

Combination Product Definition Combination Product Types

Combination products are defined in 21 CFR 3.2(e). The term combination product includes:

1. A product comprised of two or more regulated components, i.e., drug/device, biologic/device, drug/biologic, or drug/device/biologic, that are physically, chemically, or otherwise combined or mixed and produced as a single entity;
2. Two or more separate products packaged together in a single package or as a unit and comprised of drug and device products, device and biological products, or biological and drug products;
3. A drug, device, or biological product packaged separately that according to its investigational plan or proposed labeling is intended for use only with an approved individually specified drug, device, or biological product where both are required to achieve the intended use, indication, or effect and where upon approval of the proposed product the labeling of the approved product would need to be changed, e.g., to reflect a change in intended use, dosage form, strength, route of administration, or significant change in dose; or
4. Any investigational drug, device, or biological product packaged separately that according to its proposed labeling is for use only with another individually specified investigational drug, device, or biological product where both are required to achieve the intended use, indication, or effect.

Combination Product Types

The table below has been created to identify and describe the 9 different types for a combination product. A package that contains only devices is not a combination product. Additionally, a product that is a combination of only drugs is not a combination product. If you have a product that does not appear to meet one of the common examples below or for questions related to Forms 1571 and 365h about combination product types contact your [Center's Product Jurisdiction Officer\(s\)](#) (</combination-products/jurisdictional-information/combination-product-contacts>) for assistance. For general questions regarding combination product types contact the [Office of Combination Products](#). (</combination-products/jurisdictional-information/combination-product-contacts>)

Type	Description	Common Example(s)
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1	<p>Convenience Kit or Co-Package</p> <p><i>Drug and device are provided as individual constituent parts within the same package</i></p>	<p>Drug or biological product vials packaged with device(s) or accessory kits (empty syringes, auto-injectors, transfer sets), first aid or surgical kits containing devices and drugs</p>
2	<p>Prefilled Drug Delivery Device/ System</p> <p><i>Drug is filled into or otherwise combined with the device AND the sole purpose of the device is to deliver drug</i></p>	<p>Prefilled drug syringe, auto-injectors, metered-dose inhalers, dry powder inhalers, nasal-spray, pumps, transdermal systems, prefilled iontophoresis system or microneedle “patch”</p>
3	<p>Prefilled Biologic Delivery Device/ System</p> <p><i>Biological product is filled into or otherwise combined with the device AND the sole purpose of the device is to deliver biological product</i></p>	<p>Vaccine or other biological product in a prefilled syringe, autoinjector, nasal spray, transdermal systems or microneedle patch pre-loaded with biological product</p>
4	<p>Device Coated/ Impregnated/ Otherwise Combined with Drug</p> <p><i>Device has an additional function in addition to delivering the drug</i></p>	<p>Drug pills embedded with sensors, contact lens coated with a drug, drug-eluting stents, drug-eluting leads, condoms with spermicide, dental floss with fluoride, antimicrobial coated catheters/sutures, bone cements with antibiotics</p>
5	<p>Device Coated or Otherwise Combined with Biologic</p> <p><i>Device has an additional function in addition to delivering the drug</i></p>	<p>Live cells seeded on or in a device scaffold, extracorporeal column with column-bound protein</p>
6	<p>Drug/Biologic Combination</p>	<p>Antibody-drug conjugates, progenitor cells combined with a drug to promote homing</p>
7	<p>Separate Products Requiring Cross Labeling</p>	<p>Light-activated drugs or biological products not co-packaged but labeled for use with a specific light source device</p>
8	<p>Possible Combination Based on Cross Labeling of Separate Products</p>	<p>Drug/biological product under development utilizes a device, but unclear whether the final product will require that the two be cross-labeled</p>

9	Other Type of Part 3 Combination Product (e.g., Drug/Device/ Biological Product) <i>Combination product not otherwise described</i>	All 3 articles are combined in a single product (e.g., a prefilled syringe containing an antibody-drug conjugate), device to manufacture a biologic also includes a drug or biologic in the kit, or the product contains two different combination product types (e.g., Type 1 and Type 2 are provided together)
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