June 24, 2019

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Connie T. Jung, R.Ph., PhD
Senior Advisor for Policy
Office of Drug Security, Integrity, and Recalls
Office of Compliance
Center for Drug Evaluation and Research
Food and Drug Administration
Room 2242, White Oak Office Building 51
10903 New Hampshire Avenue
Silver Spring, MD 20993
connie.jung@fda.hhs.gov

Peter Fox
Regulatory Counsel
Office of Regulatory Affairs
Food and Drug Administration
12420 Parklawn Dr., Element Building, Rm. 4146
Rockville, MD 20857
Peter.Fox@fda.hhs.gov


Dear Doctor Jung and Mr. Fox:


1. About HDA

HDA represents primary pharmaceutical distributors — the vital link between the nation’s pharmaceutical manufacturers and pharmacies, hospitals, long-term care facilities, clinics and others nationwide. Since 1876, HDA has helped members navigate regulations and innovations to get the right medicines to the right patients at the right time, safely and efficiently. The HDA Research Foundation, HDA’s non-profit charitable foundation, serves the healthcare industry by providing research and education focused on priority healthcare supply chain issues.

2. The Role Of Wholesale Distributors In Recalls

HDA commends FDA for the issuance of the Recall Draft Guidance and the clarity and assistance it offers to recalling firms and their trading partners. Though wholesale distributors are not, typically, the firm initiating the recall, they are critically important to execution of effective recalls.
HDA’s primary wholesale distributors purchase pharmaceuticals, medical devices, dietary supplements, health and beauty aids, and other FDA-regulated products from manufacturers, warehouse these products, and then, in turn, sell and distribute them to healthcare providers for dispensing and administration to patients and to retail outlets for resale to consumers. As a result, a manufacturer must rely upon the wholesale distributor to notify downstream buyers when a recall extends beyond the wholesale level.

Wholesale distributors are critical to the success of recalls and HDA’s members all have business processes and procedures for their execution. There are processes for receiving and handling recall notices, conducting shelf checks and removing recalled product from inventory, searching distribution records to determine which customers might have received product subject to a recall, and then providing the recalling firm’s notice downstream to trading partners. As the entity that sold the recalled product to a healthcare or retail customer, wholesale distributors can also play an important role in receipt of, accounting for, and dispositioning of recalled product as provided for in the recalling entity’s recall notification. The wholesale distributor also reports on recall notifications so that the recalling firm can satisfy its effectiveness checks obligations. Recalling firms and the FDA rely upon wholesale distributors to help provide product counts of the number of recalled products that were received, are still in inventory, were sold, and, where provided for in the recall strategy, the number of recalled products returned.

As a consequence of being such an important part of recalls of FDA-regulated products, wholesale distributors are very interested in the Recall Draft Guidance. In substantial part, we support the Recall Draft Guidance and offer no suggested changes to it. However, we are concerned with overly broad language in two parts of Section III.A.1. and recommend clarification to assure that the expectations for regulated industry in recalls are consistent with important legal requirements under the federal Food, Drug and Cosmetic Act (FDC Act). We believe that the Recall Draft Guidance, as currently drafted, could be interpreted as – unintentionally and impermissibly – accelerating and even contradicting important statutory deadlines and obligations. We conclude with a brief legal discussion of potential consequences to the Recall Draft Guidance’s interpretations of the requirements of 21 C.F.R. Part 7, Subpart C.

3. The Drug Supply Chain Security Act And Its Future Impact Upon Recalls

a. The DSCSA

The Drug Supply Chain Security Act (DSCSA), signed into law on November 27, 2013, amends the FDC Act to incrementally build a system for the electronic interoperable tracing of certain prescription drug products at the package level over a period of ten years. An early step to achieving full traceability is that each package and homogenous case of covered prescription drug product must bear a product identifier. The product identifier is a standardized graphic in human-readable form and

1 See, e.g., FDA’s DSCSA Implementation Plan available here (accessed June 2, 2019).

2 § 582(b)(2) (product identifier requirement for manufacturers); § 582(c)(2) (product identifier requirement for repackagers).
on a machine-readable carrier that conforms to international standards and includes the product’s unique standardized numerical identifier (SNI), lot number and expiration date.\(^3\)

A second significant milestone in the 10-year march to prescription product traceability is that, under § 582, purchasers of covered products must receive and maintain, and those who sell to anyone other than a patient must also provide and maintain, product tracing data about each DSCSA-covered product transaction, that is, each purchase and sale.\(^4\) The product tracing data to be received, maintained and, as applicable, provided, includes “transaction information” or “TI.” At the present time, TI includes:

- the proprietary or established name or names of the product;
- the strength and dosage form of the product;
- the National Drug Code number of the product;
- the container size;
- the number of containers;
- the lot number of the product;
- the date of the transaction;
- the date of the shipment, if more than 24 hours after the date of the transaction;
- the business name and address of the person from whom ownership is being transferred; and
- the business name and address of the person to whom ownership is being transferred.\(^5\)

Selling and purchasing trading partners must maintain this product tracing data for six years.\(^6\)

There are important limitations upon the TI a trading partner must provide. At this time, the product’s unique identifier is not included with TI. The FDC Act also explicitly exempts a wholesale distributor from providing a drug product’s lot number to a downstream customer if it purchased the product from the manufacturer, the manufacturer’s exclusive distributor, or a repackager that purchased directly from the manufacturer.\(^7\)

Though they do not have to do so yet, trading partners will have to add the product identifier (which includes the lot number as one of the values embedded within it) to the TI tracing data they

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\(^3\) § 581(14) (definition of product identifier); § 581(20) (definition of SNI).

\(^4\) § 582(b)(1) (manufacturers); § 582(c)(1) (wholesale distributors); § 582(d)(1) (dispensers – who must receive and maintain TI but do not have to provide it when dispensing to patients); § 581(e)(1) (repackagers).

\(^5\) § 581(25) (definition of TI).

\(^6\) See, e.g., § 582(c)(1)(v)(I) (wholesale distributors must maintain transaction data for six years from the date of the transaction).

\(^7\) §582(c)(1)(A)(ii)(II) states: “For purposes of transactions described in subclause (I) [that is, sales from a direct purchase wholesale distributor], transaction history and transaction information shall not be required to include the lot number of the product, the initial transaction date, or the initial shipment date from the manufacturer (as defined in subparagraphs (F), (G), and (H) of section 581(26))” (emphasis supplied).
provide beginning November 27, 2023. By November 27, 2023, it will then be possible to identify, for each and every covered prescription product, the transaction in which a trading partner acquired the product, and, if it sold the product, who purchased the product, and when. FDA and industry believe that these 10 years of arduous and expensive supply chain work to implement product tracing will aid enormously in recall administration and effectiveness.

b. The Draft Recall Guidance Is Not Aligned With DSCSA Requirements

The Draft Recall Guidance recognizes one part of the DSCSA by noting that human prescription drug products generally use a “product identifier” which will “make possible positive lot identification and … facilitate the effective recall of all violative lots.” Lines 109-113. Beyond this, however, the Recall Draft Guidance does not address the DSCSA, or appear to acknowledge that it will take 10 years of incremental steps to implement full traceability of covered prescription pharmaceuticals. Specifically, it appears that certain interpretations of 21 C.F.R. Part 7, Subpart C set out in the product coding and distribution records provisions in Section III.A.1. of the Draft Recall Guidance do not align with the statutory requirements of the FDC Act as amended by the DSCSA. We explain below our concerns that the Recall Draft Guidance interprets 21 C.F.R. Part 7, Subpart C in a manner that substantially and impermissibly accelerates the timetable of DSCSA implementation.

4. Lines 108-115, Product Coding

Lines 108-115 of the Recall Draft Guidance state (citations and footnotes omitted):

Use adequate product coding. While many products have specific product coding requirements — e.g., human prescription drug products generally use a “product identifier,” … — whether required or not, firms should use sufficient coding of regulated products to make possible positive lot identification and to facilitate the effective recall of all violative lots. (21 CFR 7.59(b)). The coding used should allow for identification of the production and control data created for each lot, batch, or unit.

We have several concerns with this language. First, we urge more precision in the human prescription drugs discussion than “generally use a ‘product identifier’” as the language currently does not acknowledge that there are many prescription drugs under the FDC Act that do not, at this time, bear a product identifier. Further, there are many prescription drugs that are not required to bear a product identifier at all. As discussed above, though manufacturers were required to affix the product identifier beginning November 27, 2013,10

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8 “On the date that is 10 years after [November 27, 2013] … [the] transaction information required under this section shall include the product identifier at the package level for each package included in the transaction.” § 582(g)(1)(B).

9 One important exception is that pharmacies, hospitals, and other healthcare providers (collectively “dispensers”) do not have to trace their dispensing of products to patients. See e.g., § 581(24)(B)(iv) (dispensing of a product pursuant to a prescription is not a covered “transaction”).

10 The product identifier on a covered prescription drug is a standardized graphic in human-readable form and on a machine-readable carrier that conforms to international standards and includes the product’s unique standardized numerical identifier (SNI), lot number and expiration date. § 581(14) (definition of product identifier); § 581(20) (definition of SNI).
identifier to products and homogenous cases beginning November 27, 2017, FDA exercised enforcement discretion and extended the compliance date for a year. Moreover, certain classes of pharmaceuticals are excluded from the product identifier requirement, and many others do not bear an identifier because they are “grandfathered” or are subject to a waiver, exception or exemption.

This lack of specificity in the Recall Draft Guidance is particularly concerning because the draft includes the phrase, “whether required or not, firms should use sufficient coding…” to assure “positive lot identification and to facilitate the effective recall of all violative lots.” This language implies that FDA is interpreting 21 C.F.R. Part 7, Subpart C to require all firms to uniquely identify all FDA-regulated products even though the FDC Act does not require it. We note that mandates to code products with unique identifiers have required acts of Congress and amendments to the FDC Act. We are, therefore, skeptical that FDA could interpret 21 C.F.R. Part 7, Subpart C as requiring all other FDA-regulated products, such as foods, dietary supplements, over-the-counter drugs, and other DSCSA-exempted products, to bear unique product codes. Though we focus here on prescription drugs, the difficulties the Recall Draft Guidance poses for other FDA regulated products would be equally challenging.

Given these concerns, we recommend the following changes to Lines 108-115:

- Expressly recognize in footnotes to this section that some products are exempt from specific coding requirements, including citation to the relevant exemptions and exceptions. For example, for the human prescription drug product identifier, a footnote could recognize that some products are not required to bear a product identifier, including grandfathered products, products subject to an applicable waiver, exception, or exemption, and certain product categories.

- Change Lines 108-115 as follows, with relevant additions in blue bold and deletions in red strikeout:

  Use adequate product coding. While many Many products have specific product coding requirements to uniquely identify the product at the unit/package level — e.g., human prescription drug products generally use a “product identifier,” …—whether required or not, firms There are products that do not have unit-level product coding requirements or are exempt from them. Firms should use sufficient coding of regulated products to make possible positive lot identification and to facilitate the effective recall of all violative lots. (21 CFR 7.59(b)). When required under the FD&C Act, the The coding used should allow for be consistent with the FD&C Act


13 See, e.g., § 519(f), that directs FDA to issue regulations establishing a unique device identification system for medical devices; § 582, establishing requirement that manufacturers and repackagers affix a product identifier to human prescription drug “products” as that term is defined.
and FDA’s implementing regulations, including identification of the production and control data created for each lot, batch, or unit as applicable.

5. **Lines 122-136**

Lines 122-136 of the Recall Draft Guidance state (citations and footnotes omitted):

Maintain distribution records. While certain products have specific requirements related to the maintenance of distribution records, e.g., distribution requirements for finished medical devices, product tracing requirements for certain human prescription drug product transactions, … distribution records should be maintained by the recalling firm to facilitate the location of products being recalled. These records should be retained for a period of time that exceeds the shelf life and expected use of the product and is at least the length of time specified in other applicable regulations concerning records retention. (21 CFR 7.59(c)). Distribution records should include enough detail to identify the consignees that actually received the recalled product and must conform with any applicable requirements. Direct accounts that further distribute the product should also maintain records of their consignees that actually received the product, to ensure that the recalling firm’s instructions are extended to all consignees in the distribution chain.

We believe this language could be construed as interpreting 21 C.F.R. Part 7, Subpart C to require that wholesale distributors be able, at this time, to identify, by product identifier and/or lot number, each covered prescription drug product a customer purchased.

a. **The Draft Recall Guidance should not set forth interpretations of DSCSA requirements that wholesale distributors are not legally obligated to comply with until 2023**

As discussed in Section 3 above, new specifications for the product identifier (comprised of a serialized numerical identifier, lot and expiration date) become effective on November 27, 2023. Specifically, unless otherwise exempt, the product identifier, which uniquely identifies each applicable prescription product package and homogenous case of applicable product must be included in the product tracing data that each owner of the product provides to the subsequent owner.

The discussion that follows is specifically limited to “product,” “applicable product” or “covered product” as “product” is defined in § 581 of the FDC Act, as amended by the DSCSA. For purposes of the DSCSA, a “product” is, subject to certain exclusions, “a prescription drug in a finished dosage form for administration to a patient without substantial further manufacturing (such as capsules, tablets, and lyophilized products before reconstitution)…” We have concerns with the Draft Recall Guidance to

14 See § 581(14) (definition of product identifier); § 581(20) (definition of standardized numerical identifier); Product Identifier Requirements Under the Drug Supply Chain Security Act – Compliance Policy, Final Guidance for Industry (September 2018) available here (accessed June 20, 2019).

15 § 582(g)(1)(B).

16 § 581(13).
the extent that it impacts DSCSA-imposed legal requirements as to these covered “products” and, unless otherwise specified, the discussion below does not include other FDA-regulated products.

The FDC Act is explicit that trading partners do not have to begin providing and storing product identifier information in transaction (that is, sales) data until November 27, 2023. The FDC Act also dictates that, in the interim, the lot number of the covered product sold is not part of the data that a direct purchase wholesale distributor must provide to a customer; and so, is similarly not yet part of the sent product tracing information that the wholesale distributor must currently capture and maintain for six years.

We are concerned that the Recall Draft Guidance sets out an interpretation of 21 C.F.R. Part 7, Subpart C that wholesale distributors should, at this time, be maintaining product identifier and specific lot number data for each covered product they sell to downstream customers. The FDC Act does not require this of wholesale distributors until November 27, 2023. In this light, the Recall Draft Guidance is, essentially and impermissibly, speeding up the timeline explicitly set out and built in the FDC Act as amended by the DSCSA.

b. Even if the Recall Draft Guidance could accelerate the statutory timeline set out in the DSCSA, the burdens upon wholesale distributors would be immense and could not be implemented at this time

The DSCSA’s incremental approach to full product traceability is critically important given the enormous volume of pharmaceutical products being sold and purchased in the supply chain every day. A typical HDA member distribution center has tens of thousands of different FDA-regulated products in inventory from over 1,000 different manufacturers. Millions of prescription medicines and healthcare products are delivered by HDA members every day to nearly 200,000 licensed pharmacies and other healthcare settings.

Capturing, maintaining, and providing lot numbers for each of these individual covered product transactions would be a laborious process that could only be done manually, one unit at a time. Each product would have to be inspected manually to locate the lot number since there is no automated method to capture this information today and lot numbers are not standardized in either a human- or machine-readable format. The lot number, usually a complex string of alphanumeric characters varying in such features as length and character order/placement, would then have to be manually entered into the transaction data the DSCSA requires and into internal databases for storage. Direct purchase wholesale distributors do not believe this task can be accomplished at this time without severe impacts to the delivery of needed medicines to patients and healthcare professionals.

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17 “On the date that is 10 years after [November 27, 2013] … [the] transaction information required under this section shall include the product identifier at the package level for each package included in the transaction.” § 582(g)(1)(B).

18 §582(c)(1)(A)(ii)(II); § 582(c)(1)(v)(I).

19 Because wholesale distributors follow good inventory management and practices, they are able to execute manufacturer-initiated recalls of specific lots. This is true for both DSCSA-covered prescription drug products and other FDA-regulated products.
It is because of these severe impacts to operations and patient access to needed medicines that Congress appropriately and intentionally did not require direct purchase wholesale distributors to provide or maintain lot numbers in transaction data until November 27, 2023 when they will be embedded in the product identifier and provided as part of the transaction data.

Further, wholesale distributors are undertaking considerable efforts to operationalize this DSCSA requirement so that they are able to scan, read, store, and provide the product identifier by 2023. Wholesale distributors must buy and program scanners to read the product data embedded in the identifier and assure the accuracy of product scanning. They must develop and test systems and processes and train employees on them. They must also build databases to store scanned product identifiers and develop the process for adding the identifier to the tracing data that must be provided to the buying customer. The buying customer also must be able to receive product identifier data even if the wholesale distributor is able to include it.

For the foregoing reasons, we have grave concerns with a guidance document that interprets 21 C.F.R. Part 7, Subpart C as requiring wholesale distributors to provide or maintain product identifiers and lot numbers in distribution records, except as otherwise required under § 582 and under the timeline the FDC Act mandates.

We note further that the lack of standardization of lot numbers and the inability to easily scan and store them pose traceability challenges for all FDA-regulated products, not just those covered by the DSCSA. We do not believe that it is possible to trace most FDA-regulated items (OTC drugs, foods, cosmetics) from wholesale distributor to retailer to customer without a unique bar code affixed to each item that includes the lot number and the ability to scan and store that bar code data at the time the item is sold.

Our recommended changes to Lines 122-136 follow, with additions in blue bold and deletions in red strikeout.

Maintain distribution records. While certain products have specific requirements related to the maintenance of distribution records, e.g., distribution requirements for finished medical devices, product tracing requirements for certain human prescription drug product transactions, … distribution records should be maintained by the recalling firm to facilitate the location of products being recalled. These records should be retained for a period of time that exceeds the shelf life and expected use of the product and is at least the length of time specified in other applicable regulations and legislation concerning records retention. (21 CFR 7.59(c) or the FD&C Act and implementing regulations, as applicable.) Distribution records should include enough detail to identify the consignees that may have actually received the recalled product and must conform with any applicable requirements. Direct accounts that further distribute the product should also maintain records of their consignees that may have actually received the product, to ensure that the recalling firm’s instructions are extended to all consignees in the distribution chain. Firms are not required to maintain records that are not required to be produced or maintained under the FD&C Act.
6. **FDA should not be able to impose extra-statutory obligations via guidance**

As discussed above, we are concerned with Section III.A.1. of the Recall Draft Guidance to the extent its interpretations of 21 C.F.R. Part 7, Subpart C appear to expand wholesale distributor obligations beyond those required in the FDC Act and even contradict other requirements of the Act as amended by the DSCSA. Below, we discuss our views as to why the agency may not impose extra-statutory burdens.

- The Recall Draft Guidance should not be construed in any way as establishing requirements for industry. It is a draft and, even when finalized, is intended to be non-binding and is interpreting a policy regarding a voluntary activity. Nevertheless, we are concerned because regulated industry takes even draft guidances very seriously and any deviation from a draft guidance is undertaken very cautiously. The experience of wholesale distributors, which are licensed, regulated, and inspected by state regulatory and other authorities, is that such authorities treat even FDA’s draft guidances as highly authoritative and even binding. For these reasons, we recommend swift clarification of the Recall Draft Guidance’s limited effect and that it should not be construed as over-riding, replacing or accelerating explicit statutory requirements.

- FDA may not interpret 21 C.F.R. Part 7, Subpart C in a manner that is inconsistent with the FDC Act. A court will review an agency’s interpretation of a statute under *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984) (*Chevron*). Under *Chevron*, the court must first determine whether Congress has spoken directly to the “precise question at issue.” 467 U.S. at 842-43. If it has, “the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress.” *Id.* As discussed above, § 582 is unambiguous in its requirements regarding product identifiers, specifying what they are, when they must be affixed, and what products must bear them. Section 582 is equally clear what distribution data wholesale distributors must maintain and when they must do so. Congress has spoken to the precise questions at issue here. The Recall Draft Guidance’s interpretation of 21 C.F.R. Part 7, Subpart C as requiring product coding and maintenance of distribution records that are inconsistent with the FDC Act would be arbitrary and capricious, an abuse of discretion, and not in accordance with law.20

- The FDC Act as amended by the DSCSA sets out specific requirements regarding product coding and records of distribution for wholesale distributors. The Recall Draft Guidance, on the other hand, seems to derive its authority from the general provisions of 21 C.F.R. Part 7, Subpart C. We do not believe the agency may use these more general provisions to impose new, additional requirements when the statute so specifically enumerates what a wholesale distributor must do and when.21

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• As compliance with interpretations of 21 C.F.R. Part 7, Subpart C set out in the Recall Draft Guidance would impose extensive new paperwork burdens as well as extra-statutory requirements upon wholesale distributors, we believe the agency would be required to submit this proposal to the Office of Management and Budget (OMB) in order to satisfy its statutory obligations under the Paperwork Reduction Act and any applicable Executive Orders. To our knowledge, OMB did not review or clear these additional paperwork burdens or have the opportunity to review the costs that would likely result from following the guidance as drafted.

• While our focus is on prescription products covered by the DSCSA, we note that the Recall Draft Guidance interprets 21 C.F.R. Part 7, Subpart C as requiring product coding and maintenance of distribution records for all FDA-regulated products. We do not believe the agency may impose non-statutory burdens of mandatory coding and recordkeeping without undertaking formal rulemaking – all assuming that the agency has the statutory authority to impose these requirements by regulation in the first instance.

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In conclusion, we are committed to the continued efforts to keep the U.S. pharmaceutical supply chain secure. HDA largely supports the Recall Draft Guidance. However, we believe that the Recall Draft Guidance has, in some instances, indicated that wholesale distributors are obligated to undertake certain actions that are not supported in the law. We ask that FDA revise the Recall Draft Guidance to correct these misapprehensions.

Sincerely,

Anita T. Ducca
Senior Vice President, Regulatory Affairs