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?

Examples and definitions posted at: https://www.fda.gov/combination-products/about-combination-products/combination-product-definition-combination-product-types

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)?

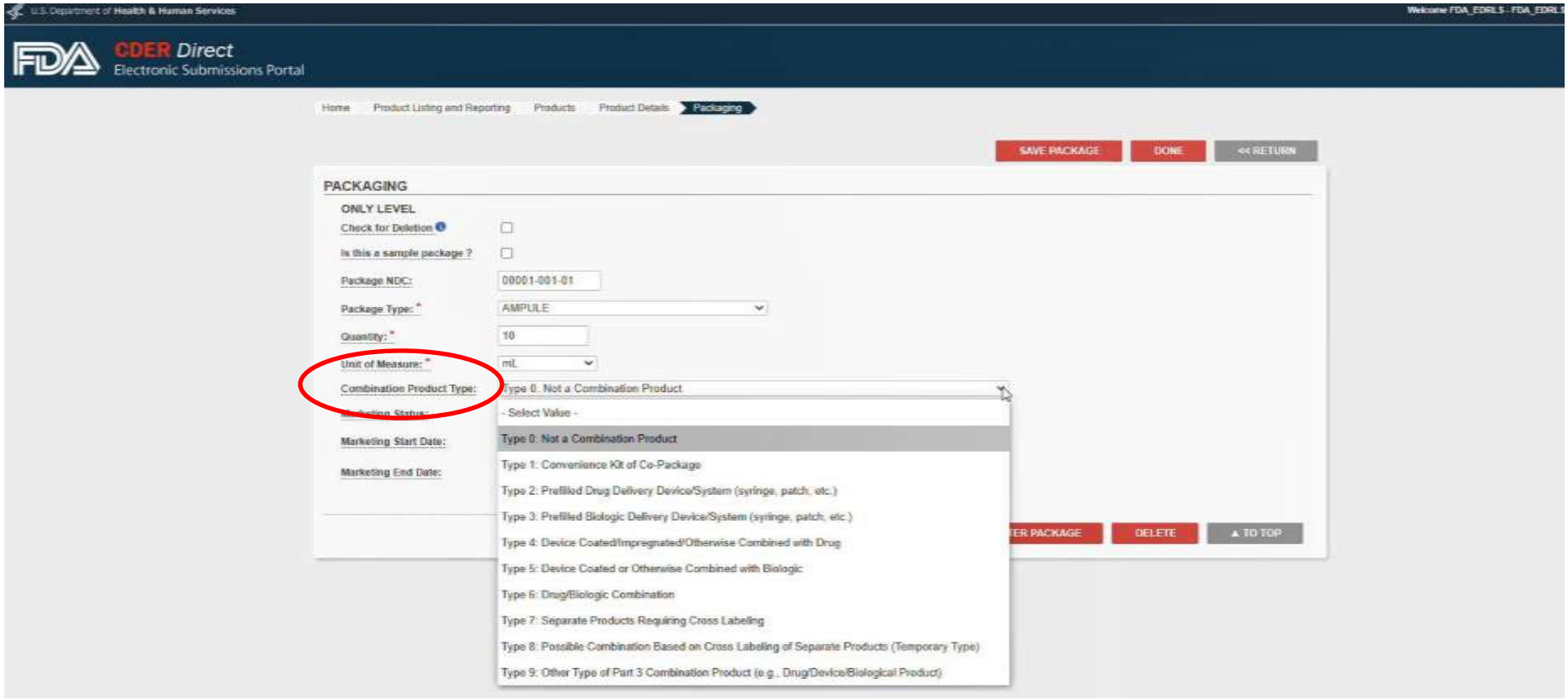
Should be clear for recently approved NDAs and ANDAs as sponsors must identify combination products on the 356h form

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”.

For explanation of the combination product types, see: https://www.fda.gov/combination-products/about-combination-products/combination-product-definition-combination-product-types.



How to designate in CDER Direct?

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

Combination Product Types

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Source: National Cancer Institute Thesaurus

NCI Thesaurus OID: 2.16.840.1.113883.3.26.1.1

SPL Acceptable Term	Code
Type 0: Not a Combination Product	C112160
Type 1: Convenience Kit of Co-Package	C102834
Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)	C102835
Type 3: Prefilled Biologic Delivery Device/System (syringe, patch, etc.)	C102836
Type 4: Device Coated/Impregnated/Otherwise Combined with Drug	C102837
Type 5: Device Coated or Otherwise Combined with Biologic	C102838
Type 6: Drug/Biologic Combination	C102839
Type 7: Separate Products Requiring Cross Labeling	C102840
Type 8: Possible Combination Based on Cross Labeling of Separate Products (Temporary Type)	C102841
Type 9: Other Type of Part 3 Combination Product (e.g., Drug/Device/Biological Product)	C102842

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