Product Identifiers Under the Drug Supply Chain Security Act Questions and Answers

Guidance for Industry

DRAFT GUIDANCE

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For questions regarding this draft document, contact CDER Office of Compliance at 301-796-3130 or drugtrackandtrace@fda.hhs.gov, or CDER's Office of Communication, Division of Drug Information, 855-543-3784; or CBER's Office of Communication, Outreach and Development (OCOD), 800-835-4709 or 240-402-8010, or email ocod@fda.hhs.gov.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)

September 2018
Labeling

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Product Identifiers Under the Drug Supply Chain Security Act Questions and Answers Guidance for Industry[1]

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or Agency) on this topic.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.

I. INTRODUCTION

This draft guidance is intended to address anticipated questions regarding product identifiers[2] that are required under section 582 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360eee-1), as amended by the Drug Supply Chain Security Act (DSCSA) (Title II of Public Law 113-54) for packages and homogenous cases of certain drug products.[3,4,5,6] Section 582(b)(2) and (e)(2) require manufacturers and repackagers, respectively, to affix or imprint a product identifier to each package and homogenous case of a product intended to be introduced in a transaction[7] in(to) commerce beginning November 27, 2017, and November 27, 2018, respectively.[8] This guidance is intended to clarify FDA's interpretation of both these requirements as they relate to the linear barcode requirements under 21 CFR 201.25. [9]

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.

[1] This guidance has been prepared by the Center for Drug Evaluation and Research (CDER) in cooperation with the Center for Biologics Evaluation and Research (CBER) at the Food and Drug Administration.

[2] Select definitions are provided under section 581 of the FD&C Act (21 U.S.C. 360eee). *Product identifier* is defined under section 581(14) of the FD&C Act.

[3] For the purposes of this guidance, all references to drug products include both human drugs and biological drug products regulated by CDER and CBER unless otherwise specified.

[4] *Package* is defined under section 581(11) of the FD&C Act.

[5] *Homogeneous case* is defined under section 581(7) of the FD&C Act. The terms "homogeneous" and "homogenous" are used interchangeably throughout the DSCSA. FDA has chosen to use only the term "homogenous" throughout this guidance.

[6] *Product* is defined under section 581(13) of the FD&C Act.

[7] *Transaction* is defined under section 581(24) of the FD&C Act.

[8] For product identifier requirements, see section 582(a)(9), (b)(2), and (e)(2) of the FD&C Act.

[9] The term *barcode* is used in the DSCSA and *bar code* in § 201.25. These terms may be used interchangeably; however, for this guidance, FDA has chosen to use only the term "barcode" except when quoting applicable language from a statute or regulation.

II. DEFINITIONS

Dispenser is defined under section 581(3) of the FD&C Act as:

> (A) a retail pharmacy, hospital pharmacy, a group of chain pharmacies under common ownership and control that do not act as a wholesale distributor, or any other person authorized by law to dispense or administer prescription drugs, and the affiliated warehouses or distribution centers of such entities under common ownership and control that do not act as a wholesale distributor; and
>
> (B) does not include a person who dispenses only product to be used in animals in accordance with section 512(a)(5).

Homogenous case is defined under section 581(7) of the FD&C Act as "a sealed case containing only product that has a single National Drug Code number belonging to a single lot."

Manufacturer is defined under section 581(10) of the FD&C Act as:

> (A) a person that holds an application approved under section 505 or a license issued under section 351 of the Public Health Service Act for such product, or if such product is not the subject of an approved application or license, the person who manufactured the product;
>
> (B) a co-licensed partner of the person described in subparagraph (A) that obtains the product directly from a person described in this subparagraph or subparagraph (A) or (C); or
>
> (C) an affiliate of a person described in subparagraph (A) or (B) that receives the product directly from a person described in this subparagraph or subparagraph (A) or (B).

Package is defined under section 581(11) of the FD&C Act as the "smallest individual saleable unit of product for distribution by a manufacturer or repackager that is intended by the manufacturer for ultimate sale to the dispenser of such product." For purposes of this definition, *Individual saleable unit* is defined under section 581(11)(B) of the FD&C Act as the "smallest container of product introduced into commerce by the manufacturer or repackager that is intended by the manufacturer or repackager for individual sale to a dispenser."

National Drug Code (NDC) is a numeric code under 21 CFR 207.33. Each finished drug product or unfinished drug subject to the listing requirements of part 207 must have a unique NDC to identify its labeler, product, and package size and type.

Product is defined under section 581(13) of the FD&C Act as "a prescription drug in a finished dosage form for administration to a patient without substantial further manufacturing (such as capsules, tablets, and lyophilized products before reconstitution)." See Section VI. below for discussion of what products fall under this definition.

Product identifier is defined under section 581(14) of the FD&C Act as a

> . . . standardized graphic that includes, in both human-readable form and on a machine-readable data carrier that conforms to the standards developed by a widely recognized international standards development organization, the standardized numerical identifier, lot number, and expiration date of the product.

Repackager is defined in section 581(16) of the FD&C Act as "a person who owns or operates an establishment that repacks and relabels a product or package for — (A) further sale; or (B) distribution without a further transaction."

Standardized numerical identifier is defined under section 581(20) of the FD&C Act as

> . . . a set of numbers or characters used to uniquely identify each package or homogenous case that is composed of the National Drug Code (NDC), that corresponds to the specific product (including the particular package configuration) combined with a unique alphanumeric serial number of up to 20 characters.

Transaction is defined under section 581(24) of the FD&C Act as "the transfer of product between persons in which a change of ownership occurs." The definition includes a list of 18 exemptions to the definition of "transaction."

III. BACKGROUND

The DSCSA was signed into law on November 27, 2013. The DSCSA outlines critical steps to build an electronic, interoperable system by November 27, 2023, that will identify and trace certain prescription drugs as they are distributed within the United States. Section 202 of the DSCSA, which added new sections 581 and 582 to the FD&C Act, sets forth new definitions and requirements related to product tracing, product identifier, and verification requirements for manufacturers, repackagers, wholesale distributors, and dispensers to facilitate the tracing of product through the pharmaceutical distribution supply chain. Failure to comply with the requirements of section 582 is prohibited under section 301(t) of the FD&C Act (21 U.S.C. 331(t)) and subject to enforcement action under the FD&C Act.

IV. SCOPE OF GUIDANCE

This guidance is intended to help manufacturers and repackagers understand the requirements to affix or imprint a product identifier on each package and homogenous case of product that they introduce in a transaction into commerce to satisfy the product identifier requirement of section 582 of the FD&C Act. The recommendations in this guidance are intended to assist manufacturers and repackagers in standardizing both the human-readable and machine-readable format of the information that is contained in the product identifier. The requirements set forth in the DSCSA do not change the linear barcode requirements under § 201.25.

V. PRODUCT IDENTIFIERS UNDER THE DSCSA

A product identifier is a standardized graphic that includes the product's standardized numerical identifier (composed of the NDC and a unique alphanumeric serial number), lot number, and expiration date, in both human- and machine-readable formats. The machine-readable format must be on a data carrier that conforms to the standards developed by a widely recognized international standards development organization.[10] The product identifier data is specifically required under section 582(a)(9) of the FD&C Act to be in a "2-dimensional data matrix barcode" for packages and in a "linear or 2-dimensional data matrix barcode" for homogenous cases, which can be verified using "human-readable or machine-readable methods."[11]

Under section 582(b)(2)(A) of the FD&C Act, manufacturers are required to "affix or imprint a product identifier to each package and homogenous case of a product intended to be introduced in a transaction into commerce" beginning no later than November 27, 2017. Under section 582(e)(2) of the FD&C Act, repackagers are required to "affix or imprint a product identifier to each package and homogenous case of a product intended to be introduced in a transaction in commerce" beginning no later than November 27, 2018.

VI. COMPLIANCE POLICY FOR PRODUCT IDENTIFIER REQUIREMENTS

In the FDA guidance *Product Identifier Requirements Under the Drug Supply Chain Security Act – Compliance Policy*, FDA states that it does not intend to take enforcement action against manufacturers who do not, prior to November 27, 2018, affix or imprint a product identifier to each package and homogenous case of product intended to be introduced in a transaction into commerce as required by section 582(b)(2)(A) of the FD&C Act.[12]

[10] Section 581(14) of the FD&C Act.

[11] See section 582(a)(9) of the FD&C Act. As described in section 582(a)(9)(i) and (ii), FDA may decide in the future to allow the use of other technologies for data instead of, or in addition to, the 2-dimensional data matrix barcode or linear barcode.

[12] See the FDA guidance *Product Identifier Requirements Under the Drug Supply Chain Security Act – Compliance Policy*. For the most recent version of a guidance, check the FDA Drugs guidance web page at https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.

VII. PRODUCTS THAT ARE SUBJECT TO THE PRODUCT IDENTIFIER REQUIREMENTS UNDER THE DSCSA

The product identifier requirements of section 582(b)(2)(A) and (e)(2)(A) of the FD&C Act apply to packages and homogenous cases of product intended to be introduced into commerce via a transaction.[13] A "product" under section 581(13) of the FD&C Act is a "prescription drug in finished dosage form for administration to a patient without substantial further manufacturing."

The following prescription drug products are excluded from the definition of a "product" under the DSCSA, and thus are not subject to the product identifier requirements:[14]

- blood or blood components intended for transfusion
- certain radioactive drugs or radioactive biological products[15]
- imaging drugs
- certain intravenous products[16]
- any medical gas[17]
- homeopathic drugs marketed in accordance with applicable guidance under the FD&C Act
- drugs compounded in compliance with sections 503A or 503B of the FD&C Act (21 U.S.C. 353a or 353b)

VIII. LINEAR BARCODE REQUIREMENTS UNDER 21 CFR 201.25

Considering the product identifier requirements under the DSCSA, manufacturers and repackagers have asked FDA whether some of their products are still required under 21 CFR 201.25 to include a linear barcode. The linear barcode requirements were established for different purposes than the DSCSA requirements and apply to additional FDA-regulated products and packaging in some instances and are still in effect. In the February 26, 2004 *Federal Register* (69 FR 9120), FDA published a final rule requiring certain human drug and biological product labels to have a linear barcode that contains, at a minimum, the drug's NDC number (§ 201.25). Manufacturers, repackers (also known as "repackagers"), relabelers, and private label distributors of human prescription drug products, biological products, and over-the-counter (OTC) drug products dispensed pursuant to an order and commonly used in hospitals are subject to the linear barcode requirement. The linear barcode must appear on the drug's label as

[13] There are exemptions to the definition of "transaction." See section 581(24)(B) of the FD&C Act

[14] Section 581(13) of the FD&C Act, defining "product."

[15] Radioactive drugs and radioactive biological products excepted from the definition of the DSCSA are defined in § 600.3(ee) (21 CFR 600.3(ee)) and regulated by the Nuclear Regulatory Commission or by a state, pursuant to an agreement with such Commission under section 274 of the Atomic Energy Act of 1954 (42 U.S.C. 2021).

[16] Certain intravenous products include those described under sections 581(24)(B)(xiv), (xv), and (xvi) of the FD&C Act.

[17] As defined in section 575 of the FD&C Act (21 U.S.C. 360ddd).

defined by section 201(k) of the FD&C Act (21 U.S.C. 321(k)). FDA has interpreted that requirement to mean the linear barcode should be on the outside container or wrapper, as well as on the immediate container unless the barcode is readily visible and machine-readable through the outside container or wrapper.[18]

As stated in the preamble to the final rule:

> Bar codes can help reduce or detect potential medication errors by enabling health care professionals to check whether they are giving the right drug via the right dose and right route of administration to the right patient at the right time.

Linear barcodes, the use of scanning equipment and computerized databases would be part of a system that could help reduce the number of medication errors that occur in hospitals and other health care settings.[19]

Manufacturers, repackers, relabelers, and private label distributors of drug products who are subject to the establishment registration and drug listing requirements in section 510 of the FD&C Act (21 U.S.C. 360) are responsible for placing the appropriate barcode on the product.[20] The following prescription drug products, however, are exempted under § 201.25 from the linear barcode requirements:

- prescription drug samples
- allergenic extracts
- intrauterine contraceptive devices regulated as drugs
- medical gases
- radiopharmaceuticals[21]
- low-density polyethylene form fill and seal containers that are not packaged with an overwrap

In addition, the linear bar code requirement does not apply to prescription drugs that are sold by a manufacturer, repacker, relabeler, or private label distributor directly to patients, unless versions of that same drug are also sold to or used in hospitals.[22]

[18] See 69 FR 9120 at 9140 (Feb. 26, 2004), https://www.gpo.gov/fdsys/pkg/FR-2004-02-26/pdf/04-4249.pdf
[19] Id. at 9120.
[20] See 21 CFR 207.17 to determine what establishments are required to register and list drug products. Private label distributors who do not also manufacture, repack, relabel, or salvage drugs are not required to register under section 207.
[21] For the purposes of these provisions, *radiopharmaceuticals* are considered "radioactive drugs or radioactive biological products."
[22] See 21 CFR 201.25(b)(1)(ii).

IX. QUESTIONS AND ANSWERS

A. Agency Contacts

1. Who should be contacted for questions related to barcode requirements for drug packages and homogenous cases under the DSCSA?

For CDER-regulated products, inquiries should be emailed to: CDERBarcodeQuestions@fda.hhs.gov. For CBER-regulated products, inquiries should be emailed to CBER's Office of Communication, Outreach and Development at: ocod@fda.hhs.gov.

2. Who should be contacted for questions related to linear barcode requirements under 21 CFR 201.25?

Because the linear barcode requirements apply to multiple FDA-regulated products (i.e., human prescription drug products, biological products, and OTC drug products), you should contact the appropriate review division for your product.

For general linear barcode questions, email CDERBarcodeQuestions@fda.hhs.gov for CDER-regulated products, or CBER's Office of Communication, Outreach and Development at ocod@fda.hhs.gov for CBER-regulated products.

B. Product Identifiers

3. How should machine-readable formats include the product identifier required by the DSCSA?

The product identifier must be included in a 2-dimensional (2D) data matrix barcode when affixed to or imprinted on a package and in a linear barcode or 2D data matrix barcode when affixed to or imprinted on a homogenous case.[23]

4. How should the human-readable portion of the product identifier required by the DSCSA be formatted to appear on the drug package label?

To aid healthcare practitioners that may use product information, such as checking the expiration date or recording the NDC and lot number into a patient record, in the human-readable portion of the product identifier, FDA recommends that the human-readable product identifier appear in the following format:[24]

[23] See section 582(a)(9) of the FD&C Act. FDA has not specified an alternative format to the 2D data matrix bar code for packages.

[24] See guidance for industry *Safety Considerations for Container Labels and Carton Labeling Design to Minimize Medication Errors* (April 2013), available at https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM349009.pdf, for recommendations concerning the NDC, lot number, and expiration date.

NDC: [insert product's NDC]
SERIAL: [insert product's serial number]
LOT: [insert product's lot number]
EXP: [insert product's expiration date]

The NDC and serial number are the two components of the Standardized Numerical Identifier (SNI) as defined in section 581(20) of the FD&C Act. The Product Identifier requires the SNI, lot number, and expiration date. The drug package label must include the product identifier information (i.e., the NDC, serial number, lot number, and expiration date) in both the human-readable form and the machine-readable, 2D data matrix barcode format. FDA recognizes that variations may exist in how to abbreviate the human-readable portion of the label for the NDC, serial number, lot number, and expiration date. For example, "No." may be used instead of "number," or may not be listed at all.

FDA recommends that the human-readable expiration date on the drug package label include a year, month, and non-zero day in YYYY-MM-DD format if using only numerical characters or in YYYY-MMM-DD if using alphabetical characters to represent the month. If there are space limitations on the drug package, the human-readable text may include only a year and month, expressed as YYYY-MM if using only numerical characters or YYYY-MMM if using alphabetical characters to represent the month. FDA recommends using a hyphen or a space to separate the portions of the expiration date.

5. Can the GS1 Global Trade Identification Number (GTIN) be used in place of the NDC to comply with the requirements for a human-readable NDC as part of the product identifier?

No. The product identifier on the product label must contain the NDC.[25] The NDC is currently a 10 or 11-digit number, in its FDA-assigned 3-segment format, that identifies the labeler, product, and trade package size.[26]

While industry's practice is to use a GTIN that may incorporate the digits of the NDC, the GTIN typically contains additional digits and is not in the 3-segment format by which the NDC is defined in FDA regulations.[27] Moreover, FDA is concerned that use of the GTIN alone in the human-readable portion of the product identifier could lead to improper identification of the NDC and drug product. If the NDC is on the label in its FDA-assigned 3-segmant format, a company may also voluntarily affix or imprint the associated GTIN on the label.

We note that a manufacturer or repackager may choose to utilize a GTIN to encode the NDC number in the machine-readable portion of the product identifier (2D data matrix barcode).

6. Can a Quick Response (QR) code be used as a product identifier?

[25] *Product identifier* is defined in section 581(14) of the FD&C Act.
[26] See 21 CFR 207.33.
[27] See 21 CFR 207.33(b) for specifications of the NDC and constituent segments.

No. Section 582(a)(9) of the FD&C Act requires that the product identifier be encoded in a 2D data matrix barcode for packages and a 2D data matrix barcode or linear barcode for homogenous cases. While a QR code is a type of 2-dimensional barcode, it is not the same as a 2D data matrix barcode and does not encode the same type of information. The 2D data matrix barcode encodes specific product information and has been adopted as a data carrier for the healthcare sector.[28] As such, a QR code cannot replace the 2D data matrix barcode on packages or the linear or 2D data matrix barcode on homogenous cases as required under the DSCSA.

7. Should the 2D data matrix barcode be near the human-readable portion of the product identifier on the package?

Yes. If space permits, the 2D data matrix barcode should be affixed or imprinted near or next to the human-readable portion of the product identifier on a package. FDA believes this placement would help downstream trading partners (repackagers, wholesale distributors, and dispensers) associate the information encoded in the 2D data matrix barcode with the human-readable information. We are aware that some trading partners may utilize the 2D data matrix barcode to electronically read or retrieve the encoded information for reasons such as data entry for inventory purposes, patient medical records, or product verification. Positioning the 2D data matrix barcode near the human-readable portion of the product identifier may help reduce the confusion when a product has multiple types of barcodes on the label because they are either required by law or are included voluntarily for other purposes (e.g., QR codes).

8. What level or size of a package is required to have a product identifier?

Under section 582(b)(2) and (e)(2) of the FD&C Act, manufacturers and repackagers are required to affix or imprint product identifiers to packages and homogenous cases of product. Based on the definition of package,[29] this means that the product identifier must be affixed or imprinted on the smallest individual saleable unit of product for distribution by a manufacturer or repackager that is intended by the manufacturer for ultimate sale to a dispenser[30] of such product.

Therefore, manufacturers and repackagers must determine the smallest individual saleable unit product configuration that they intend to be sold to the dispenser, and affix or imprint a product identifier (included in a 2-dimensional data matrix barcode) to that package.

To determine what constitutes a package, manufacturers and repackagers should consider how their packages of product may be opened and separated by wholesale distributors, who may sell smaller individual units of product that were inside the larger package to a dispenser for ultimate dispensing or administration to a patient. For example, although a carton of 10 individual product units may be sold to a dispenser, manufacturers and repackagers may want to apply a product identifier to each of the 10 product units that could conceivably be sold individually by a wholesale distributor to a dispenser. See examples provided in Section E of this guidance. Also, see Section C for additional regulatory requirements that may apply.

[28] See GS1 General Specifications (Release 18, Ratified, January 2018), Section 2.1.6 Healthcare primary packaging (https://www.gs1.org/sites/default/files/docs/barcodes/GS1_General_Specifications.pdf).

[29] *Package* is defined in section 581(11) of the FD&C Act.

[30] *Dispenser* is defined in section 581(3) of the FD&C Act.

9. Do manufacturer and repackager activities related to affixing or imprinting the product identifier need to comply with current good manufacturing practice (CGMP)?

Yes, the CGMP requirements under 21 CFR parts 210 and 211 apply to the manufacture, processing, packing, or holding of a drug product, including packaging and labeling operations, testing, and quality control of drugs.

10. Can manufacturers and repackagers request a waiver, exemption, or exception from the DSCSA requirement to include a product identifier?

Yes. FDA has authority under section 582(a)(3) of the FD&C Act to grant a waiver, exception, or exemption for products and transactions from certain requirements in section 582. Manufacturers and repackagers should use the processes set for in FDA's guidance *Waivers, Exceptions, and Exemption from the Requirements of Section 582 of the Federal Food, Drug, and Cosmetic Act*, to make a request.[31] This guidance also describes what information should be included with the requests.

11. Do the product identifier requirements under DSCSA apply to prescription drugs marketed without FDA approval?

Yes. The DSCSA establishes requirements for "products," which are defined under section 581(13) as prescription drugs in a finished dosage form for administration to patients without substantial further manufacturing. "Prescription drugs" in the DSCSA refer to drugs for human use,[32] which meet the requirements of section 503(b)(1) of the FD&C Act (21 U.S.C. 353(b)(1)), independent of approval status.

[31] See the draft guidance for industry *Waivers, Exceptions, and Exemption from the Requirements of Section 582 of the Federal Food, Drug, and Cosmetic Act* (May 2018). The guidance, when finalized, will represent FDA's current thinking on that topic. To make sure you have the most recent version of a guidance, always consult the FDA's Drugs guidance web page at: https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.

[32] See section 581(12) of the FD&C Act.

12. For prescription drugs that are marketed without FDA approval, is the manufacturer required to submit the product identifier as part of its product labeling during registration and listing?

Yes. FDA interprets the definition of "labeling" in section 201(m) of the FD&C Act to include the product identifier. Accordingly, as part of registration and listing under 21 CFR part 207, a manufacturer of any prescription drug for commercial distribution[33] must submit a copy of all current labeling as specified under § 207.49(a)(15)(i), independent of approval status.

C. Submission of Label Changes Under the DSCSA

13. How should manufacturers or repackagers submit a package label change to FDA that is solely for incorporating the product identifier of an already approved prescription drug?[34]

Applicants who submit annual reports should be aware of product identifier changes made by manufacturers and repackagers in the supply chain. Under section 582(a)(8) of the FD&C Act, a change made to the drug package label *solely* to incorporate the product identifier may be submitted in an applicant's annual report[35] in accordance with 21 CFR 314.70(d). Under § 314.70(d), the applicant must document certain changes in the next annual report in accordance with § 314.81(b)(2).[36] Under § 314.81(b)(2)(i), the annual report must contain a brief summary of significant new information from the previous year that might affect the safety, effectiveness, or labeling of the drug product.

A table of contents may be included in the annual report which indicates the inclusion of the labeling change for incorporating the product identifier on products.

In certain instances, it may be appropriate to submit a labeling change in a Prior Approval Supplement (PAS) or in a Changes Being Effected instead of in an annual report.[37]

[33] *Commercial distribution* is defined in 21 CFR 207.1.

[34] For purposes of this guidance, the term *drug* includes biological drug products that are licensed by CDER and CBER.

[35] For purposes of this guidance, the term *establishment*, as used in section 582(a)(8) of the FD&C Act, refers to the applicant.

[36] For biological products, see 21 CFR 601.12(d) for additional changes to be described in an annual report.

[37] For further information, consult the guidance for industry *Changes to an Approved NDA or ANDA* (April 2004), available at: https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.

14. Is a manufacturer or repackager required to submit to FDA information encoded in the product identifier for each package and homogenous case of product?

In general, the information encoded in each product identifier for packages and homogenous cases is not required to be submitted to FDA. However:

FDA may request information from a manufacturer or repackager in the event of a recall or to investigate a suspect or illegitimate product. In this circumstance, the manufacturer or repackager must provide the applicable transaction information,[38] which includes the NDC number and lot number, as well as the transaction history and transaction statement for the product.[39]

Also:

FDA may request information from a manufacturer or repackager to verify if it has made the determination that a suspect product is in the possession or control of such manufacturer or repackager. In this circumstance, the manufacturer or repackager must provide relevant information[40] that can be used to determine whether the product identifier affixed to or imprinted on a package or homogenous case corresponds to the standardized numerical identifier[41] or lot number and expiration date assigned to the product by the manufacturer or repackager.

15. Can a manufacturer submit a placeholder when submitting initial or updated product labeling as part of an application or supplemental application (i.e., New Drug Application [NDA], Abbreviated New Drug Application [ANDA], or Biologics License Application [BLA]) to reflect its commitment to affix or imprint the product identifier on its product?

Yes. CDER and CBER will accept the submission of a drug product label that contains a placeholder when submitting initial or updated product labeling as part of an application or supplemental application (i.e., NDA, ANDA, BLA) in lieu of an image of the final product identifier that the manufacturer intends to use at the time of drug manufacturing. The placeholder should be represented on the initial or updated product labeling submission as a blank space with labels to sufficiently describe what information will be placed in that space at the time the product is manufactured (e.g., "lot number" and "expiration date").

D. The Product Identifier Requirement of the DSCSA and the Linear Barcode Requirement Under 21 CFR 201.25

[38] See Section 582(b)(1)(B) of the FD&C Act for manufacturer requirement; 582(e)(1)(C) of the FD&C Act for repackager requirement.

[39] *Transaction information*, *transaction history*, and *transaction statement* are defined in section 581(26), (25), and (27) of the FD&C Act, respectively.

[40] See Section 582(b)(4)(A) of the FD&C Act for manufacturer requirement; 582(e)(4)(A) of the FD&C Act for repackager requirement.

[41] *Standardized numerical identifier* is defined in section 581(20) of the FD&C Act.

16. Is my product package required to have both a linear barcode and a 2D data matrix barcode?

It depends. There will be instances when a product package is required to have both a linear barcode, pursuant to § 201.25, and a 2D data matrix barcode, pursuant to the DSCSA. For a product for which a manufacturer, under DSCSA, has determined that a package is the smallest individual saleable unit of product for ultimate sale to a dispenser, the package may require a 2D data matrix barcode to comply with DSCSA in addition to the requisite linear barcode under § 201.25. See Section E of this guidance for examples of when a 2D data matrix barcode may not be required.

17. With the enactment of the DSCSA, is *Bar Code Label Requirements Questions and Answers: Guidance for Industry* (August 2011) still valid for the linear barcode rule under § 201.25?

Yes. *Bar Code Label Requirements Questions and Answers: Guidance for Industry* remains applicable to the linear barcode rule under § 201.25 unless or until such time the guidance is revised, replaced, or withdrawn. This guidance should be consulted for questions specific to the linear barcode requirements under § 201.25.[42]

18. Can I put only a 2D data matrix barcode on my product as required under the DSCSA in lieu of the linear barcode that is required under § 201.25, since it also includes the NDC number?

No, at this time, a 2D data matrix barcode may not be used as a substitution for a linear barcode when one is required under § 201.25 for packages of product.

19. Can a manufacturer or repackager put the 2D data matrix barcode, as required under the DSCSA, on all levels of packaging, including the immediate container?

Yes. A manufacturer or repackager may voluntarily put the 2D data matrix barcode on all levels of packaging, including the immediate container, if the product remains compliant with all other labeling requirements, including the linear barcode requirements under § 201.25.

E. Examples of When the Product Identifier is Required Under the DSCSA and the Linear Barcode is Required Under § 201.25

For each of their products, manufacturers and repackagers are responsible for determining the smallest individual saleable unit that they intend for ultimate sale to a dispenser. Under the DSCSA, both a 2D data matrix barcode and the human-readable part of the product identifier are required to be affixed or imprinted on each individual saleable unit. While other levels of product packaging may exist that do not require a 2D data matrix barcode, as noted in Q19, manufacturers and repackagers may voluntarily affix or imprint a 2D data matrix barcode if the

[42] See guidance for industry *Bar Code Label Requirements Questions and Answers* (August 2011), available at: https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.

product remains compliant with all other labeling requirements, including the linear barcode requirements under § 201.25.

The following table provides examples of different units of a package or case and what barcode would be required under the DSCSA and under § 201.25. It is not an exhaustive list because the information required will depend on the specific details of particular product packaging.

Examples of potential individual saleable units	**Unit**	**Type of Product Identifier required by the DSCSA under Sec. 582(a)(9)(A)(i) and (ii) of the FD&C Act**	**Linear barcode required under § 201.25(c) (Yes / No)**
A 60-count bottle of tablets	Bottle	2D data matrix barcode	Yes
A homogenous case of 10 bottles; each bottle contains 100 capsules	Case Bottle	Linear barcode or 2D data matrix barcode 2D data matrix barcode	No Yes
A carton containing one bottle of 50-count of capsules and labeling	Carton Bottle	2D data matrix barcode No requirement for 2D data matrix barcode	Yes Yes
A homogenous case of 20 cartons (*where each carton is intended for individual sale to a dispenser*); each carton contains 5 pre-filled syringes (*where each pre-filled syringe is available to be sold individually as the retail package*)	Case Carton Pre-filled syringe only	Linear barcode or 2D data matrix barcode 2D data matrix barcode No requirement for 2D data matrix barcode	No No Yes
A homogenous case of 20 cartons (*where each carton is intended for individual sale to a dispenser and as the retail package*); each case contains 5 pre-filled syringes	Case Carton Pre-filled syringe only	Linear barcode or 2D data matrix barcode 2D data matrix barcode No requirement for 2D data matrix barcode	No Yes Yes