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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


Dear Dr. Jung:


HDA represents primary pharmaceutical distributors – the vital link between the nation’s pharmaceutical manufacturers and more than 200,000 pharmacies, hospitals, long-term care facilities, clinics and others nationwide. This essential function is provided with little public recognition or visibility, and at great savings to the healthcare system. HDA members serve as the central link in a sophisticated national supply chain. HDA members take this mission very seriously, and we support manufacturers, healthcare providers, and the government in ongoing efforts to ensure the U.S. medicine supply remains secure, efficient, and highly regulated.

HDA thanks FDA for issuing the Grandfathering Draft Guidance. We support the majority of the Grandfathering Draft Guidance and believe it will be an enormously helpful, clarifying aid in successful implementation of the Drug Supply Chain Security Act (“DSCSA”). We particularly appreciate that FDA conscientiously considered the concerns and positions of stakeholders set forth
in comments to the Draft Guidance and Compliance Policy, Product Identifier Requirements Under the Drug Supply Chain Security Act (“Product Identifier Compliance Policy”) 82 Fed. Reg. 30868 (July 3, 2017). Though distinct, the Grandfathering Draft Guidance and Product Identifier Compliance Policy both address when unserialized product may continue to be sold. We believe the Grandfathering Draft Guidance significantly improves upon the Product Identifier Compliance Policy.

Though HDA supports most of the Grandfathering Draft Guidance, we do have concerns discussed further below.

1. We ask the Agency to align the repackager and manufacturer provisions and permit repackagers to transfer ownership of unserialized product as long as it was packaged before November 27, 2018.

The Grandfathering Draft Guidance states:

if a repackager wishes to transfer ownership of a package or homogenous case of product without a product identifier on or after November 27, 2018, it must, in accordance with section 582(e)(2)(A)(i), first add a product identifier to the package or homogenous case of product.\(^1\)

Therefore, under the Grandfathering Draft Guidance, all product and homogenous cases a repackager sells after November 27, 2018 must bear a product identifier.

In contrast, a manufacturer may transfer ownership of unserialized product so long as it was packaged before November 27, 2018. See Grandfathering Draft Guidance at lines 151-153 (“A package or homogenous case of product that is not labeled with a product identifier shall be exempted from certain requirements in section (i.e., grandfathered) where there is documentation that it was packaged by a manufacturer before November 27, 2018.”).

HDA urges FDA to align the requirements for repackagers to those for manufacturers and to revise the operative date for grandfathering of unserialized product from the date of ownership transfer to the date the product was repackaged. The same arguments and practical realities that necessitated the “packaged by” grandfathering date for manufacturers are true for repackagers.

First, given inventory levels of unserialized product, repackagers report that they would already have to be serializing products to comply with a November 27, 2018 “sell” date. Repackagers are subject to the time and technology pressures that force manufacturers to delay conversion of packaging lines over to serialization. Further, given that both manufacturers and repackagers must transact only in serialized product after November 27, 2018, permitting manufacturers but not repackagers to use a “packaged” date for serialization means repackagers

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1 Draft Guidance at lines 260 – 263 (emphasis in original).
may have to begin serializing product even before manufacturers, which would appear contrary to the intent of the DSCSA.

Second, HDA elaborated upon the need for the “packaged before” date for serialization rather than “sold after” date in its comments on the Product Identifier Compliance Policy. HDA and our members support the approach long advocated by industry stakeholders that the key to determining when manufacturers must begin serializing packages lies in the date a product is “intended to be introduced in a transaction in commerce” (§ 582(b)(2)(A)), and this is the date of packaging. That same “intended to be introduced into a transaction in commerce” language appears in the repacker provisions of § 582(e)(2)(A) as well. Therefore, the statute supports the date of packaging as the operative date of grandfathering for both manufacturers and repackers.

Third, we explained in our previous comment that the focus upon the packaging date was consistent with FDA’s other product identifier initiatives, the Unique Device Identifier (UDI) regulation (21 C.F.R. Part 801, Subpart B), and the Bar Code Rule, 21 C.F.R. 201.25. See 78 Fed. Reg. 58786, 58798 (Sept. 24, 2013).

Additionally, we believe using different dating measures could pose significant operational challenges. It is far easier to do business if all unserialized product is treated in the same way and subject to the same business and grandfathering assumptions. It will be confusing and inefficient if, after November 27, 2018, a wholesaler would be able to purchase unserialized product from a manufacturer because it is grandfathered but not be able to purchase unserialized product from a repackager.

Further, repackaged product often is not easily distinguished operationally from product that is not repackaged. The lack of alignment between manufacturer and repackager grandfathering dates negates the careful consideration FDA gave to reliance upon the transaction statement (TS) when a trading partner receives unserialized product. This means that, contrary to the Grandfathering Draft Guidance at lines 159-164, trading partners would no longer be able to conclude that, absent other indicia, any unserialized product was packaged prior to November 27, 2018 and is grandfathered. We strongly urge one, single, seamless standard to avoid operational complexity and confusion.

For these reasons, and to assure that requirements for repackagers and manufacturers are aligned and consistent, we urge FDA to grant to repackagers the same flexibility that it provided to manufacturers and grandfather unserialized product based upon the date of packaging rather than the date of ownership change. In particular, HDA urges the Agency to modify the Draft Guidance as follows (deletions shown with a strikethrough).

Third, if a repackager initially repackaged and sold product without a product identifier before November 27, 2018, it is exempted from that part of section 582(e)(4)(C) of the DSCSA… [Lines 276-280]

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2 Our comments were submitted to Dkt. No. FDA-2017-D-2232 and are available here.
and

Repackagers are exempted from the requirements of 582(e)(2)(A)(i) and (e)(2)(A)(iii) to add product identifiers before redistributing such product if they initially repackaged and sold the product without a product identifier before November 27, 2018. [Lines 326 – 328.]

2. Imposition of the sold-after rather than packaged-by date for repackagers may have other repercussions.

Repackagers believe it is inequitable if they must begin serializing before manufacturers when, as discussed above, they are subject to the same operational pressures and difficulties as manufacturers that have necessitated enforcement discretion and a packaged-by grandfathering date. If the “sold-after” grandfathering date is imposed, repackagers will need to begin serializing much sooner than expected and may have difficulty converting their repackaging lines and retooling operations. Like manufacturers, repackagers may need to seek enforcement discretion and an extension of the November 27, 2018 serialization requirements. A consistent “packaged by” grandfathering date for repackagers and manufacturers might help minimize the need for a possible compliance date extension.

3. We ask the Agency to align the Grandfathering Draft Guidance and the Product Identifier Compliance Policy.

When it issued the Product Identifier Compliance Policy, FDA further stated that it would address, as it now has, grandfathering in a later guidance. Product Identifier Compliance Policy at lines 294-301. While recognizing that the Grandfathering Draft Guidance and the Product Identifier Compliance Policy serve different purposes, the Product Identifier Compliance Policy used the ownership change date rather than the packaging date for purposes of exercise of agency enforcement discretion regarding transacting with unserialized product. Unlike the Grandfathering Draft Guidance, the Product Identifier Compliance Policy also did not permit reliance upon the seller’s TS as “one indication that the product in the pharmaceutical distribution supply chain” had been packaged before November 27, 2018. Grandfathering Draft Guidance at lines 159-164.

We believe the positions set forth in the Grandfathering Draft Guidance are sound and that the alternative interpretations in the Product Identifier Compliance Policy introduce needless complexity and confusion. The Grandfathering Draft Guidance carefully considered and addressed the concerns stakeholders raised in their comments to the Product Identifier Compliance Policy and is, we believe, the better, clearer, and more implementable document. We believe the Grandfathering Draft Guidance sets out (with the repackager modification recommended above), a reasonable path for DSCSA implementation and the gradual introduction of serialized product into the supply chain. We ask that FDA reissue the Product Identifier Compliance Policy so that it aligns with the Grandfathering Draft Guidance.
4. HDA supports use of the TS as one indication of grandfathering status.

FDA states that “absent any other indicia that a product may be suspect or illegitimate, the [TS] is one indication that a product is grandfathered and in the pharmaceutical supply chain before [November 27, 2018].” (Grandfathering Draft Guidance at lines 159-164). HDA supports this language.

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HDA thanks FDA for this opportunity to comments and suggestions on FDA’s Grandfathering Draft Guidance. If you have any questions, please contact me at 703-885-0240 or at aducca@hda.org.

Sincerely,

Anita T. Ducca
Senior Vice President, Regulatory Affairs