June 8, 2015

Dr. Ilisa Bernstein
Deputy Director, Office of Compliance
Food and Drug Administration
10903 New Hampshire Avenue
Bldg. 51, Rm 5271
Silver Spring, MD 20993-0002

Re: DSCSA Guidance and Processes for Exceptions and Grandfathering

Dear Dr. Bernstein:

As you know, the Pharmaceutical Distribution Security Alliance (PDSA) is a coalition of companies and organizations dedicated to the safety and integrity of the pharmaceutical distribution supply chain. As you also know, Section 582(a)(3) of the Drug Supply Chain Security Act (DSCSA) requires the Agency to establish, by guidance, processes for granting waivers, exceptions, exemptions. Section 582(a)(5) also requires the Agency to issue guidance on grandfathering of certain products. The Agency is required to issue each of these guidances by November 27, 2015.

On May 14, 2015, PDSA submitted a letter to you outlining its initial recommendations with regard to exemptions and waivers in hope that those suggestions would be helpful to the Agency in developing the required guidances. In this letter we provide similar recommendations with regard to grandfathering and exceptions.

Exceptions

Section 583(a)(3)(ii) requires the Agency to "establish a process by which [it] determines exceptions, and a process through which a manufacturer or repackager may request such an exception, to the requirements relating to product identifiers if a product is packaged in a container too small or otherwise unable to accommodate a label with sufficient space to bear the information required for compliance with [section 582]." The process must include a biennial review and renewal of such exceptions.

Exceptions address unique situations in which packaging constraints make it difficult, impractical, or impossible to accommodate the product identifier required to be affixed under section 582(b)(2)(A). We do not expect exceptions to be common, and we anticipate that any exceptions will be granted on a manufacturer- (or repackager-) and package-specific basis.

PDSA believes the following principles will assist in developing an effective and reliable process for granting exceptions.

- The Agency should not require exception requests to be submitted on a standardized form. If there are certain types of information that the Agency will expect to accompany every request, it should clearly identify those categories of information. Each request will involve unique circumstances, and it is important that each requestor is able to tailor its request to the relevant situation.
- The Agency should commit to making a determination on all exception requests within 30 days. A timely, reliable process is critical. If an exception request is denied, a manufacturer or repackager may be required to change its packaging. The related regulatory approval process and the process of changing packaging operations can take a significant amount of time.
- The Agency should establish a clear review and/or appeal process for denied requests. Such process could be modeled after, or incorporated into, existing review and appeal processes.
- While we recognize that each request, and review of the merits of each request, will involve different considerations, we urge the Agency to identify by guidance the factors and considerations that it may take into account when reviewing an exception request. Such clarity and predictability will facilitate submission of all information the Agency needs to make an informed decision thereby streamlining the process and reducing the burden on both the Agency and the requestor.
- The transaction statement attests that a given transaction is compliant with the DSCSA, and thus is inherently an attestation (and source of confirmation to downstream trading partners) that the unserialized product may be legally moved through the supply chain (*i.e.*, the product identifier is excepted, grandfathered, or waived).

We believe each of these recommendations will help establish an efficient and effective process for receiving, reviewing, and granting exceptions.

Grandfathering

Section 582(a)(5) requires the Agency to "finalize guidance [by November 27, 2015] specifying whether and under what circumstances product that is not labeled with a product identifier and that is in the pharmaceutical distribution supply chain at the time of the effective date of the requirements of [section 582] shall be exempted from the requirements of this section." This provision effectively exempts unserialized product in the supply chain as of November 27, 2017 (or November 27, 2018 with respect to repackaged product) from the requirements related to serialized product.

PDSA members learned valuable lessons from the January 1, 2015 transition to DSCSA information exchange that can be applied to the transition to serialization.

- The Agency can provide flexibility in implementation without creating a security risk, safety concerns, or confusion in the marketplace.
- Transition rules should be simple and clear. Simplicity and clarity were essential to the successful transition to DSCSA information exchange.

- Transition rules should be tailored to avoid unnecessary and costly rework/repackaging of existing inventory, to minimize disruptions in the product movement, and to minimize return of good product.

The key to determining which products are grandfathered is defining the phrase "in the pharmaceutical supply chain." PDSA believes that determination should be tied to the date on which product is packaged. Specifically, we ask the Agency to clarify that any product packaged by a manufacturer prior to November 27, 2017 or repackaged by a repackager prior to November 27, 2018 is grandfathered. A homogenous case containing grandfathered product should also be grandfathered.

Use of the packaging date to determine whether product is grandfathered is critically important to an effective and efficient transition to serialization. Such an approach is an appropriate interpretation of the statute. The statutory obligation to serialize product requires a manufacturer or repackager, as of November 27, 2017 and 2018 respectively, to affix a product identifier to each package "intended to be introduced in a transaction into commerce." The phrase "intended to be introduced" indicates that the obligation applies at the point of packaging.

The date on which a product is packaged or repackaged is well-documented by the manufacturer or repackager and will allow the Agency to easily confirm, upon request, whether a product not affixed with a product identifier was grandfathered. The transaction statement attests that a given transaction is compliant with the DSCSA, and thus is inherently an attestation that unserialized product is grandfathered. The transaction statement will therefore confirm to downstream trading partners that any unserialized product may properly be moved through the supply chain. Additionally, the proposed approach will provide manufacturers and repackagers an opportunity to deplete inventory of product packaged or repackaged prior to November 27, 2017 and 2018, respectively.[1] Finally, a different approach could force manufacturers and repackagers to begin serializing product prior to November 27, 2017 and 2018, respectively. In the case of infrequently manufactured lower-volume products, that time difference could be substantial and create significant problems for manufacturers that have already planned their processes for changing their packaging lines to add serialization capabilities. Such early serialization would also be inconsistent with sections 582(b)(2)(A) and 582(e)(2)(A), which do not require a product identifier to be affixed during packaging until November 27, 2017 and 2018, respectively.

It is also critically important the Agency clarify that a grandfathered product is exempt from all DSCSA requirements related to serialization. For example, it should be clarified that the obligation to conduct enhanced verification (*i.e.*, verify the product identifier and standardized numerical identifier (SNI)) of a saleable return does not prohibit the saleable return of a grandfathered, unserialized product. This is the clear intent of section 581(a)(5), which provides that grandfathered product is exempt from "the requirements of this section," referring section 582. Specifically, those exempted requirements include:

- Manufacturers' obligation to affix a product identifier to all packages and homogeneous cases (section 582(b)(2)(A)).

[1] The proposed approach is consistent with the policy objectives of other transition schemes, such as the addition of unique device identifiers. *See* 78 Fed. Reg. 58,785, at 58,798 (Sep. 24, 2013).

- Manufacturers' obligation to verify the product identifier and standardized numerical identifier (SNI) as part of an investigation of suspect product (section 582(b)(4)(A)(i)(II)).
- Manufacturers' obligation to respond to requests for verification of a product identifier or SNI (section 582(b)(4)(C)).
- Manufacturers' obligation to verify the product identifier and SNI of saleable returns (section 582(b)(4)(E)).
- Repackagers' obligation to engage in a transaction only if the product is encoded with a product identifier (section 582(e)(2)(A)(iii)).
- Repackagers' obligation to affix a product identifier to all packages and homogeneous cases (section 582(e)(2)(A)).
- Repackagers' obligation to verify the product identifier and SNI as part of an investigation of suspect product (section 582(e)(4)(A)(i)(II)).
- Repackagers' obligation to respond to requests for verification of a product identifier or SNI (section 582(e)(4)(C)).
- Repackagers' obligation to verify the product identifier and SNI of saleable returns (section 582(e)(4)(E)).
- Wholesale distributors' obligation to engage in a transaction only if the product is encoded with a product identifier (section 582(c)(2)).
- Wholesale distributors' obligation to verify the product identifier and SNI as part of an investigation of suspect product (sections 582(c)(4)(B)(iii) and 582(c)(4)(A)(i)(II)).
- Wholesale distributors' obligation to verify the product identifier and SNI of saleable returns (section 582(c)(4)(D)).
- Dispensers' obligation to engage in a transaction only if the product is encoded with a product identifier (section 582(d)(2)).
- Dispensers' obligation to verify the product identifier and SNI as part of an investigation of suspect product (section 582(d)(4)(A)(i)(II)).

We believe each of the clarifications described above will help industry effectively transition to serialization.

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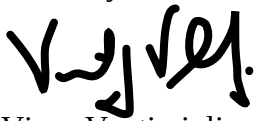
PDSA appreciates the FDA's continued efforts in implementation of the DSCSA. We welcome the opportunity to discuss these important topics or provide any other assistance that would be valuable to the Agency.

Sincerely,



Vince Ventimiglia
President, Leavitt Partners Collaborative Advocates and Advisor to PDSA
1050 K Street NW, Suite 310
Washington, D.C. 20001-4448
vince@leavittpartners.com