Unique Device Identifier (UDI) Requirements for Combination Products

Guidance for Industry and FDA Staff

DRAFT GUIDANCE

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Unique Device Identifier (UDI) Requirements for Combination Products Guidance for Industry and FDA Staff

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page of this guidance.

I. INTRODUCTION

This document is intended to assist industry and FDA staff in understanding how FDA's unique device identifier (UDI) requirements at 21 CFR part 801 subpart B and part 830 subpart E apply to combination products with device constituent parts. This guidance outlines the requirements, recommendations, and best practices for UDI labeling and for submission of information to the Global Unique Device Identification Database (GUDID) for such combination products. This guidance also provides some hypothetical examples to illustrate how UDI requirements can be met for these combination products.

Throughout this guidance document, the terms *we* and *our* refer to FDA staff. *You* and *your* refer to the labeler of the combination product.[1]

In general, FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

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[1] As defined in 21 CFR 801.3, *labeler* means:

(1) Any person who causes a label to be applied to a device with the intent that the device will be commercially distributed without any intended subsequent replacement or modification of the label; and
(2) Any person who causes a label to be replaced or modified with the intent that the device will be commercially distributed without any subsequent replacement or modification of the label, except that the addition of the name of, and contact information for, a person who distributes the device without making any other changes to the label, is not a modification for purposes of determining whether a person is a labeler.

As explained in this guidance in regard to UDI requirements, the device at issue may be a constituent part of a combination product. See 21 CFR part 801 subpart B and part 830 subpart E.

II. BACKGROUND

A. Unique Device Identification System

FDA established the unique device identification system on September 24, 2013 (78 FR 58786) (UDI rule). The UDI rule requires that the label and device package of every medical device bear a UDI, unless an exception or alternative applies[2] (see 21 CFR 801.20). UDI is defined as "an identifier that adequately identifies a device through its distribution and use by meeting the requirements of [21 CFR 830.20]" (21 CFR 801.3). The UDI is composed of two parts (see 21 CFR 801.3):

- Device Identifier (DI) – a mandatory, fixed portion of a UDI that identifies the specific version or model of a device and the labeler of that device, and

- Production Identifier (PI) – a conditional, variable portion of a UDI that identifies one or more of the following when included on the label of the device: (1) the lot or batch within which a device was manufactured; (2) the serial number of a specific device; (3) the expiration date of a specific device; (4) the date a specific device was manufactured; (5) for a human cell, tissue, or cellular or tissue-based product (HCT/P) regulated as a device, the distinct identification code required by 21 CFR 1271.290(c).

The UDI rule also requires specified information to be submitted to FDA's GUDID (see 21 CFR part 830 subpart E).

The UDI rule is intended to create a standardized identification system for medical devices used in the United States. As stated in the preamble of the UDI rule, the goals of implementing a standardized identification system are to rapidly and definitively identify a device and some key attributes that affect its safe and effective use (78 FR 58786). Under the UDI rule, each labeler must use one or more systems operated by FDA or an FDA-accredited issuing agency to assign UDIs that appear on, as applicable, device labels, device packages, and devices themselves as direct markings (21 CFR 801.20, 801.45, and 830.20), and must comply with applicable GUDID submission requirements (21 CFR part 830 subpart E).

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[2] In addition to specific exceptions set forth in 21 CFR part 801, 21 CFR 801.55(a) provides labelers the opportunity to request an exception from or alternative to UDI labeling requirements. If requesting an exception, the labeler must, among other things, describe why UDI labeling requirements are not technologically feasible (21 CFR 801.55(a)(3)). If requesting an alternative, the labeler must, among other things, describe the alternative proposed and explain why it would provide for more accurate, precise, or rapid device identification than the UDI labeling requirements or how the alternative would better ensure the safety or effectiveness of the device (21 CFR 801.55(a)(4)). Under 21 CFR 801.55(c), FDA may grant an exception or alternative as set forth in that regulation, either in response to a labeler request or on the Agency's own initiative. Labelers must submit requests for an exception or alternative in writing to the appropriate Center as noted in 21 CFR 801.55(b). FDA also may initiate or grant an exception or alternative if the Agency determines that doing so is in the best interest of public health, as set forth in 21 CFR 801.55(d).

B. Combination Products

Combination products, as described in 21 CFR part 3, are comprised of two or more different types of products (i.e., a combination of a drug, device, and/or biological product with one another).[3] Each drug, device, and biological product included in a combination product is referred to as a *constituent part*[4] of the combination product. The term combination product includes:

- A product comprised of two or more regulated components, i.e., drug/device, biological product/device, drug/biological product, or drug/device/biological product, that are physically, chemically, or otherwise combined or mixed and produced as a single entity (see 21 CFR 3.2(e)(1)). Such products are often described as *single-entity* combination products (e.g., prefilled syringe, transdermal patch, or drug-eluting stent).

- 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 (see 21 CFR 3.2(e)(2)). Such products are often described as *co-packaged* combination products (e.g., surgical and first-aid kits containing drugs and devices).

- 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 (see 21 CFR 3.2(e)(3)). Such products are often described as *cross-labeled* combination products.

- 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 (see 21 CFR 3.2(e)(4)). Such products are often described as *cross-labeled* combination products.

[3] Applicants may seek FDA feedback regarding the classification of a product (e.g., whether it is a combination product as defined in 21 CFR part 3) or its Center assignment. See the guidance for industry *How to Write a Request for Designation (RFD)* (April 2011) or, if you wish to obtain informal feedback, you may submit a *Pre-RFD*; see the guidance for industry *How to Prepare a Pre-Request for Designation (Pre-RFD)* (February 2018). We update guidances periodically. For the most recent version of a guidance, check the FDA guidance web page at https://www.fda.gov/regulatory-information/search-fda-guidance-documents.

[4] See 21 CFR 4.2.

III. UDI REQUIREMENTS FOR COMBINATION PRODUCTS

This section explains when UDI requirements do and do not apply to combination products, how the requirements can be met, and certain FDA recommendations regarding UDI labeling for combination products.

A. Is my combination product subject to UDI requirements, and if so, what requirements apply?

Combination products with one or more device constituent parts are generally subject to UDI requirements.

Such combination products, however, are considered not subject to UDI requirements if all of their device constituent parts are considered otherwise excepted from UDI requirements.[5, 6] For example[7]:

- 21 CFR 801.30(a)(2) excepts from UDI requirements class I devices that FDA has by regulation exempted from the good manufacturing practice (GMP) requirements of 21 CFR part 820, exclusive of any continuing requirement for recordkeeping under §§ 820.180 and 820.198. If all device constituent parts of a combination product would otherwise be considered class I devices that FDA has by regulation exempted from the GMP requirements of 21 CFR part 820 if they were stand-alone devices intended for the same use in the combination product (hereafter *otherwise GMP exempt*), then the combination product is considered not subject to UDI requirements.[8]

- 21 CFR 801.30(a)(6) excepts investigational devices within the meaning of 21 CFR part 812 from UDI requirements. If the device constituent part of a combination product is an investigational device, then the investigational combination product is considered not subject to UDI requirements.

Other exceptions and regulations may be relevant to the applicability of UDI requirements for certain combination products. For example:

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[5] Such exceptions are specific to certain device types and changes to the intended use of a device constituent part may mean the device constituent part does not fall within an exception and thus the combination product may be subject to UDI requirements.

[6] In such instances, when no device constituent part is required to bear a UDI, subjecting the combination product to UDI requirements would not align with FDA's intent "to make the overall UDI system more efficient and to ensure the burdens imposed by the UDI system are reasonably balanced with its benefits." 77 Fed. Reg. 40736, 40749 (July 2012). Any questions on the applicability of the UDI exceptions to combination products should be directed to combination@fda.gov.

[7] See also illustrative examples in section IV.

[8] For additional discussion of the application of GMP requirements to combination products, see the guidance for industry and FDA staff *Current Good Manufacturing Practice Requirements for Combination Products* (January 2017). See 21 CFR part 4 subpart A for GMP requirements for combination products.

- 21 CFR 801.30(d) excepts class I devices from including production identifiers in the UDI. If all device constituent parts of a combination product would otherwise be considered class I devices if they were stand-alone devices intended for the same use in the combination product (hereafter *otherwise class I devices*), then the combination product is considered not subject to production identifier requirements. See section II.A regarding production and device identifiers.

- 21 CFR 801.40(d) provides that, for a class I device that bears a universal product code (UPC) on its label, the UPC may serve as the UDI. For a combination product that contains only device constituent part(s) that would be otherwise class I devices, the combination product would be deemed to have met UDI labeling requirements if it has a UPC.[9] Moreover, the device constituent part(s) in such a combination product would be deemed to have met the UDI labeling requirements if: (1) each device constituent part in that combination product bears a UPC on its label or (2) the overall combination product bears a UPC on its label (see 21 CFR 801.30(a)(11)).

Generally, the requirements that apply to the combination product labeler depend on the type of combination product[10] (see section II.B regarding types of combination products).

(Continued on the next page)

[9] This aligns with FDA's intent "to make the overall UDI system more efficient and to ensure the burdens imposed by the UDI system are reasonably balanced with its benefits." 77 Fed. Reg. at 40749.

[10] The bullets below assume the combination product contains at least one device constituent part that does not fall into an exception at 21 CFR 801.30(a), and assumes the use of UDI instead of UPC.

- **Single-Entity Combination Products** – A single-entity combination product is required to bear a UDI *unless* it properly bears a National Drug Code (NDC) (see 21 CFR 801.30(b)(1)).[11, 12]

- **Co-Packaged Combination Products** – A co-packaged combination product would be in compliance with UDI labeling requirements if: (1) the combination product bears a UDI or (2) the combination product properly bears an NDC (see 21 CFR 801.30(b)(1)) and the label of each device constituent part(s) bears a UDI (801.30(b)(3)).[13, 14]

  - For drug- or biologic-led combination products that properly bear an NDC and do not bear a UDI, the device constituent parts are required to bear a UDI.

  - For device-led co-packaged combination products that bear a UDI, the device constituent parts are not required to bear UDIs (see 801.30(a)(11)). For example, if device constituent parts are packaged together as a sub-package within a co-packaged combination product, that is a "device convenience kit",[15] then the individual device constituent parts need not bear a UDI if the device convenience kit bears a UDI (21 CFR 801.30(a)(11)).

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[11] For purposes of the UDI requirements, a product "properly bears an NDC" if, the product is subject to and complies with the barcode label requirements under 21 CFR 201.25, and/or subject to and in compliance with the requirement added by the Drug Supply Chain Security Act (DSCSA) to affix or imprint a product identifier (as defined by section 581(14) of the FD&C Act) on each package and homogenous case of the product under section 582(b)(2) or 582(e)(2) of the FD&C Act. The NDC is included as a component of the standardized numerical identifier (SNI), which, along with the lot number and expiration date, make up the product identifier that is required for many drug products under section 582(b)(2) and (e)(2) of the FD&C Act. Sections 582(b)(2)(B) and (e)(2)(B) clarify that a package that is required to have an SNI is not required to have a UDI. The product identifier is different from the production identifier portion of the UDI. All drug-led combination products are subject to the drug listing requirements described in 21 CFR part 207 and are required to be assigned an NDC. However, not all drug-led combination products that are assigned an NDC will necessarily "properly bear an NDC" because not all drug-led combination products are subject to or in compliance with the barcode label requirements or the requirement to affix or imprint a product identifier on each package and homogenous case of the product.

[12] Device-led single-entity and co-packaged combination products should not bear an NDC as device-led combination products are not subject to part 207 and may be deemed misbranded if the combination product bears an NDC (see 21 CFR 207.37(a)(3)), nor should they bear a product identifier for the same reason because the NDC is part of the product identifier. Additionally, they should not bear a product identifier as device-led combination products are exempt from the DSCSA definition of "transaction" (see section 581(24)(B)(xii)) and therefore do not require a product identifier, which are required under section 582(b)(2) or 582(e)(2) on certain drug products that are intended for introduction in a "transaction" in commerce. However, an NDC may be included on the label of a drug or biological product constituent part of a device-led co-packaged combination product.

[13] See footnote 11.

[14] See footnote 12.

[15] A convenience kit is "two or more different medical devices packaged together for the convenience of the user" (21 CFR 801.3). As previously noted in guidance, FDA interprets this to mean a device that contains two or more different medical devices packaged together and intended to remain packaged together and not to be replaced, substituted, repackaged, sterilized, or otherwise processed or modified before being used by an end user. See the guidance for industry and FDA staff *Unique Device Identification: Convenience Kits* (April 2019), section II.B.

- **Cross-Labeled Combination Products** – Because the constituent parts of cross-labeled combination products are separately distributed, there is no single combination product label. The device constituent parts of a cross-labeled combination product are required to bear a UDI, unless excepted (see 21 CFR 801.20).

B. Does FDA have recommendations for whether to use a UDI or an NDC for combination products and any other recommendations regarding UDI for the device constituent parts of combination products?

Combination products can be subject to multiple requirements related to product identification. Moreover, the UDI rule does not prohibit including multiple identifiers (such as the NDC and UDI) on the label or package of a combination product; however, to reduce the risk of error and otherwise facilitate ordering, reimbursement, inventory stocking, or other supply chain activities, among other things, we recommend the following:

- **Single-Entity Combination Products** – A single-entity device-led combination product should bear only a UDI and a single entity drug/biologic-led combination product should not bear a UDI if it properly bears an NDC.[16]

- **Co-Packaged Combination Products** –

  - When the co-packaged combination product is device led, and the combination product bears a UDI, each device constituent part within the immediate container of the co-packaged combination product is not required to bear a UDI (as described in section III.A); however, those device constituent parts may bear a UDI.

  - When the co-packaged combination product is drug or biologic led, and the combination product properly bears an NDC, we recommend that the label of each device constituent part within the immediate container of the co-packaged combination product bear a UDI, and that the combination product not bear a UDI.

  We understand that for some co-packaged combination products that properly bear an NDC, labelers may be able to identify each device constituent part based on information captured in the product identifier[17] and the combination product's quality system (e.g., the device version or model number and device lot/batch for each device). FDA is considering what approach or approaches to take in such circumstances, such as granting, on our own initiative, exceptions/alternatives under 21 CFR 801.55 (as permitted and appropriate) for the UDI requirements for types of device constituent parts in such combination products, or having an enforcement discretion policy regarding UDI requirements for such device constituent parts. At this point, we are not considering

[16] See footnote 11.

[17] As described in footnote 11, the product identifier is different from the production identifier portion of the UDI; see footnote 11 for information on product identifier.

including circumstances where the device constituent parts are subject to direct marking requirements under 21 CFR 801.45 in our approach(es).[18] If labelers have specific questions or proposals for a product, contact the lead Center for the product or the Office of Combination Products (OCP), as needed.

If multiple identifiers are included on the label or package of a combination product, the identifiers should be clearly marked so users can distinguish between them (e.g., a UDI should be clearly identified as the UDI to distinguish it from an NDC or another identifier also on the label/package). To help clearly identify the UDI, FDA recommends that labelers consider using the UDI symbol contained in the FDA recognized voluntary consensus standard *ISO-15223-1:2021 Medical devices — Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements*, see https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfstandards/search.cfm for FDA Recognized Consensus Standards: Medical Devices.

C. I purchase the device constituent parts of my co-packaged combination product from a supplier. How do the UDI requirements apply to me?

Firms that manufacture and introduce into interstate commerce co-packaged combination products may receive device constituent parts from a supplier who is itself a labeler subject to UDI requirements. In these situations, the combination product firm has no additional UDI responsibilities *with respect to the supplied device constituent part* if:

- The device constituent part already properly bears a UDI when received from the supplier (and the device supplier has submitted required information to GUDID),[19] and
- The label for the device constituent part is not replaced or modified when incorporated into the combination product.

This is also true for device constituent parts received from a supplier as a device convenience kit which properly bears a UDI.[20]

Notably, the combination product may still have UDI requirements as discussed in section III.A.

[18] See also guidance for industry and FDA staff *Unique Device Identification: Direct Marking of Devices* (November 2017).

[19] The combination product sponsor should confirm the device constituent part properly bears a UDI and data is submitted to GUDID by checking Access GUDID (available at: https://accessgudid.nlm.nih.gov/) and/or by obtaining documentation from the supplier of the device constituent part that the data were submitted to GUDID, when required.

[20] See the "Co-Packaged Combination Products" bullet in section III.A of this guidance.

D. How do I submit information to the Global Unique Device Identification Database (GUDID) for my combination product?

Labelers of combination products with device constituent parts that are required to bear a UDI on the device constituent part and/or the combination product are generally required to submit data pertaining to the combination product and/or device constituent parts to GUDID[21] (see 21 CFR 830.300(a)), though see discussion in section III.C. Complying with UDI labeling and data submission requirements is a multistep process. As a first step, we recommend you review the information presented on FDA's UDI website.[22] To submit information to GUDID, the labeler first requests a GUDID account via the UDI website.[23] Opening a GUDID account generally requires an FDA premarket authorization number or an active FDA listing number, which can be a new drug application (NDA), biologics license application (BLA), abbreviated new drug application (ANDA), premarket approval application (PMA), premarket notification (510(k)), de novo classification request, product development protocol (PDP), or humanitarian device exemption (HDE) application number.[24, 25] Firms that are not UDI labelers should not submit information to GUDID.

IV. EXAMPLES

The hypothetical examples in this section illustrate UDI considerations for single-entity and co-packaged combination products.[26] This section is not intended to reflect a complete analysis of labeling and obligations for product identification that may apply, such as requirements related to direct marking[27] or specific expectations for submitting information to GUDID. Specific products and circumstances may raise distinct issues that are not considered in the hypothetical

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[21] For additional information on opening a GUDID account and submitting data to GUDID, see the guidance for industry and FDA staff *Global Unique Device Identification Database (GUDID)* (December 2024) and https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/UniqueDeviceIdentification/GlobalUDIDatabaseGUDID/default.htm.

[22] https://www.fda.gov/udi.

[23] See footnote 22.

[24] Combination product sponsors should list their combination products only with the lead Center, identifying the product as a combination product in the listing. Although not the focus of this guidance, sponsors should include UDI device identifier information in the registration and listing (R&L) databases. For additional information on R&L requirements applicable to device-led combination products, see Device Registration and Listing, available at https://www.fda.gov/medical-devices/how-study-and-market-your-device/device-registration-and-listing. For additional information on R&L requirements applicable to drug- or biologic-led combination products, see Electronic Drug Registration and Listing System (eDRLS) available at https://www.fda.gov/drugs/guidance-compliance-regulatory-information/electronic-drug-registration-and-listing-system-edrls. See 21 CFR 3.4 for additional information on Center assignment for combination products, or contact OCP at combination@fda.gov.

[25] If your product is exempt from premarket notification, you may indicate the same in the GUDID. If, for any other reason, there is not an authorization number or active FDA listing number for your product, contact the FDA UDI HELP Desk at gudidsupport@fda.hhs.gov for assistance.

[26] The examples assume the combination product contains at least one device constituent part that does not fall into an exception at 21 CFR 801.30 (unless otherwise noted), and assumes the use of UDI instead of UPC.

[27] See footnote 18.

scenarios presented below. If labelers have specific questions, contact the lead Center for the product or OCP, as needed, for assistance.

A. Single-Entity Combination Product Examples

Example 1. Device-led combination products – these products must bear a UDI and should *not* bear an NDC, and the labeler must submit information to GUDID for the products for which it is a labeler. Examples may include drug eluting stents, drug eluting leads, antimicrobial coated sutures, bone cements containing antibiotics, and condoms with spermicide.

Example 2. Drug- or biologic-led combination products – if the combination product properly bears an NDC,[28] the combination product is not required to and should *not* bear a UDI. Examples may include prefilled drug or biologic delivery devices (e.g., syringes, auto-injectors, metered-dose inhalers, dry powder inhalers, nasal sprays, pumps, and transdermal systems), solid oral dosage form drugs embedded with sensors, and contact lenses coated with drugs.

B. Co-Packaged Combination Product Examples

See section III.B for Agency recommendations regarding use of multiple identifiers including for co-packaged combination products that are drug- or biologic-led combination products.

Example 1. A reusable auto-injector is co-packaged with a supply of drug cartridges. This product properly bears an NDC on the label of the co-packaged, drug-led combination product.

- **Scenario 1.A**. **Device constituent part that does not bear a UDI is supplied to the combination product firm** – the auto-injector device constituent part is packaged with the drug cartridges, and the firm distributes that co-packaged combination product.

  - This firm is a labeler for the device constituent part and combination product. The firm must submit information to GUDID for the products for which it is the labeler.

    Because the combination product properly bears an NDC, a UDI is not required on it.

    For the device constituent part, the firm must place a UDI either on the label of the auto-injector within the co-package or the label for the combination product – we recommend the UDI be on the device constituent parts (see section III.B).

- **Scenario 1.B**. **Device constituent part that bears a UDI is supplied to the combination product firm** – the auto-injector is supplied from a device manufacturer to the firm that packages and distributes the co-packaged combination product. The auto-injector is received with a UDI on the label and the device supplier has submitted related

[28] See footnote 11.

information to GUDID. The combination product firm includes its contact name and address on the label of the co-packaged combination product but does not alter the label on the device constituent part when placing it into the combination product co-package.

- The combination product firm is not a labeler for the device constituent part (see footnote 1) but should confirm the device constituent part properly bears a UDI and data is submitted to GUDID.

  A UDI is not required on the label of the combination product because it properly bears an NDC.

  The device constituent part has a UDI and so a UDI is not needed on the label of the combination product and we recommend a UDI not be on the label of the combination product (see section III.B).

Example 2. A combination product co-package consisting of a vial of lyophilized powder, vial of diluent, and three device constituent parts – a syringe, a vial adapter, and a needle. This product properly bears an NDC on the label of the co-packaged, drug-led combination product.

- **Scenario 2.A**. **Some device constituent parts bear UDIs and are supplied to the combination product firm, others do not bear UDI** – the needle is received by the combination product firm already sterilized and individually labeled with a UDI and the labeler has submitted information to GUDID. The needle label is not modified by the combination product firm. The syringe and vial adapters are received in bulk with no individual UDIs. The combination product firm sterilizes the syringes and vial adapters before including them in the co-package.

  - The combination product firm is a labeler for the syringe and vial adapter device constituent parts. The firm must submit information to GUDID for the products for which it is the labeler. The combination product firm is not the labeler for the needle but should confirm the device constituent part properly bears a UDI and data is submitted to GUDID.

    A UDI is not required on the label of the combination product because it properly bears an NDC.

    For the device constituent parts, the firm must place UDIs either on the label of the syringe and vial adapter or on the label of the combination product – we recommend the UDI be on the device constituent parts (see section III.B).

- **Scenario 2.B**. **Device constituent parts that are a device convenience kit with a UDI and are supplied to the combination product firm** – A supplier packages a syringe, vial adapter, and needle into a device convenience kit, sterilizes the convenience kit, and provides the convenience kit to the combination product firm. The convenience kit is

provided labeled with a UDI and the convenience kit labeler has submitted information to GUDID. The combination product firm makes no changes to this device convenience kit[29] and places the convenience kit into a co-package with the two vials.

- The combination product firm should confirm the device convenience kit properly bears a UDI and data is submitted to GUDID.

  A UDI is not required on the label of the combination product because it properly bears an NDC.

  The combination product firm is not a labeler for the device constituent parts and does not need to generate UDI for the device constituent parts.

Example 3. A drug-led, co-packaged combination product that properly bears an NDC on its label, contains, in addition to its drug constituent part, only device constituent part(s) that would be otherwise GMP exempt or otherwise class I devices.

- **Scenario 3.A**. **Combination product includes, in addition to its drug constituent part, only a device constituent part or parts that would be otherwise GMP exempt** – A liquid oral drug product is co-packaged with an oral dosing cup. The oral dosing cup in the combination product would be otherwise GMP exempt (see 21 CFR 880.6430 and footnote 8).

  - The device constituent part is excepted from UDI requirements and the combination product is therefore considered not subject to UDI requirements.

- **Scenario 3.B**. **Combination product includes a device constituent part that would be otherwise a class I device that is *not* GMP exempt** – Several single-use obstetric-gynecologic general manual instruments (e.g., a vaginal applicator) are co-packaged with a therapeutic drug product. These devices would be otherwise class I devices that are *not* GMP exempt (see 21 CFR 884.4520).

  - The firm must submit information to GUDID for the products for which it is the labeler.

    A UDI is not required on the label of the combination product because it properly bears an NDC.

    The individual device constituent parts or the label of the combination product must bear a UDI; the UDI does *not* need to include the production identifier (21 CFR

[29] For this example, the devices are intended to remain packaged together and not to be replaced, substituted, repackaged, sterilized or otherwise processed or modified before being used by an end user (a *device convenience kit*, see also footnote 15).

801.30(d)). We recommend the UDI be on the device constituent parts and not the combination product label (see section III.B).

Appendix - Summary of the UDI requirements and related recommendations for combination products and their device constituent parts

This table assumes the combination product contains at least one device constituent part that does not fall into an exception at 21 CFR 801.30(a)(1) - (10), see section III.A, and assumes the use of unique device identifier (UDI) instead of universal product code (UPC).

Combination Product Type	Combination Product UDI Requirements	Device Constituent Part UDI Requirements	Related Recommendations
Single-Entity Combination Products	Device-led combination products – Satisfied by having a UDI	N/A because there is no separate label for the device constituent part(s)	Device-led combination products – Should not bear an NDC
	Drug- or biologic-led combination products – UDI not required if combination product properly bears a National Drug Code (NDC)		Drug- or biologic-led combination products – Recommend no UDI on the combination product if the combination product properly bears an NDC
Co-packaged Combination Products[1]	Device-led combination products – Satisfied by having a UDI	Satisfied by: 1) Having a UDI on each device constituent part not excepted from UDI requirements; or 2) Having a UDI on the combination product	Device-led combination products – Should not bear an NDC
	Drug- or biologic-led combination products – UDI not required if combination product properly bears an NDC		Drug- or biologic-led co-packaged combination products (and the device constituent part(s) thereof) – Recommend UDI on each device constituent part (or device convenience kit) and no UDI on the combination product if the combination product properly bears an NDC

Continued

[1] FDA understands that for some of these combination products, labelers may be able to identify each device constituent part based on information captured in the product identifier and the combination product's quality system. See section III.B.

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Combination Product Type	Combination Product UDI Requirements	Device Constituent Part UDI Requirements	Related Recommendations
Cross-Labeled Combination Products	N/A because there is no single combination product label	Satisfied by having a UDI on each device constituent part not excepted from UDI requirements	N/A

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