
<tr>
<td>Veterinary drugs</td>
<td>rabacfosadine</td>
</tr>
</tbody>
</table>
## More Things We Name

<table>
<thead>
<tr>
<th>Category</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>Solid state compounds</td>
<td>ferric citrate, sodium zirconium cyclosilicate</td>
</tr>
<tr>
<td>cell therapies</td>
<td>vesigenurtucel-L</td>
</tr>
<tr>
<td>enzymes</td>
<td>Senrebotase</td>
</tr>
<tr>
<td>therapeutic vaccines/gene therapy products</td>
<td>seviprotimut-L</td>
</tr>
<tr>
<td>monoclonal antibodies and conjugates</td>
<td>diridavumab, pinatuzumab vedotin</td>
</tr>
<tr>
<td>Some mixtures and extracts</td>
<td>omega 3 carboxylic acids</td>
</tr>
</tbody>
</table>
Things We Don’t Name

- Combination products
- New formulations of an active ingredient that has a USAN
- Inactive ingredients (excipients)
- Most mixtures
- Prophylactic vaccines (e.g., flu vaccine)
- Drugs and dietary supplements for human use not yet in clinical trials
- Blood coagulation products
Negotiation Steps: What to Expect When You Apply

1. Application and initial review
2. USANC balloting
3. Firm reviews the USANC's suggestion
4. International review and clearance (WHO)
5. USANC and firm review of the INN decision
6. Adoption and publication
### When to File

<table>
<thead>
<tr>
<th>Phase</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preclinical</td>
<td>Too early!</td>
</tr>
<tr>
<td>IND</td>
<td>USAN requires an IND number for review</td>
</tr>
<tr>
<td>Phase 1</td>
<td>Firms may request a USAN, if desired</td>
</tr>
<tr>
<td>Phase 2</td>
<td>Best time to apply</td>
</tr>
<tr>
<td></td>
<td>When firm and USANC agree on a name, INN application filed</td>
</tr>
<tr>
<td>Phase 3</td>
<td>A bit late to apply</td>
</tr>
<tr>
<td></td>
<td>USAN wanted for publications, press releases, etc.</td>
</tr>
<tr>
<td></td>
<td>Name adopted and published</td>
</tr>
<tr>
<td>NDA or BLA</td>
<td>Definitely too late!</td>
</tr>
<tr>
<td></td>
<td>USAN needed for packaging, labeling, advertising</td>
</tr>
</tbody>
</table>
5 Reasons Names are Rejected

1. Conflicts with other names
2. Incorrect stem assignment
3. Prefixes that refer to a trade name, company name, anatomy, duration of action or imply a benefit
4. Names with restricted letters (k, j, h)
5. Pronunciation problems
After Adoption

- You may use a USAN when you receive the Statement of Adoption
- SOA published on USAN web site
- Nomenclature information sent to CAS, USP
- Publication on pINN and rINN lists
4 Trade Name Do’s and Don’ts

1. Don’t register the USAN as a trademark
2. Don’t use the stem in the trade name
3. Don’t use the USAN Prefix in the trade name
4. Do make the trade name different from the USAN
Resources

Rules for Coining Names

Stem List

Naming biologics

USAN names and trademarks

Application forms