
Verification Systems Under the Drug Supply Chain Security Act for Certain Prescription Drugs 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DRAFT GUIDANCE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)**

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Verification Systems Under the Drug Supply Chain Security Act for Certain Prescription Drugs Guidance for Industry

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1 **Verification Systems Under the Drug Supply Chain Security Act for**
2 **Certain Prescription Drugs**
3 **Guidance for Industry¹**
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6
7 This draft guidance, when finalized, will represent the current thinking of the Food and Drug
8 Administration (FDA or Agency) on this topic. It does not establish any rights for any person
9 and is not binding on FDA or the public. You can use an alternative approach if it satisfies the
10 requirements of the applicable statutes and regulations. To discuss an alternative approach,
11 contact the FDA staff responsible for this guidance as listed on the title page.
12

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15
16 **I. INTRODUCTION**
17

18 Section 582 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360eee-1), as
19 added by the Drug Supply Chain Security Act (DSCSA) (Title II of Public Law 113-54),
20 established requirements to facilitate the tracing and verification² of certain prescription drug
21 products through the U.S. pharmaceutical distribution supply chain. Certain trading partners³
22 (manufacturers, wholesale distributors, dispensers, and repackagers) are required to have
23 verification systems in place to comply with the requirements under section 582(b)(4), (c)(4),
24 (d)(4), and (e)(4) of the FD&C Act. For the purposes of this guidance, FDA interprets a *system*
25 to mean a coordinated body of processes and procedures that forms an organizational scheme.
26 Verification system requirements include quarantine and investigation of suspect products and
27 quarantine, disposition,⁴ and notification of illegitimate products.⁵ If a suspect product is

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

² *Verification* or *verify* is defined in section 581(28) of the FD&C Act (21 U.S.C. 360eee(28)):

The term “verification” or “verify” means determining whether the product identifier affixed to, or imprinted upon, a package or homogeneous case corresponds to the standardized numerical identifier or lot number and expiration date assigned to the product by the manufacturer or the repackager, as applicable in accordance with section 582.

³ *Trading partner* is defined in section 581(23) of the FD&C Act. Although third-party logistics providers are also considered trading partners under section 581(23)(B), the provisions of section 582(b)-(e) do not impose requirements on them.

⁴ *Disposition* is defined in section 581(4) of the FD&C Act:

The term “disposition,” with respect to a product within the possession or control of an entity, means the removal of such product from the pharmaceutical distribution supply chain, which may include disposal or return of the product for disposal or other appropriate handling and other actions, such as retaining a sample of the product for further additional physical examination or laboratory analysis of the product by a manufacturer or regulatory or law enforcement agency.

⁵ *Suspect product* is defined in section 581(21) and *illegitimate product* is defined in section 581(8) of the FD&C Act.

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28 determined after investigation not to be an illegitimate product, a trading partner is required to
29 notify FDA that the product has been cleared, if applicable, and the product may then be further
30 distributed (section 582(b)(4)(A)(ii), (c)(4)(A)(ii), (d)(4)(A)(iii), and (e)(4)(A)(ii)). Trading
31 partners must keep records of the investigation of a suspect product for not less than 6 years after
32 the conclusion of the investigation (section 582(b)(4)(A)(iii), (c)(4)(A)(iii), (d)(4)(A)(iv), and
33 (e)(4)(A)(iii) of the FD&C Act). Records of the disposition of an illegitimate product must also
34 be kept by a trading partner for not less than 6 years after the conclusion of the disposition
35 (section 582(b)(4)(B)(v), (c)(4)(B)(v), (d)(4)(B)(v), and (e)(4)(B)(v)).

36
37 Section 582(b)(4)(C) and (e)(4)(C) also requires manufacturers and repackagers to respond to
38 requests for verification from other trading partners, and section 582(b)(4)(E), (c)(4)(D), and
39 (e)(4)(E) requires manufacturers, wholesale distributors, and repackagers to verify certain
40 information prior to further distributing returned product.⁶

41
42 FDA is issuing this guidance to describe FDA's interpretation of the requirements of section 582
43 of the FD&C Act regarding verification systems. This guidance provides recommendations for a
44 robust verification system for the determination, quarantine, and investigation of suspect
45 products, as well as the quarantine, notification, and disposition of illegitimate products. The
46 guidance also addresses the manner in which FDA recommends that trading partners submit
47 cleared product notifications. Finally, this guidance addresses the statutory requirements for
48 verification, including verification of saleable returns, at the package level for product identifiers
49 on packages and homogenous cases intended to be introduced in a transaction into commerce.

50
51 In general, FDA's guidance documents do not establish legally enforceable responsibilities.
52 Instead, guidances describe the Agency's current thinking on a topic and should be viewed only
53 as recommendations, unless specific regulatory or statutory requirements are cited. The use of
54 the word *should* in Agency guidances means that something is suggested or recommended, but
55 not required.

56 57 **II. BACKGROUND**

58 59 **A. DSCSA Verification Requirements**

60
61 On November 27, 2013, the DSCSA was signed into law. Section 202 of the DSCSA added
62 section 582 to the FD&C Act, which set forth verification requirements that took effect on
63 January 1, 2015 for manufacturers, wholesale distributors, dispensers, and repackagers of certain
64 drug products.

65
66 Under section 582(b)(4), (c)(4), (d)(4), and (e)(4) of the FD&C Act, trading partners must:

- 67
68
 - Have a system in place to enable them to identify and determine whether a product is a
69 suspect product.

70

⁶ These requirements will be phased in over a period of years as outlined in sections 582(b)(4)(C) & (E), (c)(4)(D), and (e)(4)(C) and (E) of the FD&C Act.

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- 71 • Have a system in place to quarantine and investigate a product that has been determined
72 to be a suspect product and to coordinate with trading partners, as applicable, in making
73 the determination as to whether that product is illegitimate.
74
- 75 • Have a system in place to clear a product for distribution, as appropriate, if, after
76 investigation, it is determined that the suspect product is not an illegitimate product. The
77 trading partner is required to notify FDA of cleared products, if applicable.
78
- 79 • Have a system in place for products determined to be illegitimate to:
80
 - 81 ○ Further quarantine the illegitimate product.
 - 82
 - 83 ○ Disposition the illegitimate product within the trading partner's possession and
84 control.
 - 85
 - 86 ○ Take reasonable and appropriate steps to assist another trading partner to
87 disposition the illegitimate product.
88
 - 89 ○ Retain a sample of the illegitimate product in an adequate amount for further
90 physical examination and laboratory analysis by the manufacturer and/or FDA or
91 other appropriate Federal or State official.
92
 - 93 ○ Provide notification of the illegitimate product to FDA and other trading partners
94 and, upon making a determination, in consultation with the FDA, that a
95 notification is no longer necessary, terminate that notification. In addition, a
96 manufacturer must have a system in place for notifying its immediate trading
97 partners and FDA of a product that has a high risk of illegitimacy, as required
98 under section 582(b)(4)(B)(ii)(II) of the FD&C Act.
99
- 100 • Have a system in place that includes procedures for taking appropriate action when the
101 trading partner has received an illegitimate product notification or a manufacturer's
102 notification of a high risk of illegitimacy.
103
- 104 • Have a system in place for creating and maintaining records related to suspect product
105 investigations and disposition of illegitimate products for a minimum of 6 years as
106 required by section 582 of the FD&C Act.
107

108 In addition, manufacturers, wholesale distributors, and repackagers have additional requirements
109 outlined in section 582(b)(4)(C) and (E), (c)(4)(D), and (e)(4)(C) and (E) of the FD&C Act:
110

- 111 • Manufacturers must have systems in place that will allow them to respond to requests
112 from trading partners to confirm that a particular product identifier, including the
113 standardized numerical identifier, on the product that is the subject of the request
114 corresponds to the product identifier that was affixed or imprinted on that product by the
115 manufacturer of that product.
116

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- 117 • Repackagers must have systems in place that will allow them to respond to requests from
118 trading partners to confirm that a particular product identifier, including the standardized
119 numerical identifier, on the product that is the subject of the request corresponds to the
120 product identifier that was affixed or imprinted on that product by the repackager of that
121 product.
122
- 123 • Manufacturers, wholesale distributors, and repackagers must have systems in place that
124 will allow them, upon receipt of a saleable returned product, to verify the product
125 identifier, including the standardized numerical identifier, for each sealed homogenous
126 case or package before further distributing such product.
127

128 To satisfy the requirements under section 582(b)(4), (c)(4), (d)(4), and (e)(4) of the FD&C Act,
129 these verification systems may be based on existing standard operating procedures (SOPs) or
130 processes, new SOPs or processes, or a combination of both that ensure that the trading partner
131 meets its verification obligations under section 582. These systems may include the use of a
132 secure electronic database as provided under section 582(b)(4)(D), (c)(4)(C), (d)(4)(C), and
133 (e)(4)(D) of the FD&C Act.
134

B. Scope of This Guidance

135
136
137 This guidance applies to the verification systems that manufacturers, wholesale distributors,
138 dispensers, and repackagers must have in place as described in section 582(b)(4), (c)(4), (d)(4),
139 and (e)(4) of the FD&C Act.
140

141 This guidance is intended to provide assistance to industry in understanding the verification
142 systems requirements under section 582 of the FD&C Act and to provide guidance on what
143 should be included in these systems. This guidance does not address all of the provisions in
144 section 582 of the FD&C Act related to verification. For example, the Agency previously issued
145 a guidance on identification of suspect products and notification of illegitimate products (Suspect
146 Product and Notification Guidance) that includes processes by which notifications to FDA and
147 other trading partners of illegitimate product are made, as well as termination of those
148 notifications, as described in section 582(h)(2)(A)(iii) of the FD&C Act.⁷
149

150 When designing and implementing the verification systems required under the DSCSA, trading
151 partners are cautioned that although section 582 of the FD&C Act may not require that a product
152 be withheld or removed from the U.S. pharmaceutical distribution supply chain because it does
153 not fit within the definition of *suspect product* or *illegitimate product*, trading partners have other
154 obligations under the FD&C Act and the Public Health Service Act regarding the introduction of
155 products into interstate commerce. Violation of those requirements may result in enforcement
156 actions regardless of a trading partner's compliance with section 582. For example, an
157 adulterated product may not be a suspect product because it is not within the definition in section
158 581(21) of the FD&C Act, but it is a prohibited act to introduce or deliver for introduction into

⁷ FDA guidance for industry *Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification*; 2016 (Suspect Product and Notification Guidance). We update guidances periodically. To make sure you have the most recent version of a guidance, check the FDA Drugs guidance web page at <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>

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159 interstate commerce an adulterated drug under section 301(a) of the FD&C Act (21 U.S.C
160 331(a)).

161

162 **III. VERIFICATION SYSTEMS UNDER SECTION 582**

163

164 Section 582 of the FD&C Act requires manufacturers, wholesale distributors, dispensers, and
165 repackagers to have “systems in place to enable [them] to comply” with certain requirements
166 relating to the identification and handling of suspect and illegitimate products. Specific
167 requirements include quarantine and investigation of a product determined to be a suspect
168 product and quarantine, disposition, and notification of a product determined to be an illegitimate
169 product.⁸

170

171 **A. Systems to Determine That a Product Is Suspect**

172

173 Trading partners must have systems in place to make a determination as to whether a product is a
174 suspect product.⁹ These systems should ensure that, when appropriate, a trading partner makes a
175 consistent, effective, and timely determination that a product is suspect. In order to help ensure
176 patient safety, it is essential that this system be well-designed to detect and assess suspect
177 product, because the determination that a product is suspect triggers quarantine and investigation
178 under section 582 of the FD&C Act. In making these determinations, trading partners should
179 focus on drugs that potentially fall into one of the categories of drugs listed in the definition of
180 suspect product in section 581(21) of the FD&C Act: product that may be counterfeit, diverted,
181 stolen, intentionally adulterated, subject of a fraudulent transaction, or unfit for distribution. In
182 the previously published draft guidance, *Definitions of Suspect Product and Illegitimate Product*
183 *for Verification Obligations Under the Drug Supply Chain Security Act*, FDA clarified its
184 interpretation of the following terms listed in the definition of suspect product in section 581(21)
185 of the FD&C Act: counterfeit, fraudulent transaction, unfit for distribution, and diverted.¹⁰

186

187 In particular, trading partners should consider the risk of such product entering the U.S.
188 pharmaceutical distribution supply chain and the scenarios that could significantly increase such
189 risk. The Suspect Product and Notification Guidance provides recommendations on how trading
190 partners can identify a suspect product and determine whether the product is a suspect product as
191 soon as practicable. The list of scenarios and recommendations in that guidance are not all-
192 inclusive, and trading partners should exercise due diligence at all times to ensure that a suspect
193 product is identified.

194

195 FDA may make a request for verification to a trading partner when FDA has determined that the
196 trading partner may have a suspect product within its possession or control.¹¹ Upon receipt of a
197 request for verification, trading partners must proceed as directed by section 582(b)(4)(A)(i),
198 (c)(4)(A)(i), (d)(4)(A)(i), and (e)(4)(A)(i) (e.g., quarantining, investigating).

⁸ See section 582(b)(4)(A) and (B), (c)(4)(A) and (B), (d)(4)(A) and (B), and (e)(4)(A) and (B) of the FD&C Act.

⁹ See section 582(b)(4), (c)(4), (d)(4), and (e)(4) of the FD&C Act.

¹⁰ That draft 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 Drugs guidance Web page at <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>.

¹¹ See section 582(b)(4)(A)(i), (c)(4)(A)(i), (d)(4)(A)(i), and (e)(4)(A)(i) of the FD&C Act.

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199
200 Upon receipt of an illegitimate product notification from a trading partner or a notification from
201 FDA that a product has been determined to be an illegitimate product, a trading partner must
202 identify all illegitimate products subject to such notification in its possession or control,
203 including any product that is subsequently received, and conduct the activities required for
204 suspect product, as applicable, described in sections 582(b)(4)(A), (c)(4)(A), (d)(4)(A), and
205 (e)(4)(A).¹² Trading partners should follow these same procedures upon receipt of a notification
206 from a manufacturer that a product has a high risk of illegitimacy.

B. System for Suspect Product Quarantine and Investigation

207
208
209 Upon determining that a product is suspect, or upon receiving a request for verification from
210 FDA, a trading partner is required to quarantine and investigate the product to determine whether
211 it is an illegitimate product.¹³ Trading partners must have systems in place to enable such
212 quarantines and investigations of suspect product.¹⁴
213
214

1. Quarantine

215
216 Under FDA's interpretation, quarantine of a suspect product may be accomplished using
217 physical separation and/or other procedures such as electronic means, when applicable. The
218 system for quarantine should be robust enough to ensure that the suspect product is not
219 inadvertently distributed. The authority to terminate a quarantine of suspect product and release
220 the product for further distribution should be assigned to an appropriate person(s) in the trading
221 partner's organization. For example, a member of the Quality Control Unit for a manufacturer or
222 repackager, a facility manager or responsible person identified by a wholesale distributor, or a
223 pharmacist-in-charge for a dispenser may be an appropriate person to exercise such authority.
224
225

2. Components of a Robust Investigation

226
227 Trading partners are required to commence and promptly conduct an investigation, in
228 coordination with other trading partners, as applicable, into whether a suspect product is an
229 illegitimate product.¹⁵ At a minimum, such investigations must include validation of any
230 applicable transaction history and transaction information¹⁶ and should include:
231
232

- 233 • Active communication and coordination of the investigation with the manufacturer and/or
234 repackager and other trading partners, as appropriate, to ensure that the investigation is
235 thorough and the conclusions are accurate.
236
- 237 • Use of appropriate laboratory standards, controls, and techniques in situations where
238 laboratory testing of suspect product is necessary to determine whether the product is an
239 illegitimate product. Note that FDA would generally consider it appropriate for trading

¹² Section 582(b)(4)(B)(iii), (c)(4)(B)(iii), (d)(4)(B)(iii), and (e)(4)(B)(iii) of the FD&C Act.

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

¹⁴ See section 582(b)(4)(A), (c)(4)(A), (d)(4)(A), and (e)(4)(A) of the FD&C Act.

¹⁵ See section 582(b)(4)(A)(i)(II), (c)(4)(A)(i)(II), (d)(4)(A)(i)(II), and (e)(4)(A)(i)(II) of the FD&C Act.

¹⁶ See section 582(b)(4)(A)(i)(II), (c)(4)(A)(i)(II), (d)(4)(A)(ii)(III), and (e)(4)(A)(i)(II) of the FD&C Act.

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240 partners participating in a coordinated investigation with the product’s manufacturer to
241 rely on the results of laboratory testing conducted by that manufacturer if the testing is
242 performed in a timely manner and the trading partner receives adequate assurance from
243 the manufacturer that the results are reliable.

244
245 After each investigation of a suspect product, a trading partner should capture the lessons learned
246 regarding the components of the verification system that worked well and those that did not and
247 make the appropriate adjustments to the verification system. If a trading partner determines
248 through its investigation that a suspect product is an illegitimate product, it should conduct a
249 root-cause analysis of how the product came to be in the possession and control of the trading
250 partner and assess ways to strengthen its procurement process to avoid future acquisition of
251 illegitimate products.

C. System for Cleared Product Notification Regarding Suspect Products

252
253
254 Under section 582 of the FD&C Act, trading partners must promptly notify the Secretary, if
255 applicable, if they determine after investigation that the suspect product is not an illegitimate
256 product.¹⁷ This notification is considered a “cleared product notification.” FDA expects cleared
257 product notifications to be submitted to FDA only if the suspect product is the subject of an FDA
258 request for verification. Other cleared product notifications should not be submitted to FDA, as
259 described in section III.C.3 below. Trading partners should be advised that once a product has
260 been cleared, they must ensure compliance with the other applicable provisions of the FD&C Act
261 before the product may be further distributed. Trading partners must have systems in place for
262 cleared product notifications.¹⁸

1. Components of Cleared Product Notifications

263
264
265
266 The cleared product notifications should include:

- 267
- 268 • A subject line that states: “Cleared Product Notification.”
 - 269 • The identity of the product that was determined to be a suspect product but has now been
270 determined, after investigation, not to be an illegitimate product. The product should be
271 identified by the:
 - 272 1. Proprietary or established name of the product¹⁹
 - 273 2. Strength and dosage form of the product
 - 274 3. National Drug Code (NDC) of the product²⁰
 - 275 4. Lot number
 - 276 5. Expiration date

¹⁷ 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.

¹⁸ See section 582(b)(4)(A)(iii), (c)(4)(A)(ii), (d)(4)(A)(iii), and (e)(4)(A)(ii) of the FD&C Act.

¹⁹ The *proper name* should be used for biological products. See 21 CFR 600.3(k).

²⁰ If an alternatively formatted NDC is approved for use in accordance with 21 CFR 207.33(b)(4), the alternatively formatted NDC should be used to identify the product.

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- 277 6. Serial number(s) of the product(s)²¹
278 7. Container size
279 8. Number of containers
- 280 • The reason why the product was determined to be suspect and a summary of the
281 investigation that led to the trading partner’s determination that the product was not an
282 illegitimate product.
- 283 • The date the product was cleared.
- 284 • The name and official position of the employee or officer of the trading partner who
285 cleared the suspect product and the signature of that officer or employee.
- 286 • The distribution or disposition of the product (i.e., details about the distribution or
287 disposition including the date that the product was distributed or appropriately
288 disposed).

2. Cleared Product Notifications to be Submitted to FDA

289
290
291 If after investigating a product that is the subject of an FDA request for verification, a trading
292 partner determines that the product is not an illegitimate product, the trading partner must
293 promptly submit a cleared product notification to FDA documenting its determination.²² The
294 cleared product notification should be submitted to *drugnotifications@fda.hhs.gov*. In addition
295 to the components identified above, the cleared product notification should include the date of
296 the FDA request for verification to which the cleared product notification applies, and the name
297 of the FDA office and/or employee who made the request for verification.
298

3. Cleared Product Notifications That Do Not Need to be Submitted to FDA and Should Be Maintained by the Trading Partner

299
300
301
302 If, after investigation, a trading partner determines that a suspect product is not an illegitimate
303 product and the product is not the subject of an FDA request for verification, the trading partner
304 should not submit a cleared product notification to FDA. However, the trading partner should
305 maintain the cleared product notification in the records of the investigation of the suspect
306 product.
307

4. Recordkeeping of Cleared Product Notifications

308
309
310 Records of suspect product investigations, including all cleared product notifications, must be
311 maintained for a period of at least 6 years after the conclusion of the investigation.²³
312

²¹ When a product identifier must be affixed or imprinted to a product per sections 582(b)(2) and 582(e)(2), trading partners should include the serial number along with the NDC, lot number, and expiration date as the product identifier of the product package(s) or sealed homogenous case of product (see sections 581(14) and (20)).

²² 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.

²³ Section 582(b)(4)(A)(iii), (c)(4)(A)(iii), (d)(4)(A)(iv), and (e)(4)(A)(iii) of the FD&C Act.

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D. System for Illegitimate Product Quarantine and Disposition

Trading partners must meet certain requirements for quarantine and disposition of illegitimate product, including coordination with other trading partners, as applicable.²⁴ In making the determination that a product is illegitimate, trading partners are required to coordinate with the manufacturer.²⁵

1. Quarantine

Products determined to be illegitimate should be kept *physically* separated from products intended for distribution because of the higher level of public health risk associated with illegitimate products.²⁶ The system for quarantine should be robust enough to ensure that an illegitimate product is not inadvertently distributed. Authority to release the illegitimate product from quarantine should only be exercised by an appropriate person in the organization expressly authorized to terminate quarantine for the illegitimate product. For example, a member of the Quality Control Unit for a manufacturer or repackager, a facility manager or responsible person for a wholesale distributor, or a pharmacist-in-charge for a dispenser may be an appropriate person to exercise such authority.

2. Disposition

The method of disposition of an illegitimate product should ensure that the public health hazards associated with that product are appropriately controlled. Trading partners should have written procedures/SOPs for disposition of the illegitimate product.²⁷ Trading partners should also audit any contractors they hire to disposition the product to ensure that the product was appropriately and effectively disposed of. Records of the disposition of an illegitimate product must be maintained by trading partners for not less than 6 years after the conclusion of the disposition.²⁸

3. Retention of Samples

Trading partners must retain a sample of the illegitimate product for further physical examination or laboratory analysis by the manufacturer or FDA (or other appropriate Federal or State official).²⁹ Samples should be:

- Representative of the illegitimate product.
- Of a sufficient amount, if available, to permit proper laboratory examination by both the manufacturer and FDA or another government agency.

²⁴ Section 582(b)(4)(B), (c)(4)(B), (d)(4)(B), and (e)(4)(B) of the FD&C Act.

²⁵ *Id.*

²⁶ Section 582(d)(4)(B)(iii) requires dispensers to quarantine product for which they receive a notice of illegitimacy. Dispensers should also quarantine product they determine to be illegitimate.

²⁷ Section 582(b)(4)(B)(i)(II), (c)(4)(B)(i)(II), (d)(4)(B), and (e)(4)(B)(i)(II) of the FD&C Act.

²⁸ Section 582(b)(4)(B)(v), (c)(4)(B)(v), (d)(4)(B)(v), and (e)(4)(B)(v) of the FD&C Act.

²⁹ Section 582(b)(4)(B)(i)(IV), (c)(4)(B)(i)(IV), (d)(4)(B)(i)(III), and (e)(4)(B)(i)(IV) of the FD&C Act.

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- 352 • Appropriately labeled and stored to preserve the identity and integrity of the sample.
353
354 • Handled, identified, and sealed in a manner ensuring that proper custody procedures are
355 maintained so that the sample and/or laboratory test results can be used as evidence, if
356 necessary. For example, a record/log identifying each person who handled the product,
357 identifying the date they handled it, and describing the manner in which they handled it
358 should be maintained and should accompany the sample when submitted for testing.
359

E. System for Illegitimate/High Risk of Illegitimacy Product Notifications

360
361
362 Trading partners must have systems in place for notifying FDA and immediate trading partners of an
363 illegitimate product and, for manufacturers, products with a high risk of illegitimacy.³⁰ The Suspect
364 Product and Notification Guidance sets forth the process by which trading partners should notify
365 FDA of the illegitimate product or products with a high risk of illegitimacy, and the process they
366 must use to terminate notifications, in consultation with FDA.³¹ Refer to that guidance for specific
367 information related to these notifications.
368

F. System for Responding to Requests for Verification

369
370
371 Manufacturers and repackagers must have systems in place to respond to requests for verification
372 from trading partners within 24 hours of receipt of a request.³² These systems must be in place
373 by November 27, 2017, for manufacturers, and by November 27, 2018, for repackagers. The
374 systems must allow the manufacturer or repackager to notify the trading partner making the
375 request whether the product identifier, including the standardized numerical identifier, that is the
376 subject of the request corresponds to the product identifier affixed or imprinted by that
377 manufacturer or repackager.³³ These systems should:
378

- 379 • Allow the manufacturer or repackager to respond to the request within the required
380 timeframe with a clear statement as to whether the product identifier has been verified or
381 not.
382
383 • Be integrated with the system used to identify suspect product and illegitimate product.
384 If a product identifier does not correspond to the product identifier affixed or imprinted
385 by the manufacturer or repackager, the product must be treated by the manufacturer or
386 repackager, as applicable, as a suspect product (i.e., it must be quarantined and
387 investigated).³⁴ If the manufacturer or repackager has reason to believe that the product is
388 illegitimate, it must indicate as much in its response to the request for verification from a
389 trading partner, and should inform them why they believe the product may be
390 illegitimate.³⁵ In addition, section III.E above describes the recommendation for a system

³⁰ Section 582(b)(4)(B)(ii)(I) and (II), (c)(4)(B)(ii), (d)(4)(B)(ii), and (e)(4)(B)(ii) of the FD&C Act.

³¹ For terminating notification requirements see section 582(b)(4)(B)(iv), (c)(4)(B)(iv), (d)(4)(B)(iv), and (e)(4)(B)(iv) of the FD&C Act.

³² See section 582(b)(4)(C) and (e)(4)(C) of the FD&C Act.

³³ Section 582(b)(4)(C) and 582(e)(4)(C) of the FD&C Act.

³⁴ See section 582(b)(4)(C) and (e)(4)(C) of the FD&C Act.

³⁵ See section 582(b)(4)(C) and (e)(4)(C) of the FD&C Act.

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391 to notify FDA and other trading partners when an illegitimate product is found (and, for
392 manufacturers, when products with a high risk of illegitimacy are found).
393

394 **G. System for Processing Saleable Returns**

395
396 Manufacturers, wholesale distributors, and repackagers must have systems in place that will
397 allow them to process saleable return products that they intend to further distribute.^{36, 37, 38} These
398 systems must allow the trading partners to verify the product identifier, including the
399 standardized numerical identifier, on each sealed homogeneous case of saleable returned product
400 or, if such product is not in a sealed homogeneous case, on each package of saleable returned
401 product.³⁹ A saleable returned product may not be further distributed until the product identifier
402 is verified. If the product identifier is not successfully verified, the product should be handled as
403 a suspect product (i.e., it must be quarantined and investigated).⁴⁰

³⁶ See section 582(b)(4)(E), (c)(4)(D), and (e)(4)(E) of the FD&C Act.

³⁷ These systems must be in place by November 27, 2017, for manufacturers, by November 27, 2018, for repackagers, and by November 27, 2019, for wholesale distributors.

³⁸ *Return* is defined in section 581(17) of the FD&C Act.

³⁹ Section 582(b)(4)(E), (c)(4)(D), and (e)(4)(E) of the FD&C Act.

⁴⁰ For how trading partners must handle suspect product, see section 582(b)(4)(A)(i), (c)(4)(A)(i), and (e)(4)(A)(i) of the FD&C Act.