



Listing a Combination Product

September 28, 2023

***Troy Cu
Drug Registration and Listing Branch
Office of Compliance***

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

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 or 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 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 conjugates)

Is 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

Kits and Combination Products

- For the purpose of registration and listing, co-packaged products are considered kits.
- Kits can be combination products:
 - Co-packaged products consisting of at least one drug or biologic and one medical device, or of at least one drug and biologic, in the same package.
- Not all kits are combination products:
 - Co-packaged products consisting only of multiple drugs, or at least one drug part co-packaged with a cosmetic or medical food.
- Not all combination products are kits:
 - Single-entity and cross-labeled combination products are not.

Combination Products and Drug Listing



- When listing a combination product, identify the product as a combination product in the listing and provide information on all constituent parts including device constituent part(s)
- Single-entity and co-packaged (see explanations above) must be listed with the lead center (CDER, CBER, or CDRH)
- Cross-labeled (see explanation above)—must be listed with the lead center if the constituent parts are approved under a single application. If constituent parts are separately authorized, they must be listed with the authorizing center.
- Lead center is the center that authorizes the marketing of the product.

Identifying Combination Products in Drug Listing

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)	C10284



LOGIN

Username:

Password:

Under [18 U.S.C. 1001](#), anyone who makes a materially false, fictitious, or fraudulent statement to the U.S. Government is subject to criminal penalties.

I Understand.

LOGIN

[Forgot your password?](#)

QUICK LINKS

[Register With CDER Direct](#)

[Resources](#)

[Tutorials](#)

[Help Desk](#)

[FAQs](#)

GETTING STARTED

To make submissions to FDA (e.g., Establishment Registration, Product Listing and Self-ID, etc.) you must first create an account. [Click here](#) to create a new account.

If you already have an account, enter your **Username** and **Password**.

WARNING: This warning banner provides privacy and security notices consistent with applicable federal laws, directives, and other federal guidance for accessing this Government system, which includes all devices/storage media attached to this system. This system is provided for Government authorized use only. Unauthorized or improper use of this system is prohibited and may result in disciplinary action and/or civil and criminal penalties. At any time, and for any lawful Government purpose, the Government may monitor, record, and audit your system usage and/or intercept, search and seize any communication or data transiting or stored on this system. Therefore, you have no reasonable expectation of privacy. Any communication or data transiting or stored on this system may be disclosed or used for any lawful Government purpose.

Is your computer secure? Before using FDA's Direct system, FDA strongly encourages you to have current antivirus and antispyware software installed on your computer to help ensure the privacy of the information being entered.

Browser Compatibility: The CDER Direct portal currently works best with the following browsers:

- Microsoft Edge
- Firefox version 28 and above
- Google Chrome
- Safari 10.0.1 and above

NOTIFICATIONS

Quick Live Demo

Challenge Question

When Identifying Combination Products in Drug Listing. What is “Type 0” ?

- A. Not a Combination Product
- B. Convenience Kit of Co-Package
- C. Prefilled Drug Delivery Device/System (syringe, patch, etc.)
- D. Prefilled Biologic Delivery Device/System (syringe, patch, etc.)



Questions?
eDRLS@fda.hhs.gov