You're Always a Day Away: DSCSA Product Identifier Requirements Delayed

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In recently issued draft guidance related to the implementation of product identifiers under the Drug Supply Chain Security Act ("DSCSA"),[1][2] FDA has stated that it intends to exercise enforcement discretion for a period of one year beyond the dates delineated in the DSCSA. The decision was made in large part because of industry indications that the initial start dates would not be feasible due to the limited number of expert vendors and the lack of readiness on the part of contract facilities that perform manufacturing operations on behalf of manufacturers.[3]

Background

AGG has written a number of articles and bulletins regarding the DSCSA.[4] As background, under section 582(b)(2) of the Food, Drug, and Cosmetic Act, beginning not later than November 27, 2017, 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". A "product identifier" is defined 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."[5] In addition, beginning November 27, 2017, manufacturers are required to (1) use the standard numerical identifier to verify product at the package level when investigating suspect product or upon receiving a verification request from FDA,[6] (2) verify the product identifier of product in the possession or control of an authorized repackager, wholesale distributor, or dispenser who believes that such product was manufactured by the manufacturer[7] and who submits a request for verification to the manufacturer, and (3) verify the product identifier on each package or sealed homogenous case of such product that they intend to further distribute as a saleable return.[8]

FDA's Guidance

The guidance document, titled the *Product Identifier Requirements under the Drug Supply Chain Security Act -- Compliance Policy*, includes the following:

- FDA issued a draft compliance policy for manufacturers, which includes the following:
  - FDA does not intend to take 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.

1 For the text of the FDA guidance, *see Product Identifier Requirements Under the Drug Supply Chain Security Act -- Compliance Policy*, U.S. FOOD AND DRUG ADMINISTRATION (June 2017), https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM565272.pdf.

2 For the text of the DSCSA, *see* 21 U.S.C. § 360eee, *et seq.*

3 *See Product Identifier Requirements Under the Drug Supply Chain Security Act -- Compliance Policy*, p. 3.

4 *See, e.g.*, http://www.agg.com/files/Publication/0c7ffbd5-ffc6-4de1-837e-2774059f64ad/Presentation/PublicationAttachment/cf6b62bb-09c2-422d-98d7-2a296832cfa1/Minsk-Nduom-Drug-Supply-Chain-Security-Act-Summary-of-Law-and-Guidance.pdf, and http://www.agg.com/Help--I-Need-Somebody--FDA-to-Hold-a-Public-Workshop-Concerning-the-Drug-Supply-Chain-Security-Act/.

5 § 360eee(14)

6 § 360eee-1(b)(4).

7 § 360eee-1(b)(4)(C).

8 § 360eee-1(b)(4)(E).

- FDA also does not intend to take action against a manufacturer that does not verify the product identifier in instances where such verification is required by 21 U.S.C. § 360eee-1(b)(4) because the package or homogeneous case does not bear a product identifier.

- Because of the delay in enforcement against manufacturers, FDA also drafted a compliance policy for downstream trading partners (repackagers, wholesale distributors, and dispensers), which similarly delays timelines for compliance.[9]
- FDA does not intend to take action against a manufacturer, repackager, or wholesale distributor who engages in prohibited acts involving products that are misbranded based on the lack of a product identifier alone, where the package and/or homogeneous case of product that lacks a product identifier was introduced in a transaction into commerce by a manufacturer between November 27, 2017, and November 26, 2018.

AGG Observations

- The guidance document does not change any provision of the law, but only confirms that FDA intends to exercise enforcement discretion until the November 2018 date.
- Given industry readiness, many predicted the delay outlined in FDA's guidance.
- This may be the first of more delays to come for the initial November 2017 date. Some in the industry predict that there will be yet another product identifier delay in November 2018.
- Only the DSCSA requirements specifically described in the draft compliance policy are subject to enforcement discretion. Compliance with other requirements of the DSCSA is still required.
- Comments and suggestions to the guidance must be submitted on or before September 1, 2017.

9 FDA does not intend to take action against: (1) "any repackager who, on or after November 27, 2018, accepts ownership of such product in a transaction, even though it lacks a product identifier, as addressed by section 582(e)(2)(A)(iii) of the FD&C Act;" (2) "any wholesale distributor who, on or after November 27, 2019, engages in a transaction involving such product, even though it lacks a product identifier, as addressed by section 582(c)(2) of the FD&C Act;" or (3) "any dispenser who, on or after November 27, 2020, engages in a transaction with such product, even though it lacks a product identifier, as addressed by section 582(d)(2) of the FD&C Act."

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