FDA Form 1571 Updates

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.	6A. IND Number *(If previously assigned)* 6B. Select One: Commercial ☐ Research X	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

7A. (Proposed) Indication for Use

Is this indication for a rare disease (prevalence <200,000 in U.S.)? ☐ Yes ☐ No

Does this product have an FDA Orphan Designation for this indication? ☐ Yes ☐ No

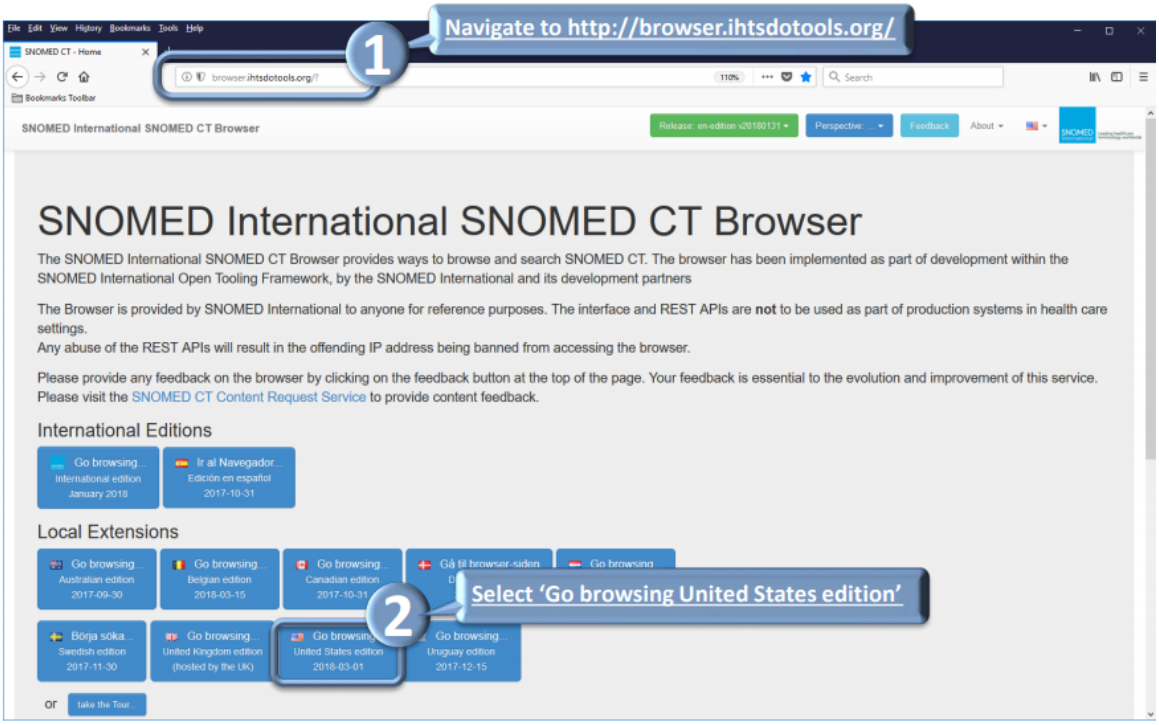
If yes, provide the Orphan Designation number for this indication:

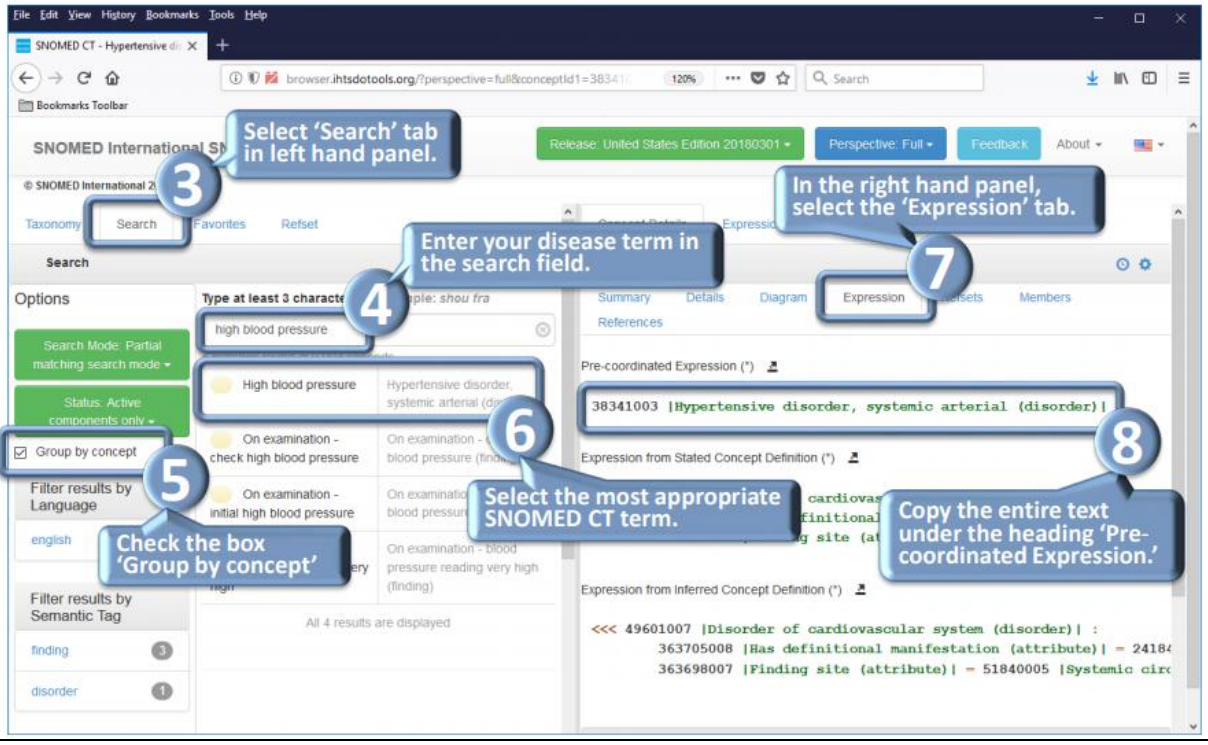
Continuation Page for #7

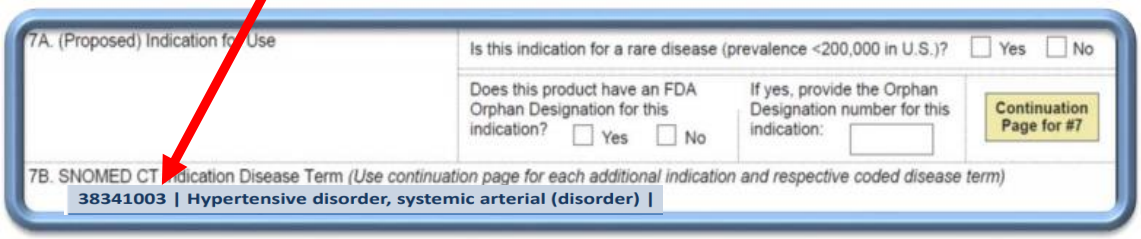
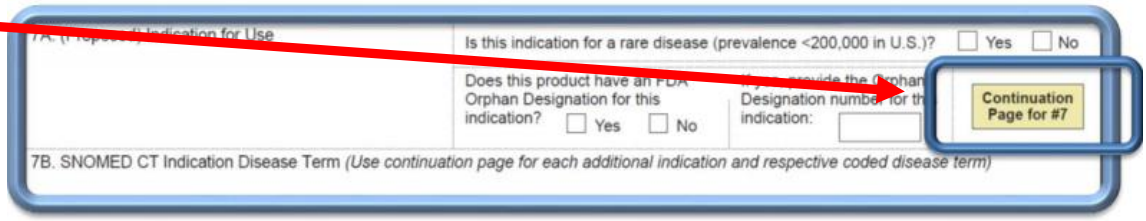
7B. SNOMED CT Indication Disease Term *(Use continuation page for each additional indication and respective coded disease term)*

How to Get SNOMED CT Information

1. Navigate to http://browser.ihtsdotools.org/
2. Select United States Edition under Local Extensions.
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.

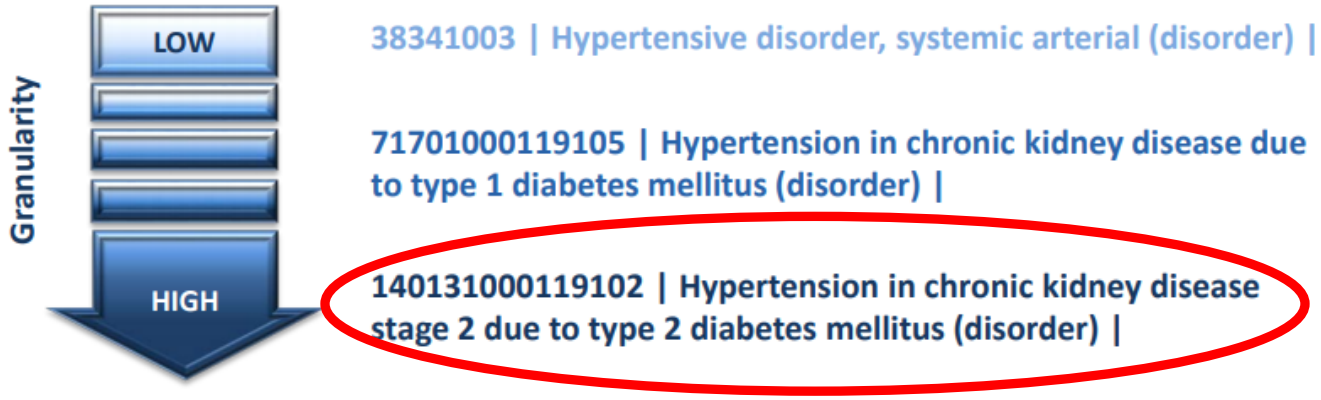




Paste the entire text copied including the upright lines from the 'Pre-coordinated Expression' field, in field 7B of the Form 1571.	**Example:** **38341003 | Hypertensive disorder, systemic arterial (disorder) |** 
Use the "Continuation Page for #7" button to provide additional indications and respective 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.

Syringe, prefilled with medication

Several items in a first-aid kit

Inhaler with active drug

Categories of Combination Products

	“Single-entity”	“Co-packaged”	“Cross-labeled”
Description	Chemically or physically combined constituents parts	Constituent parts packaged together	Constituent parts that are packaged separately, but labeled and need to be used specifically with one another to achieve the intended theraptutic effect
Examples	• Prefilled syringe • Transdermal patch • Drug-eluting stent	• First-aid or surgical kit • Syringe packaged with a vial of drug • Drug + prefilled diluent, resonstitution/ transfer device, fillable cartridge and wearable patch	• Some light activated drug product packaged separately from the light activation device
Reference	21 CFR 3.2(e)(1)	21 CFR 3.2(e)(2)	21 CFR 3.2(e)(3) and 21 CFR 3.2(e)(4)

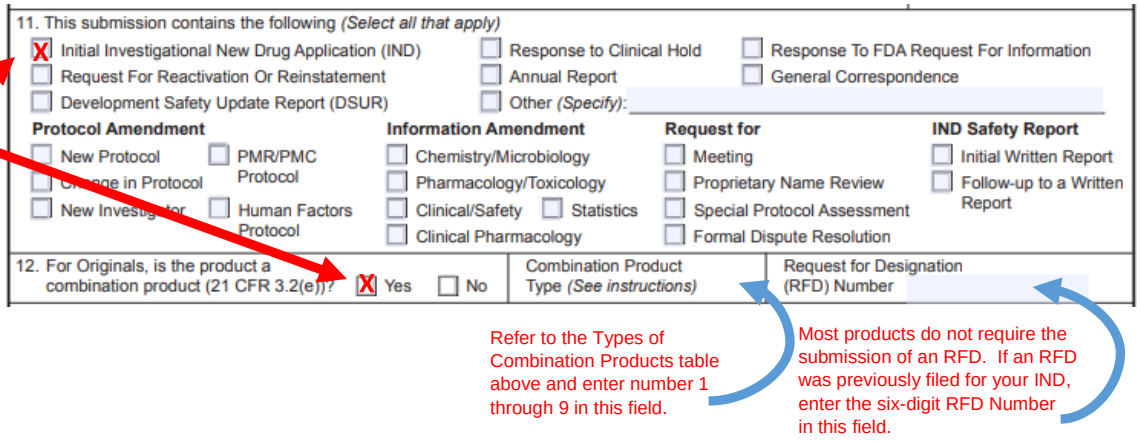
Types of Combination Products

Type	Description	Common Example(s)
1	Convenience Kit or Co-Package Drug and device are provided as individual constituent parts within the same package	Drug or biological product vials packaged with device or accessory kits (empty syringes, auto-injectors, transer sets)
2	Prefilled Drug Delivery Device/System Drug is filled into or otherwise combined with the device AND the sole purpose of the device is to deliver drug	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
3	Prefilled Biologic Delivery Device/ System Biological product is filled into or otherwise combined with the device AND the sole purpose of the device is to deliver biological product	Prefilled vaccine or other biological product syringes, autoinjectors, nasal Sprays, dropper bottles, transdermal or microneedle patches pre-coated with biological product
4	Device Coated/ Impregnated/ Otherwise Combined with Drug Device has an additional function in addition to delivering the drug	Drug pills embedded with sensors, contact lens coated with a drug
5	Devoce Coated or Otherwise Combined with Biologic Device has an additional function in addition to delivering the drug	Live cells seeded on a device scaffold
6	Drug/Biologic Combination	Antibody-drug conjugates
7	Separate Products Requiring Cross Labeling	Light-activated drugs or biological products labeled for use with a specific light-activiation device
8	Possible Combination Based on Cross Labeling of Separate Products	Drug/biological product labeling discusses a device, but submitter is unsure whether the product constitutes a cross-labeled combination product
9	Other Type of Part 3 Combination Product (e.g., Drug/Device/Biological Product)	Combination product not otherwise described above All 3 articles are combined in a single product (e.g., a prefilled syringe containing an antibody-drug conjugate)

Contact Reg_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	Combination Products Source
Leposava Antonovic, PhD Science Policy Analyst Office of New Drugs (OND) – Immediate Office (IO) Center for Drug Evaluation and Research U.S. Food and Drug Administration	**Melissa Burns** Senior Program Manager CAPT, US Public Health Service Office of Combination Products Office of Special Medical Programs U.S. Food and Drug Administration

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