# *Listing a Combination Product*

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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

# 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

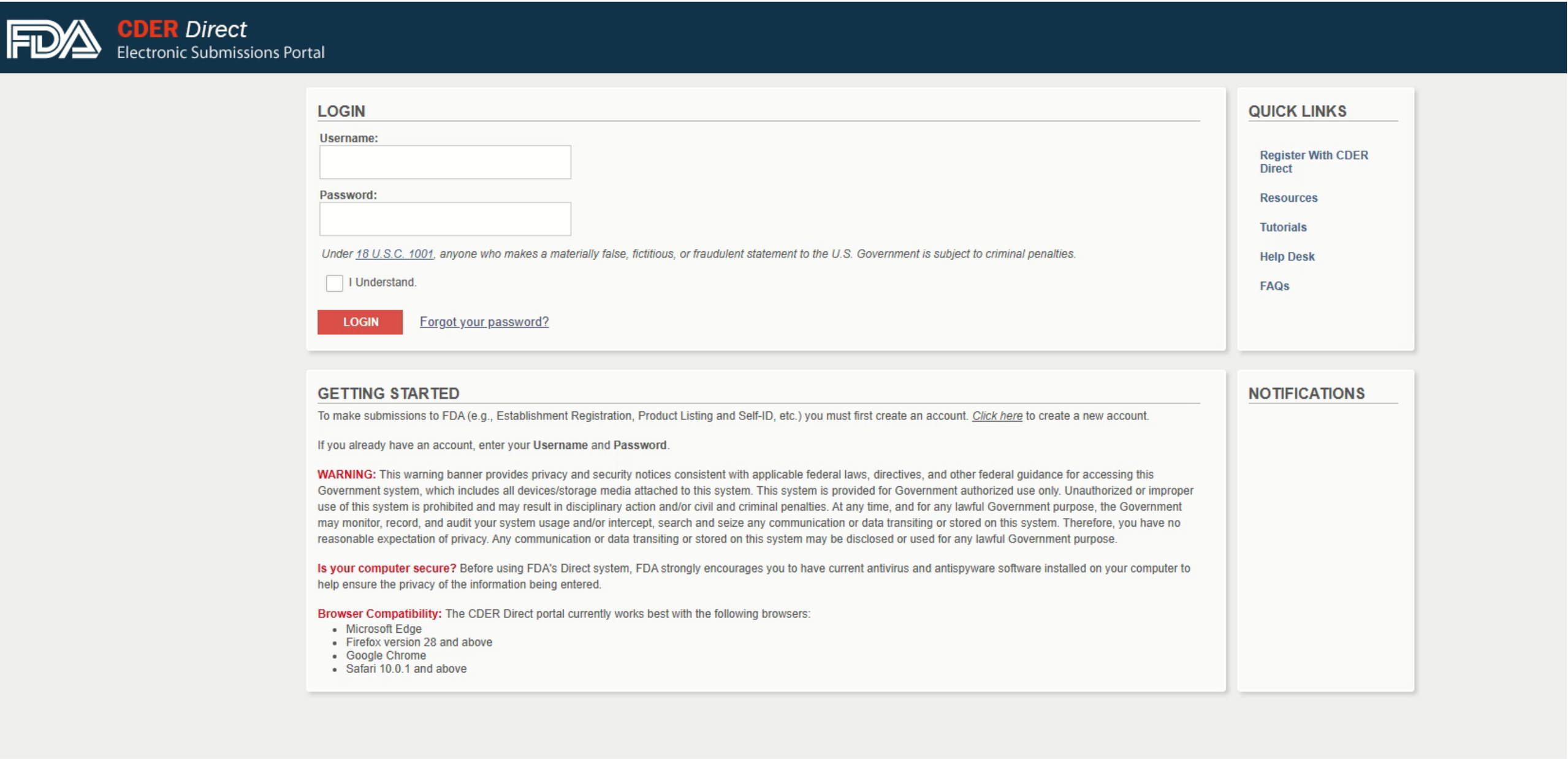
- For the purpose of registration and listing, co-packaged products are considered kits.
- Kits can be combination products:
  - Co-packaged products consisting of at least one drug or biologic and one medical device, or of at least one drug and biologic, in the same package.
- Not all kits are combination 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 |




# 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?

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