Brief Discussion of Listing for Combination Products

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In Brief...

- **Goal**, to help registrants submit accurate, compliant product listings

- **Accurate listings facilitate efficient engagement with FDA**

- **Combination products are a separate legal category of medical products (not a drug or biological product)**

- **The 21st Century Cures Act created a duty to identify combination products when seeking FDA action**

- **Combination product identification is accomplished at the package level within a drug listing**
What are combination products?

Two or more types of medical products combined (drug-device, biologic-device, drug-biologic, drug-device-biologic)

Categories

- **Single-entity**—articles chemically/physically combined (e.g., prefilled injector, filled IV bag, transdermal system)
- **Co-packaged**—products in same package (e.g., first-aid kit, surgical kit, toothbrush boxed with toothpaste)
- **Cross-labeled**—certain separately distributed products for combined use, expressly related through labeling

Combination products are a distinct legal category from drugs, devices, and biological products
Is my product a combination product?


Other indicators:
- Components of the product assist delivery/application
- An implant that holds the drug
- Electronics or software
- Moving parts or specialized connectors
- Anything included in the package that could be sold separately as a device
- Information in the labeling or product description that specifically refers to a device type or name
- Both a drug and a biologic in the product (e.g., antibody-drug conjugators)
Is my product a combination product (cont’d)?

Should be clear for recently approved NDAs and ANDAs as sponsors must identify combination products on the 356h form

If unclear, e.g., for older approved products, or products not subject to premarket approval, contact Office of Combination Products at Combination@FDA.GOV
How to designate in CDER Direct?

Within the Packaging data entry screen, select the appropriate type on the drop-down listing for “combination product”.

The list of all SPL acceptable Combination Product Type codes can be found on the SPL Web page at [https://www.fda.gov/industry/structured-product-labeling-resources/combination-product-types](https://www.fda.gov/industry/structured-product-labeling-resources/combination-product-types)

### Combination Product Types

Source: National Cancer Institute Thesaurus

NCI Thesaurus OID: 2.16.840.1.113883.3.26.1.1

<table>
<thead>
<tr>
<th>SPL Acceptable Term</th>
<th>Code</th>
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<tbody>
<tr>
<td>Type 6: Not a Combination Product</td>
<td>C112160</td>
</tr>
<tr>
<td>Type 1: Convenience Kit of Co-Package</td>
<td>C102834</td>
</tr>
<tr>
<td>Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)</td>
<td>C102835</td>
</tr>
<tr>
<td>Type 3: Prefilled Biologic Delivery Device/System (syringe, patch, etc.)</td>
<td>C102836</td>
</tr>
<tr>
<td>Type 4: Device Coated/Impregnated/Otherwise Combined with Drug</td>
<td>C102837</td>
</tr>
<tr>
<td>Type 5: Device Coated or Otherwise Combined with Biologic</td>
<td>C102838</td>
</tr>
<tr>
<td>Type 6: Drug/Biologic Combination</td>
<td>C102839</td>
</tr>
<tr>
<td>Type 7: Separate Products Requiring Cross Labelling</td>
<td>C102840</td>
</tr>
<tr>
<td>Type 8: Possible Combination Based on Cross Labeling of Separate Products (Temporary Type)</td>
<td>C102841</td>
</tr>
<tr>
<td>Type 9: Other Type of Part 3 Combination Product (e.g., Drug/Device/Biological Product)</td>
<td>C102842</td>
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</tbody>
</table>
How to designate in CDER Direct?

For a “single-entity” drug-device or biologic-device combination product, select the device type from the packaging type drop-down menu (e.g., “syringe, glass”, “syringe, plastic”, or “inhaler”).

See https://www.fda.gov/industry/structured-product-labeling-resources/package-type

For a “co-packaged” drug-device or biologic-device combination product, select “kit” for the dosage form, and then identify each device included in the kit as a component/part.

For “cross-labeled” drug-device combination products, complete drug listing as appropriate for this constituent part and packaging. (Product and package information for the device should be included in a separate listing for the device facility.)
Some helpful links for you...

Office of Combination Products main page:
Combination Products | FDA

Contact the Office of Combination Products:
Combination@fda.gov

Definitions of the combination product codes:
Combination Product Definition Combination Product Types | FDA

SPL page for combination product codes:
Combination Product Types | FDA

Thank you