# Combination Product Types

The table below has been created to identify and describe the 9 different types for a combination product.

<table>
<thead>
<tr>
<th>Type</th>
<th>Description</th>
<th>Common Example(s)</th>
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</thead>
</table>
| 1    | Convenience Kit or Co-Package  
*Drug and device are provided as individual constituent parts within the same package* | 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 |
| 2    | Prefilled Drug Delivery Device/ System  
*Drug is filled into or otherwise combined with the device AND the sole purpose of the device is to deliver drug* | Prefilled drug syringe, auto-injectors, metered-dose inhalers, dry powder inhalers, nasal-spray, pumps, transdermal systems, prefilled iontophoresis system or microneedle “patch” |
| 3    | Prefilled Biologic Delivery Device/ System  
*Biological product is filled into or otherwise combined with the device AND the sole purpose of the device is to deliver biological product* | Vaccine or other biological product in a prefilled syringe, autoinjector, nasal spray, transdermal systems or microneedle patch pre-loaded with biological product |
| 4    | Device Coated/ Impregnated/ Otherwise Combined with Drug  
*Device has an additional function in addition to delivering the drug* | 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 |
| 5    | Device Coated or Otherwise Combined with Biologic  
*Device has an additional function in addition to delivering the drug* | Live cells seeded on or in a device scaffold, extracorporeal column with column-bound protein |
| 6    | Drug/Biologic Combination | Antibody-drug conjugates, progenitor cells combined with a drug to promote homing |
| 7    | Separate Products Requiring Cross Labeling | Light-activated drugs or biological products not co-packaged but labeled for use with a specific light source device |
| 8    | Possible Combination Based on Cross Labeling of Separate Products | Drug/biological product under development utilizes a device, but unclear whether the final product will require that the two be cross-labeled |
| 9    | Other Type of Part 3 Combination Product (e.g., Drug/Device/ Biological Product)  
*Combination product not otherwise described* | 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 |