
Product Identifier Requirements Under the Drug Supply Chain Security Act – Compliance Policy Guidance for Industry

DRAFT GUIDANCE

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**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)
Office of Regulatory Affairs (ORA)**

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Procedural**

Product Identifier Requirements Under the Drug Supply Chain Security Act – Compliance Policy Guidance for Industry

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1 **Product Identifier Requirements Under the Drug Supply Chain**
2 **Security Act – Compliance Policy**
3 **Guidance for Industry¹**
4

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6 This draft guidance, when finalized, will represent the current thinking of the Food and Drug
7 Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not
8 binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the
9 applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible
10 for this guidance as listed on the title page.
11

12
13 **I. INTRODUCTION**
14

15 This draft guidance describes FDA’s intention with regard to the enforcement of certain
16 requirements related to product identifiers under the Drug Supply Chain Security Act.
17 Specifically, this draft guidance addresses the requirement in section 582(b)(2) of the Federal
18 Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360eee-1(b)(2)) that manufacturers
19 “affix or imprint a product identifier² to each package³ and homogenous case⁴ of a product⁵
20 intended to be introduced in a transaction⁶ into commerce” beginning not later than November
21 27, 2017.⁷ A drug product is misbranded if it fails to bear the product identifier as required by
22 section 582 of the FD&C Act.⁸ This draft guidance also addresses the requirements in section
23 582(b)(4) of the FD&C Act that, beginning November 27, 2017, manufacturers must: (1) use the
24 standard numerical identifier, which is part of the product identifier, to verify product at the
25 package level, when investigating suspect product or upon receiving a verification request from
26 FDA;⁹ (2) verify the product identifier of product in the possession or control of an authorized
27 repackager, wholesale distributor, or dispenser who believes that such product was manufactured

¹ This guidance has been prepared by the Office of Compliance in the Center for Drug Evaluation and Research (CDER) in cooperation with the Center for Biologics Evaluation and Research (CBER) and the Office of Regulatory Affairs (ORA) at the Food and Drug Administration.

² *Product identifier* is defined in section 581(14) of the FD&C Act (21 U.S.C. 360eee(14)) 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.

³ *Package* is defined in section 581(11) of the FD&C Act.

⁴ *Homogeneous case* is defined in 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.

⁵ *Product* is defined in section 581(13) of the FD&C Act.

⁶ *Transaction* is defined in section 581(24) of the FD&C Act.

⁷ See section 582(b)(2)(A) of the FD&C Act.

⁸ See section 502(cc) of the FD&C Act (21 U.S.C. 352(cc)).

⁹ See section 582(b)(4)(i)(II) of the FD&C Act.

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28 by the manufacturer and who submits a request for verification to the manufacturer,¹⁰ and (3)
29 verify the product identifier on each package or sealed homogenous case of such product that
30 they intended to further distribute as a saleable return.¹¹ In addition, this draft guidance
31 addresses the requirements for wholesale distributors, dispensers, and repackagers related to
32 engaging in transactions involving product with a product identifier¹² and product verification.¹³
33 Lastly, this draft guidance addresses the requirements for wholesale distributors and repackagers
34 related to saleable returns.¹⁴

35

36 The compliance policy set forth in this draft guidance applies only to the requirements regarding
37 product identifiers described above. In brief, FDA does not intend to take action against
38 manufacturers who do not affix or imprint a product identifier to each package and homogenous
39 case of products intended to be introduced in a transaction into commerce before November 26,
40 2018. This represents a one year delay in enforcement of the requirement for manufacturers to
41 affix or imprint product identifiers. For the products that manufacturers introduce in a
42 transaction into commerce before November 26, 2018, without a product identifier, FDA also
43 does not intend to take action against manufacturers who do not use a product identifier to verify
44 such product at the package level.

45

46 FDA recognizes that downstream trading partners of manufacturers may wish to acquire product
47 that was first introduced in a transaction into commerce by the manufacturer between November
48 27, 2017, and November 26, 2018, and does not have a product identifier. Therefore, this draft
49 guidance addresses responsibilities of downstream trading partners as well. In that regard, FDA
50 does not intend to take action against a repackager, wholesale distributor, or dispenser that
51 engages in a transaction involving such product, regardless of when such a transaction occurs,
52 except where a repackager's transaction triggers an independent responsibility to affix or imprint
53 a product identifier. Furthermore, FDA does not intend to take action against a wholesale
54 distributor, repackager or dispenser who does not verify the product identifier for such product.
55 Lastly, FDA does not intend to take action against a repackager or wholesale distributor who
56 does not verify the product identifier on each package or sealed homogenous case of such
57 product that they intended to further distribute as a saleable return.

58

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

¹⁰ See section 582(b)(4)(C) of the FD&C Act.

¹¹ See section 582(b)(4)(E) of the FD&C Act.

¹² See section 582(c)(2), (d)(2), and (e)(2)(A)(iii) of the FD&C Act.

¹³ See section 582(c)(4), (d)(4), and (e)(4) of the FD&C Act.

¹⁴ See section 582(c)(4)(D) and (e)(4)(E) of the FD&C Act.

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II. BACKGROUND

The Drug Supply Chain Security Act (DSCSA) (Title II of Public Law 113-54) was signed into law on November 27, 2013. Section 202 of the DSCSA added section 582 to the FD&C Act. This section established product tracing, product identifier, and verification requirements for manufacturers, repackagers, wholesale distributors, and dispensers to facilitate the tracing of a product through the pharmaceutical distribution supply chain. Failure to comply with the requirements of section 582 is a prohibited act under section 301(t) of the FD&C Act (21 U.S.C. 331(t)).

An important requirement of the product tracing scheme outlined in the DSCSA is the product identifier. Section 582 requires that each package and homogenous case of product in the pharmaceutical distribution supply chain bear a product identifier in both a human-readable form and on a machine-readable data carrier. The product identifier includes the product’s standardized numerical identifier,¹⁵ lot number, and expiration date. Manufacturers are required to begin affixing or imprinting a product identifier to each package and homogenous case of a product intended to be introduced in a transaction into commerce no later than November 27, 2017. Repackagers are required to do the same no later than November 27, 2018.¹⁶

III. COMPLIANCE POLICY FOR REQUIREMENTS RELATED TO THE PRODUCT IDENTIFIER

FDA has received comments and feedback from manufacturers and other trading partners expressing concern with industry-wide readiness for implementation of the product identifier requirements for manufacturers. Specifically, stakeholders have described challenges with implementation of product identifier requirements due to: (1) a limited number of vendors that have the expertise to provide solutions related to information technology systems for data management or specific equipment for packaging or manufacturing lines, and (2) capabilities and readiness of contract facilities that perform manufacturing operations on behalf of the manufacturer. Given the concerns expressed, FDA recognizes that some manufacturers may need additional time beyond November 27, 2017, to ensure that products are properly labeled with a product identifier. To minimize possible disruptions in the distribution of prescription drugs in the United States, FDA has adopted the compliance policy set forth below.

¹⁵ *Standard numerical identifier* is defined in 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 that corresponds to the specific product (including the particular package configuration) combined with a unique alphanumeric serial number of up to 20 characters.

¹⁶ See section 582(e)(2)(A)(i) of the FD&C Act.

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A. Compliance Policy for Manufacturers

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 not later than November 27, 2017. As a result, FDA expects that, under the statute any package or homogenous case of product that is introduced in a transaction into commerce by a manufacturer as of November 27, 2017, must be encoded with a product identifier. For the purpose of this draft guidance, we consider a product to be “introduced in a transaction into commerce” when the manufacturer first engages in a transaction involving that product.

Additionally, section 582(b)(4) of the FD&C Act requires that a manufacturer verify the product at the package level, including the standardized numerical identifier, which is part of the product identifier, when they determine that product in their possession or control is suspect or they receive a verification request from FDA.¹⁷ A manufacturer is also required, upon receiving a request from an authorized trading partner that believes a product in its possession or control was manufactured by the manufacturer, to verify whether the product identifier affixed or imprinted on the product in such trading partner’s possession or control corresponds to the product identifier affixed or imprinted by the manufacturer.¹⁸ Manufacturers also must verify a product identifier on a saleable returned product before the manufacturer further distributes such product.¹⁹

1. Affixing or Imprinting Product Identifiers to Each Package or Homogenous Case of Product by Manufacturers

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 as required by section 582(b)(2)(A) of the FD&C Act.

2. Verification of Packages or Homogenous Cases of Product Without Product Identifiers by Manufacturers

As explained above, section 582(b)(4) of the FD&C Act establishes several requirements for manufacturers relating to the verification²⁰ of product identifiers that take effect on November 27, 2017. Under the policy outlined in this draft guidance, FDA does not intend to take action against a manufacturer that does not verify the product identifier in instances where such verification is required by section 582(b)(4) because the package or homogenous case does not bear a product identifier. Specifically, beginning November 27, 2017, FDA does not intend to

¹⁷ See section 582(b)(4)(A)(i)(II) of the FD&C Act.
¹⁸ See section 582(b)(4)(C) of the FD&C Act.
¹⁹ See section 582(b)(4)(E) of the FD&C Act.
²⁰ *Verify* is defined in section 581(28) of the FD&C Act.

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140 take action against a manufacturer who initially introduces product in a transaction into
141 commerce without a product identifier between November 27, 2017, and November 26, 2018,
142 and:

- 143 • does not verify product without a product identifier, at the package level, in situations
144 where such verification is required by section 582(b)(4)(A)(i)(II) of the FD&C Act (i.e.,
145 the manufacturer has determined that such product is a suspect product or it has received
146 a verification request for such product from the FDA);
- 147 • does not, upon receiving a request from an authorized trading partner, verify a product
148 without a product identifier, as required by section 582(b)(4)(C) of the FD&C Act (i.e.,
149 the manufacturer has received a request for verification from an authorized trading
150 partner that is in possession or control of a product that such trading partner believes to
151 be manufactured by such manufacturer); or
- 152 • does not verify a package or sealed homogenous case of product without a product
153 identifier that is intended for further distribution as a saleable returned product, as
154 required by section 582(b)(4)(E) of the FD&C Act.
155

156 A manufacturer must still validate any applicable transaction history and transaction information
157 in its possession if the manufacturer has determined that a product in its possession or control is
158 a suspect product or if the manufacturer receives a verification request from the FDA or an
159 authorized trading partner that is in possession or control of such product.²¹
160

161 Moreover, this compliance policy applies solely to product without a product identifiers that was
162 first introduced in a transaction into commerce by a manufacturer between November 27, 2017,
163 and November 26, 2018, and the requirements for manufacturers to verify the product identifier
164 on such products as described in section 582(b)(4)(A)(i)(II), (b)(4)(C), and (b)(4)(E) of the
165 FD&C Act. The compliance policy does not apply to any other provisions of section 582(b)(4).
166 If a product has a product identifier, FDA expects manufacturers and downstream trading
167 partners to use it in verification.
168

B. Compliance Policy for Repackagers, Wholesale Distributors, and Dispensers

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171 After products with product identifiers are introduced in a transaction into commerce, the
172 requirements for how other trading partners engage in transactions involving such products and
173 use the product identifier are phased-in over 3 years. Beginning November 27, 2018,
174 repackagers are generally required by section 582(e)(2)(A)(iii) of the FD&C Act to engage only
175 in transactions involving products that bear a product identifier. Parallel requirements go into
176 effect for wholesale distributors and dispensers on November 27, 2019, and November 27, 2020,
177 respectively, under section 582(c)(2) and (d)(2). Repackagers, wholesale distributors, and
178 dispensers, starting November 27, 2018, November 27, 2019, and November 27, 2020,
179 respectively, are required to verify product in certain circumstances at the package level,
180 including the standardized numerical identifier, under section 582(e)(4)(A)(i)(II), (c)(4)(A)(i)(II),

²¹ See section 582(b)(4)(A)(i)(II) and (b)(4)(C) of the FD&C Act.

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181 and (d)(4)(A)(ii)(II). For a saleable returned product that wholesale distributors or repackagers
182 intend to further distribute, the wholesale distributor or repackager must verify the product
183 identifier, including the standardized numerical identifier, of each package or sealed
184 homogenous case of such product, under section 582(c)(4)(D) and (e)(4)(E), respectively.
185

1. Engaging in Transactions Involving Product Without a Product Identifier

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188 FDA notes that there may be product in the supply chain that was introduced into the
189 pharmaceutical supply chain by a manufacturer between November 27, 2017, and November 26,
190 2018, and that does not contain a product identifier affixed or imprinted on the package and/or
191 homogeneous case of product by the manufacturer. FDA does not intend to take action against:
192

- 193 • any repackager who, on or after November 27, 2018, accepts ownership of such product
194 in a transaction, even though it lacks a product identifier, as addressed by section
195 582(e)(2)(A)(iii) of the FD&C Act;
- 196 • any wholesale distributor who, on or after November 27, 2019, engages in a transaction
197 involving such product, even though it lacks a product identifier, as addressed by section
198 582(c)(2) of the FD&C Act; or
- 199 • any dispenser who, on or after November 27, 2020, engages in a transaction with such
200 product, even though it lacks a product identifier, as addressed by section 582(d)(2) of the
201 FD&C Act.²²
202

203 This compliance policy does not affect the requirement that begins November 27, 2018, for
204 repackagers to affix or imprint a product identifier on each package or homogenous case of
205 product intended to be introduced in a transaction into commerce.²³ Consequently, beginning
206 November 27, 2018, wholesale distributors and dispensers who purchase products from a
207 repackager should ensure that they bear product identifiers.
208

2. Verification of Packages or Homogenous Cases of Product Without Product Identifiers by Repackagers, Wholesale Distributors, and Dispensers

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212 FDA recognizes that packages and homogenous cases of product introduced in a transaction into
213 commerce by a manufacturer between November 27, 2017, and November 26, 2018, without a
214 product identifier will not be able to be verified using a product identifier at the package level by
215 trading partners due to the products' lack of a product identifier. Therefore, FDA does not intend
216 to take action against:

²² This compliance policy regarding the requirement under section 582(d)(2) of the FD&C Act for dispensers to engage in transactions only involving product only if such product is encoded with a product identifier beginning not later than November 27, 2020, applies to dispensers as defined in section 581(3) of the FD&C Act, which includes pharmacies or licensed health care practitioners authorized to prescribe or administer medication under State law or other licensed individuals under the supervision or direction of such practitioners who dispense or administer product in the usual course of professional practice.

²³ See section 582(e)(2)(A)(i) and (iii) of the FD&C Act.

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- 217 • any repackager who does not use a product identifier to verify such product at the
218 package level, including the standardized numerical identifier, beginning November 27,
219 2018, as required by section 582(e)(4)(A)(i)(II) of the FD&C Act;
- 220 • any wholesale distributor who does not use a product identifier to verify such product at
221 the package level, including the standardized numerical identifier, beginning November
222 27, 2019, as required by section 582(c)(4)(A)(i)(II) of the FD&C Act; or
- 223 • any dispenser who does not verify that the product identifier, including the standardized
224 numerical identifier, of at least 3 packages or 10 percent of such product, whichever is
225 greater, or all packages, if there are fewer than 3, corresponds with the product identifier
226 for such product, beginning November 27, 2020, as required by section
227 582(d)(4)(A)(ii)(II) of the FD&C Act.²⁴
228

229 However, repackagers, wholesale distributors, and dispensers must still validate any applicable
230 transaction history and transaction information for such product that is in their possession and
231 otherwise investigate the product to determine if it is suspect; the compliance policy does not
232 extend to these requirements.²⁵ Similarly, where product does have a product identifier, FDA
233 expects trading partners to use it in verifying product.
234

3. Saleable Returns by Wholesale Distributors or Repackagers

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237 A wholesale distributor or repackager may receive a returned product without a product
238 identifier if the returned product was introduced in a transaction into commerce by a
239 manufacturer prior to November 27, 2018. For these saleable returned products, FDA does not
240 intend to take action against:
241

- 242 • any wholesale distributor who does not verify the product identifier of a saleable returned
243 package or sealed homogenous case of such product without a product identifier that is
244 intended for further distribution, as required by section 582(c)(4)(D) of the FD&C Act; or
- 245 • any repackager who does not verify the product identifier of a saleable returned package
246 or sealed homogeneous case of such product without a product identifier that is intended
247 for further distribution, as required by section 582(e)(4)(E) of the FD&C Act.
248

²⁴ Under section 582(d)(5) of the FD&C Act, licensed health care practitioners authorized to prescribe or administer medication under State law or other licensed individuals under the supervision or direction of such practitioners who dispense or administer product in the usual course of professional practice are exempt from the dispenser requirements for verification described in section 582(d)(4) of the FD&C Act.

²⁵ See section 582(b)(4)(A)(II), (c)(4)(A)(II), (d)(4)(A)(III) and (e)(4)(A)(II) of the FD&C Act.

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4. Documentation of the Date of Introduction in a Transaction Into Commerce

The compliance policy described in this draft guidance for packages and homogeneous cases of products only applies to product without a product identifier that is introduced by a manufacturer in a transaction into commerce between November 27, 2017, and November 26, 2018. Trading partners who believe that product may be subject to this compliance policy should take steps to determine that the product was introduced in a transaction into commerce by the manufacturer in this time frame. FDA recommends that a trading partner make such a determination for a product without a product identifier based on the following:

- At least one of the transaction information documents that compose the transaction history for the product describes an initial transaction date from the manufacturer that occurs between November 27, 2017, and November 26, 2018; or
- There is other documentary evidence created by a trading partner in the ordinary course of business and containing a product description that matches the package or homogenous case of product that is not labeled with a product identifier. In addition, this other documentary evidence should contain a date from which it can be determined that the product was introduced in a transaction into commerce by the manufacturer between November 27, 2017, and November 26, 2018. Examples of such documents may include, but are not limited to, bills of lading, commercial invoices, and shipping invoices.

C. Compliance Policy Regarding Product Misbranded for Failure To Bear a Product Identifier

Under this compliance policy, 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 lack of 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.

As previously stated, a package or homogeneous case of product that does not have a product identifier as required under section 582 of the FD&C Act is misbranded under section 502(cc) of the FD&C Act. The FD&C Act describes several prohibited acts involving misbranded drugs, which include introduction or delivery for introduction into interstate commerce of a drug that is misbranded, receipt in interstate commerce of a misbranded drug and the delivery or proffered delivery thereof, and the doing of an act that causes a drug to become misbranded while held for sale after shipment in interstate commerce.²⁶

²⁶ See, e.g., section 301(a), (c), and (k) of the FD&C Act.

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291 **IV. RELATIONSHIP TO “GRANDFATHERED” PRODUCTS UNDER SECTION**
292 **582(a)(5) OF THE FD&C ACT**

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294 This compliance policy addresses products a manufacturer introduces in a transaction into
295 commerce without product identifiers between November 27, 2017, and November 26, 2018. In
296 the future, FDA intends to issue additional guidance that will outline FDA’s current thinking on
297 the “grandfathering product” provision of section 582(a)(5)(A) of the FD&C Act regarding
298 products not labeled with a product identifier that are in the pharmaceutical distribution supply
299 chain at the time of the effective date of the requirements of section 582. In that guidance, FDA
300 intends to address the relationship of the compliance policy set forth in this guidance with
301 “grandfathered” products.