On May 4th, 2018, the FDA updated FDA Form 1571. Information is provided in this document on the three major changes.

- Commercial IND or Research IND
- Combination Products, and
- Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT)

### Commercial vs. Research

Beginning May 5, 2018, the latest fillable Form FDA 1571, found on the FDA Forms Website, allows the submitter to identify an IND submission as either Commercial or Research.

See field 6B on the 1571.

INDs submitted for the University of Rochester should be reported as Research.

### Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT)

SNOMED CT is the most comprehensive clinical healthcare terminology in the world supported by National Library of Medicine (NLM), Center for Disease Control (CDC) and Prevention and the Office of National Coordinator (ONC) for Health Information Technology.

SNOMED CT is the required FDA terminology standard for coding study data indications of IND submissions.

See field 7A and 7B on the 1571.

- Field 7 changed to 7A
- Field 7B added to capture the SNOMED CT Indication Disease Term
How to Get SNOMED CT Information

1. Navigate to http://browser.ihtsdotools.org/
3. Follow steps 3-8 depicted in the screen shots below.
4. NOTE: If no results are returned from the keyword search used in Step 4, try either broadening or narrowing the specificity of the search terminology. You may also try searching by treatment type vs. disease terminology. Once the appropriate disease term populates, be sure to copy the entire string of text including the upright bars then paste it in the ‘Pre-coordinated Expression’ field in step 8.
Paste the entire text copied including the upright lines from the ‘Pre-coordinated Expression’ field, in field 7B of the Form 1571.

Use the “Continuation Page for #7” button to provide additional indications and respective SNOMED CT Codes.

FAQs about SNOMED CT

- SNOMED CT terminology can have multiple levels of “granularity”. Some indication disease terms may have low granularity, while some may have high granularity.
- Use the term with the highest granularity possible.

New versions of SNOMED CT US Edition are generally available in March and September of each year. Be sure to check for updated information when submitting additional information or supplement submissions for every new 1571 that goes to the FDA.

http://browser.ihtsdotools.org
**Combination Products**

A "combination product" is a product comprised of two or more different types of medical products (e.g., drug and device, drug and biological product, device and biological product, or all three together).

**Categories of Combination Products**

<table>
<thead>
<tr>
<th>Description</th>
<th>“Single-entity”</th>
<th>“Co-packaged”</th>
<th>“Cross-labeled”</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemically or physically combined constituents parts</td>
<td>Constituent parts packaged together</td>
<td>Constituent parts that are packaged separately, but labeled and need to be used specifically with one another to achieve the intended therapeutic effect</td>
<td></td>
</tr>
<tr>
<td>Examples</td>
<td>Prefilled syringe, Transdermal patch, Drug-eluting stent</td>
<td>First-aid or surgical kit, Syringe packaged with a vial of drug, Drug + prefilled diluent, resstitution/transfer device, fillable cartridge and wearable patch</td>
<td>Some light activated drug product packaged separately from the light activation device</td>
</tr>
<tr>
<td>Reference</td>
<td>21 CFR 3.2(e)(1)</td>
<td>21 CFR 3.2(e)(2)</td>
<td>21 CFR 3.2(e)(3) and 21 CFR 3.2(e)(4)</td>
</tr>
<tr>
<td>Type</td>
<td>Description</td>
<td>Common Example(s)</td>
<td></td>
</tr>
<tr>
<td>------</td>
<td>-----------------------------------------------------------------------------</td>
<td>----------------------------------------------------------------------------------</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>Convenience Kit or Co-Package</td>
<td>Drug or biological product vials packaged with device or accessory kits (empty syringes, auto-injectors, transer sets)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Drug and device are provided as individual constituent parts within the same package</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Prefilled Drug Delivery Device/System</td>
<td>Prefilled drug syringe, auto-injectors, metered-dose inhalers, dry power inhalers, nasal-spray, pumps or spray bottles, transdermal patches, prefilled iontophoresis system or microneedle patch</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Drug is filled into or otherwise combined with the device AND the sole purpose of the device is to deliver drug</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Prefilled Biologic Delivery Device/ System</td>
<td>Prefilled vaccine or other biological product syringes, autoinjectors, nasal Sprays, dropper bottles, transdermal or microneedle patches pre-coated with biological product</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Biological product is filled into or otherwise combined with the device AND the sole purpose of the device is to deliver biological product</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Device Coated/ Impregnated/ Otherwise Combined with Drug</td>
<td>Drug pills embedded with sensors, contact lens coated with a drug</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Device has an additional function in addition to delivering the drug</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>Device Coated or Otherwise Combined with Biologic</td>
<td>Live cells seeded on a device scaffold</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Device has an additional function in addition to delivering the drug</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>Drug/Biologic Combination</td>
<td>Antibody-drug conjugates</td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>Separate Products Requiring Cross Labeling</td>
<td>Light-activated drugs or biological products labeled for use with a specific light-activation device</td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>Possible Combination Based on Cross Labeling of Separate Products</td>
<td>Drug/biological product labeling discusses a device, but submitter is unsure whether the product constitutes a cross-labeled combination product</td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>Other Type of Part 3 Combination Product (e.g., Drug/Device/Biological Product)</td>
<td>Combination product not otherwise described above</td>
<td></td>
</tr>
<tr>
<td></td>
<td>(e.g., Drug/Device/Biological Product)</td>
<td>All 3 articles are combined in a single product (e.g., a prefilled syringe containing an antibody-drug conjugate)</td>
<td></td>
</tr>
</tbody>
</table>

Contact [Req.Support@urmc.rochester.edu](mailto:Req.Support@urmc.rochester.edu) if you are unsure if your product is a combination product, or have questions about the category and/or type of combination product.
When to enter the Combination Product Information

If an IND Original and "Initial Investigational New Drug Application" is checked on field 11; and the product is a combination product, check Yes on field 12 on Form 1571.

Resources

Instructions For Filling Out Form FDA 1571
Investigational New Drug Application

FDA 1571 Form

Webinar

Credits

SNOMED CT Source

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Combination Products Source

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