

Contains Nonbinding Recommendations

Exemption and Exclusion from Certain Requirements of the Drug Supply Chain Security Act During the COVID-19 Public Health Emergency

Guidance for Industry

April 2020

**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research
Center for Biologics Evaluation and Research**

Preface

Public Comment

This guidance is being issued to address the Coronavirus Disease 2019 (COVID-19) public health emergency. This guidance is being implemented without prior public comment because the Food and Drug Administration (FDA or the Agency) has determined that prior public participation for this guidance is not feasible or appropriate (see section 701(h)(1)(C) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 371(h)(1)(C)) and 21 CFR 10.115(g)(2)). This guidance document is being implemented immediately, but it remains subject to comment in accordance with the Agency's good guidance practices.

Comments may be submitted at any time for Agency consideration. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Submit electronic comments to <https://www.regulations.gov>. All comments should be identified with the docket number FDA-2020-D-1136 and complete title of the guidance in the request.

Additional Copies

Additional copies are available from the FDA webpage titled "COVID-19-Related Guidance Documents for Industry, FDA Staff, and Other Stakeholders," *available at* <https://www.fda.gov/emergency-preparedness-and-response/mcm-issues/covid-19-related-guidance-documents-industry-fda-staff-and-other-stakeholders> and from the FDA webpage titled "Search for FDA Guidance Documents" *available at* <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>. You may also send an e-mail request to druginfo@fda.hhs.gov and/or ocod@fda.hhs.gov to receive an additional copy of the guidance. Please include the document number FDA-2020-D-1136 and complete title of the guidance in the request.

Questions

For questions about this document, contact the DSCSA implementation team at drugtrackandtrace@fda.hhs.gov, 301-796-3130.

Table of Contents

I.	Introduction.....	1
II.	Background.....	2
	A. COVID-19.....	2
	B. DSCSA.....	2
III.	Scope of the Exemption and Exclusion During the COVID-19 Public Health Emergency.....	4
	A. DSCSA Statutory Exemption and Exclusion for Public Health Emergency	4
	(1) Exemption from Certain Product Tracing and Product Identification Requirements Under Section 582 of the FD&C Act.....	4
	(2) Exclusion from Wholesale Distribution Under Section 503(e) of the FD&C Act.....	6
	B. Distribution of Covered COVID-19 Products for COVID-19 Under the Public Health Emergency Declaration.....	6
	C. Distribution of Other Products Affected by the COVID-19 Public Health Emergency	7
	D. Authorized Trading Partner Requirements – Compliance Policy During the COVID-19 Public Health Emergency.....	7
	E. Time Frame	8
IV.	Business With Trusted Trading Partners	8

Exemption and Exclusion from Certain Requirements of the Drug Supply Chain Security Act During the COVID-19 Public Health Emergency

Guidance for Industry

This guidance represents 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 or Office responsible for this guidance as listed on the title page.

I. Introduction

FDA plays a critical role in protecting the United States from threats such as emerging infectious diseases, including the Coronavirus Disease 2019 (COVID-19) pandemic. FDA is committed to providing timely guidance to support response efforts to this pandemic.

Due to the COVID-19 pandemic, FDA has been monitoring requests related to provisions of the Drug Supply Chain Security Act (DSCSA) because the provisions may affect the prescription drug supply chain during the COVID-19 outbreak. FDA is issuing this guidance to clarify the scope of the public health emergency exemption and exclusion under the DSCSA for the duration of the public health emergency declared by the Secretary of Health and Human Services (HHS) on January 31, 2020, effective January 27, 2020, and renewed for 90 days on April 21, 2020, effective April 26, 2020, to help ensure adequate distribution of finished prescription drug products throughout the supply chain to combat COVID-19. In addition, this guidance announces FDA's policy regarding the exercise of its discretion in the enforcement of authorized trading partner requirements under section 582(b)(3), (c)(3), (d)(3), and (e)(3) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for certain distributions during the COVID-19 public health emergency involving other trading partners that may not be authorized trading partners.

This policy is intended to remain in effect only for the duration of the COVID-19 public health emergency, including any renewals made by the HHS Secretary in accordance with section 319(a)(2) of the Public Health Service Act (PHS Act) (42 U.S.C. 247d(a)(2)).

Contains Nonbinding Recommendations

Given this public health emergency, and as discussed in the Notice in the *Federal Register* of March 25, 2020 (85 FR 16949), titled “Process for Making Available Guidance Documents Related to Coronavirus Disease 2019,” available at <https://www.govinfo.gov/content/pkg/FR-2020-03-25/pdf/2020-06222.pdf>, this guidance is being implemented without prior public comment because FDA has determined that prior public participation for this guidance is not feasible or appropriate (see section 701(h)(1)(C) of the FD&C Act (21 U.S.C. 371(h)(1)(C)) and 21 CFR 10.115(g)(2)). This guidance document is being implemented immediately, but it remains subject to comment in accordance with the Agency’s good guidance practices.

In general, FDA’s guidance documents, including this guidance, 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 guidance means that something is suggested or recommended, but not required.

II. Background

A. COVID-19

There is currently an outbreak of respiratory disease caused by a novel coronavirus. The virus has been named “SARS-CoV-2” and the disease it causes has been named “Coronavirus Disease 2019” (COVID-19). On January 31, 2020, HHS issued a declaration of a public health emergency related to COVID-19 effective January 27, 2020, and mobilized the Operating Divisions of HHS, in accordance with section 319(a)(2) of the PHS Act. The declaration was renewed for another 90 days on April 21, 2020, effective April 26, 2020.¹ In addition, on March 13, 2020, the President declared a national emergency in response to COVID-19.²

B. DSCSA

The DSCSA (Title II of Pub. L. 113-54) was signed into law on November 27, 2013. Section 202 of the DSCSA added section 582 to the FD&C Act (21 U.S.C. 360eee-1), establishing the product tracing, product identifier, authorized trading partner, and verification requirements for manufacturers, repackagers, wholesale distributors, and dispensers to facilitate the tracing of products through the pharmaceutical distribution supply chain.

The DSCSA outlines critical steps to build an electronic, interoperable system by November 27, 2023, that will enable the identification and tracing of certain prescription drugs as they are

¹ Secretary of Health and Human Services Alex M. Azar, Determination that a Public Health Emergency Exists (Jan. 31, 2020, effective Jan. 27, 2020, and April 21, 2020, effective April 26, 2020), available at <https://www.phe.gov/emergency/news/healthactions/phe/Pages/default.aspx>.

² Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID-19) Outbreak (Mar. 13, 2020), available at <https://www.whitehouse.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/>.

Contains Nonbinding Recommendations

distributed within the United States. For example, since 2015, for each transaction³ of product,⁴ trading partners (manufacturers, wholesale distributors, dispensers, and repackagers) are required under section 582 of the FD&C Act to capture, maintain, and provide subsequent purchasing trading partners with transaction information, transaction history, and a transaction statement (product tracing information) and to notify FDA and certain immediate trading partners when they have determined that a product in their possession or control is an illegitimate product. By 2018, manufacturers and repackagers were 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. Once products have product identifiers affixed or imprinted on them, manufacturers and repackagers are required to verify products using the product identifiers in circumstances specified in the DSCSA. In addition, sections 583 and 584 of the FD&C Act (21 U.S.C. 360eee-2 and 360eee-3) direct FDA to establish national licensure standards for wholesale distributors and third-party logistics providers, and require that these entities report licensure and other information to FDA annually.

Under the DSCSA, specific activities are automatically excluded from certain DSCSA requirements upon the declaration of a public health emergency under section 319 of the PHS Act. The distribution⁵ of a product for emergency medical reasons, including a public health emergency declaration pursuant to section 319 of the PHS Act, is exempted from the definition of a *transaction*⁶ and excluded from the definition of *wholesale distribution*⁷ under the DSCSA. This guidance is being issued to provide detailed information addressing the scope of the DSCSA public health emergency exemption and exclusion during the COVID-19 public health emergency and to clarify the types of distribution activities related to COVID-19 that fall under the *transaction* definition exemption and the *wholesale distribution* definition exclusion. The above exemption and exclusion provided under the DSCSA during the COVID-19 public health emergency strike a balance between the need to facilitate the effective distribution of products under emergency conditions while helping protect consumers from exposure to products that may be counterfeit,

³ *Transaction* is defined as the transfer of product between persons in which a change of ownership occurs (section 581(24) of the FD&C Act (21 U.S.C. 360eee(24))). For specific exemptions, see section 581(24)(B) of the FD&C Act.

⁴ *Product* is defined as a prescription drug for human use in a finished dosage form for administration to a patient without further manufacturing (section 581(13) of the FD&C Act). See section 581(13) of the FD&C Act for specific exclusions.

⁵ In section 581(5) of the FD&C Act, *distribute or distribution* is defined as the sale, purchase, trade, delivery, handling, storage, or receipt of a product, and does not include the dispensing of a product pursuant to a prescription executed in accordance with section 503(b)(1) of the FD&C Act (21 U.S.C. 353(b)(1)) or dispensing of a product approved under section 512(b) of the FD&C Act (21 U.S.C. 360b(b)).

⁶ Section 581(24)(B)(iii) of the FD&C Act exempts from the definition of *transaction* “the distribution of a product for emergency medical reasons[,] including a public health emergency declaration pursuant to section 319 of the Public Health Service Act, except that a drug shortage not caused by a public health emergency shall not constitute an emergency medical reason.”

⁷ *Wholesale distribution* is defined as, “distribution of a drug . . . to a person other than a consumer or patient, or receipt of a drug . . . by a person other than [a] consumer or patient” (section 503(e)(4) of the FD&C Act). Section 503(e)(4)(C) excludes from the definition of *wholesale distribution*, “the distribution of a drug or an offer to distribute a drug for emergency medical reasons, including a public health emergency declaration pursuant to section 319 of the Public Health Service Act, except that . . . a drug shortage not caused by a public health emergency shall not constitute an emergency medical reason.”

stolen, or otherwise harmful.

III. Scope of the Exemption and Exclusion During the COVID-19 Public Health Emergency

A. DSCSA Statutory Exemption and Exclusion for Public Health Emergency

The declaration of the COVID-19 public health emergency pursuant to section 319 of the PHS Act automatically triggered two statutory provisions in the FD&C Act under which, for the duration of the declaration, certain DSCSA requirements do not apply to a range of product distribution activities to address the public health emergency.⁸ These automatically-triggered statutory provisions are as follows:

- the *exemption* of certain product distribution activities from the definition of *transaction* under FD&C Act section 581(24); and
- the *exclusion* of certain product distribution activities from the definition of *wholesale distribution* under FD&C Act section 503(e)(4).

As a result of this statutory exemption and exclusion, the DSCSA requirements described below in sections III.A (1) and (2) do not apply to the following types of product distribution activities conducted during the COVID-19 public health emergency:

- the distribution of *covered COVID-19 products*, as defined in section III.B below, to address the public health emergency; and
- certain distribution activities, with respect to other affected products, which are directly impacted by the COVID-19 public health emergency and which meet emergency medical needs, as described in section III.C below.

FDA interprets the above exemption and exclusion to apply to product distributed to address the COVID-19 public health emergency during the public health emergency, including product that was already in distribution in the supply chain at the time the COVID-19 public health emergency was first declared. We note that neither the exemption nor the exclusion applies to a drug shortage unless it is caused by the public health emergency.⁹

(1) Exemption from Certain Product Tracing and Product Identification Requirements Under Section 582 of the FD&C Act

Because the statutory definition of *transaction* explicitly exempts the distribution of “a product for emergency medical reasons including a public health emergency declaration pursuant to section 319 of the [PHS] Act,” the product tracing and product identification requirements in section 582

⁸ See sections 581(24)(B)(iii) and 503(e)(4)(C) of the FD&C Act.

⁹ *Id.*

Contains Nonbinding Recommendations

of the FD&C Act that are triggered by a “transaction” do not apply to distribution activities that address the COVID-19 public health emergency during the COVID-19 public health emergency.¹⁰ This means that trading partners engaging in (a) the distribution of covered COVID-19 products (as defined in section III.B below) or (b) distribution activities directly impacted by the COVID-19 public health emergency (as described in section III.C below) are not required to comply with the product tracing and product identification requirements in section 582 of the FD&C Act that are triggered by a “transaction” during the COVID-19 public health emergency.

However, if a trading partner is distributing product during the COVID-19 public health emergency for purposes other than emergency medical reasons then that trading partner must comply with all applicable DSCSA requirements with respect to distribution of such product. In the context of COVID-19, the exemption provided under the *transaction* definition is limited to distributions of product for emergency medical reasons during the COVID-19 public health emergency.

The exemption described above does not extend to the DSCSA requirements under section 582 of the FD&C Act that are not triggered by a “transaction.” For example, it does not extend to the requirements for applicable valid registration with FDA,¹¹ licensure for authorized trading partners,¹² or verification,¹³ including quarantine and investigation of suspect product¹⁴ and quarantine and disposition of illegitimate product.¹⁵ As a result, the DSCSA verification requirements remain operative (except for wholesale distributors conducting activities described in section (2) below). The DSCSA verification requirements assist trading partners in detecting if a suspect or illegitimate product has entered the supply chain and call for a proper response when such product is found in the supply chain.

¹⁰ See section 581(24)(B)(iii) of the FD&C Act. As noted above, this section specifies that “a drug shortage not caused by a public health emergency” does not constitute an emergency medical reason.

¹¹ Manufacturers and repackagers must have a valid registration in accordance with section 510 of the FD&C Act in order to be considered authorized trading partners under the DSCSA. See section 581(2) of the FD&C Act.

¹² *Authorized* is defined in section 581(2) of the FD&C Act. For authorized trading partner requirements, see section 582(b)(3), (c)(3), (d)(3), and (e)(3) of the FD&C Act. During the COVID-19 public health emergency, a wholesale distributor engaged in the distribution of a product for emergency medical reasons would not meet the definition of *wholesale distributor* under the DSCSA and would not be required to be an authorized trading partner or comply with the authorized trading partner requirements under the DSCSA solely with respect to the distribution of products for such emergency medical reasons. For its distribution of all other products during the COVID-19 public health emergency, the entity meeting the definition of *wholesale distributor* under the DSCSA would be required to be an authorized trading partner and comply with the authorized trading partner requirements.

¹³ For verification requirements, see section 582(b)(4), (c)(4), (d)(4), and (e)(4) of the FD&C Act. During the COVID-19 public health emergency, a wholesale distributor engaged in the distribution of a product for emergency medical reasons would not meet the definition of *wholesale distributor* under the DSCSA and would not be required to comply with verification requirements under the DSCSA with respect to the distribution of products for such emergency medical reasons. For its distribution of all other products during the COVID-19 public health emergency, the entity meeting the definition of *wholesale distributor* under the DSCSA would be required to comply with the DSCSA verification requirements.

¹⁴ *Suspect product* is defined in section 581(21) of the FD&C Act.

¹⁵ *Illegitimate product* is defined in section 581(8) of the FD&C Act.

(2) Exclusion from Wholesale Distribution Under Section 503(e) of the FD&C Act

The statutory definition of *wholesale distribution* under section 503(e)(4) of the FD&C Act explicitly excludes “the distribution of a drug . . . for emergency medical reasons, including a public health emergency declaration pursuant to section 319 of the [PHS] Act.”¹⁶ As a result, DSCSA requirements related to *wholesale distribution* do not apply to distribution activities that address the COVID-19 public health emergency during the COVID-19 public health emergency. This means that entities engaging in (a) the distribution of covered COVID-19 products (as defined in section III.B below) or (b) certain distribution activities directly impacted by the COVID-19 public health emergency (as described in section III.C below) are not required to comply with the DSCSA’s licensure provisions and reporting requirements under section 503(e) of the FD&C Act or the wholesale distributor requirements under section 582 of the FD&C Act during the COVID-19 public health emergency. We do not interpret the exclusion from *wholesale distribution* for emergency medical reasons, including a public health emergency declaration pursuant to section 319 of the PHS Act, to affect the ability of States to require licensure of such entities as wholesale distributors under State law.

During the COVID-19 public health emergency, if an entity is engaged in activities that meet the definition of *wholesale distribution* but such activities are not for emergency medical reasons then that entity would be a wholesale distributor with respect to such activities and would need to comply with sections 503(e) and 582(c) of the FD&C Act for the distribution of the products involved. In the context of COVID-19, the exclusion provided under the *wholesale distribution* definition is limited to those distributions of product for emergency medical reasons during the COVID-19 public health emergency.

B. Distribution of Covered COVID-19 Products for COVID-19 Under the Public Health Emergency Declaration

The definitions of *transaction* and *wholesale distribution* under the DSCSA exempt and exclude the distribution of a product for emergency medical reasons, including a public health emergency declaration pursuant to section 319 of the PHS Act. During the COVID-19 public health emergency, FDA interprets the exemption and exclusion to cover the distribution of prescription drug products either (a) issued an emergency use authorization under section 564 of the FD&C Act (21 U.S.C. 360bbb-3) to combat COVID-19¹⁷ or (b) approved by FDA to diagnose, cure, mitigate, treat, or prevent COVID-19. For the purposes of this guidance, we refer to these products collectively as *covered COVID-19 products*. Entities engaged in the distribution of covered COVID-19 products during the COVID-19 public health emergency should maintain the security of the supply chain as these products are distributed to address the urgent public health need. To the extent that compliance with DSCSA requirements covered by an exemption or exclusion is not a barrier to timely distribution of covered COVID-19 products, entities should continue to comply

¹⁶ See section 503(e)(4)(C) of the FD&C Act.

¹⁷ See FDA webpage for emergency use authorizations at <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization>.

Contains Nonbinding Recommendations

with those requirements during the COVID-19 public health emergency.

C. Distribution of Other Products Affected by the COVID-19 Public Health Emergency

During the COVID-19 public health emergency, and based on the unique circumstances and unprecedented disruptions caused by this emergency, FDA also interprets the *transaction* exemption and *wholesale distribution* exclusion to extend to the distribution¹⁸ of other affected products in certain circumstances. Specifically, in the particular context of the COVID-19 public health emergency, these circumstances exist where (1) an entity is engaging in distribution activities directly impacted by the COVID-19 public health emergency, as described in the examples below, and (2) the distribution activities are for emergency medical reasons, including to treat symptoms of COVID-19. Examples of situations where the COVID-19 public health emergency could directly affect distribution of other affected product for emergency medical reasons could include the following:

- a. Distribution of a product to an area where there is limited availability locally of such product and there is higher demand for such product in that region as a result of COVID-19, for example because the drug treats symptoms of COVID-19 or is used to provide supportive care to those with severe cases of COVID-19.
- b. Distribution of a product by an authorized trading partner that needs to establish a new, temporary facility for distribution during the COVID-19 public health emergency as a result of the direct impact COVID-19 had on the operating capabilities of the original facility, such as if the original facility is located in a State or local jurisdiction which has a very high number of reported COVID-19 cases (hot zone) or a rapidly accelerating number of COVID-19 cases.
- c. Dispenser-to-dispenser transfers of products that are needed as a result of COVID-19, regardless of whether there is a specific patient need.¹⁹

To the extent that compliance with DSCSA requirements covered by an exemption or exclusion is not a barrier to timely distribution of other affected products under the circumstances described above during the COVID-19 public health emergency, entities should continue to comply with those requirements during the COVID-19 public health emergency.

D. Authorized Trading Partner Requirements – Compliance Policy During the COVID-19 Public Health Emergency

¹⁸ See section 581(5) of the FD&C Act (defining *distribute* or *distribution*).

¹⁹ *Specific patient need* is defined as the transfer of a product from one pharmacy to another to fill a prescription for an identified patient (section 581(19) of the FD&C Act). This term does not include the transfer of a product from one pharmacy to another for the purpose of increasing or replenishing stock in anticipation of a potential need.

Contains Nonbinding Recommendations

Although the requirements to trade only with authorized trading partners²⁰ still apply in most circumstances during the COVID-19 public health emergency, FDA generally does not intend to take enforcement action against trading partners during the COVID-19 public health emergency for engaging in either of the following activities:

- COVID-19-related distribution involving entities that would otherwise meet the definition of *wholesale distributor* under the DSCSA, except that—as a result of the exclusion from the definition of *wholesale distribution* for emergency medical reasons—these entities would not be considered wholesale distributors because they are currently engaged in distributing product for emergency medical reasons resulting from COVID-19.
- Distributions involving other trading partners that are not authorized solely because of circumstances directly related to the COVID-19 public health emergency, but are working with or have been permitted by respective State authorities to operate during the COVID-19 public health emergency, if compliance with the authorized trading partner requirements under the DSCSA would pose a barrier to timely distribution of needed products during the COVID-19 public health emergency.

E. Time Frame

The policies described in this guidance, including the compliance policy and exemption and exclusion from certain DSCSA requirements, apply only during the COVID-19 public health emergency. The COVID-19 public health emergency will last until the HHS Secretary declares that the public health emergency no longer exists or until it expires 90 days after the date of a COVID-19 public health emergency determination, whichever occurs first.²¹ The HHS Secretary may extend the COVID-19 public health emergency determination for subsequent 90-day periods for as long as the public health emergency related to COVID-19 continues to exist.²²

IV. Business With Trusted Trading Partners

Some people and companies are trying to profit from the COVID-19 pandemic by selling unproven and illegally marketed products with false claims, such as claims that the products are effective in the diagnosis, treatment, or prevention of COVID-19. Some of these products may result in serious adverse health consequences. Wherever possible, trading partners should engage in transactions of product with trusted sources. Trading partners should ensure that their trading partners are

²⁰ For authorized trading partner requirements, see section 582(b)(3), (c)(3), (d)(3), and (e)(3) of the FD&C Act. For example, section 582(b)(3) states that beginning not later than January 1, 2015, “the trading partners of a manufacturer may be only authorized trading partners.”

²¹ See section 319(a)(2) of the PHS Act.

²² *Id.*

Contains Nonbinding Recommendations

appropriately licensed or registered by checking with FDA²³ and State authorities²⁴ for confirmation or assurance that the trading partner being considered is actively working with the relevant authorities to operate during the COVID-19 public health emergency. FDA cautions trading partners from obtaining product from nontraditional sources that are not known, trusted sources for product. Buying drugs from unknown sources could put patients at risk of receiving drugs that may be ineffective or harmful such as counterfeit, stolen, diverted, or intentionally adulterated products.

As noted in the discussion of DSCSA verification requirements above,²⁵ trading partners in most circumstances remain obligated to take appropriate steps when suspect or illegitimate products are found to ensure that these products are not further distributed and do not reach patients. Verification steps include quarantine and investigation of suspect product, quarantine and disposition of illegitimate product, and notification to FDA and other trading partners of illegitimate product. Trading partners should refer to the following guidance for more recommendations about complying with the DSCSA verification requirements,²⁶ and they may also wish to review these additional draft guidances²⁷ for further information:

- *Guidance for Industry, Drug Supply Chain Security Act Implementation: Identification of Suspect Product and Notification* (Dec. 2016), which provides recommendations for identifying a suspect product and describes the process for submitting required notifications of illegitimate product to FDA and how to terminate these notifications in consultation with FDA.
- *Draft Guidance for Industry, Verification Systems Under the Drug Supply Chain Security Act for Certain Prescription Drugs* (Oct. 2018), which describes FDA's draft interpretation of the requirements of section 582 of the FD&C Act regarding verification systems.
- *Draft Guidance for Industry, Definitions of Suspect Product and Illegitimate Product for Verification Obligations Under the Drug Supply Chain Security Act* (March 2018), which describes FDA's draft interpretations of the terms used in the definitions of suspect product and illegitimate product in order to assist trading partners to identify suspect and illegitimate products in the drug distribution system.

²³ See FDA webpage for wholesale distributor and third-party logistics providers reporting at <https://www.accessdata.fda.gov/scripts/cder/wdd3plreporting/index.cfm>. See also FDA's Drug Establishments Current Registration Site for manufacturers and repackagers at <https://www.accessdata.fda.gov/scripts/cder/drls/default.cfm>.

²⁴ See FDA webpage listing U.S. State agencies responsible for licensing wholesale distributors at <https://www.fda.gov/drugs/drug-supply-chain-integrity/verify-wholesale-drug-distributor-licenses>.

²⁵ For verification requirements, see section 582(b)(4), (c)(4), (d)(4), and (e)(4) of the FD&C Act.

²⁶ We update guidances periodically. For the most recent version of the guidance, check the FDA guidance web page at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>.

²⁷ When finalized, these guidances will represent FDA's current thinking on the issues addressed therein.