May 14, 2015

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

Re: DSCSA Guidance and Processes for Exemptions and Waivers

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, and 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.

PDSA and its members have considered and evaluated what we believe to be the most appropriate approaches to exemptions and waivers. We anticipate that the Agency is currently in process of developing its own thinking on these topics, and PDSA offers these initial comments and suggestions to assist the Agency in developing the required guidances.

Exemptions

Section 582(a)(3)(iii) requires the Agency to "establish a process by which [it] may determine other products or transactions that shall be exempt from the requirements of [section 582]." The process must include a biennial review and renewal of such exemptions.

Exemptions prevent the requirements of the DSCSA from unduly hampering the movement or availability of product. To effectively accomplish this end, all stakeholders must have access to and a common understanding of exemptions information. This is especially important for downstream trading partners that may receive similar products from multiple sources and distribution channels.

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

- The Agency should not require exemption 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 characteristics; 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 exemption requests within 30 days of receiving all information that the FDA has indicated in guidance is needed for a complete exemption request (or if there is a public comment period, within 30 days of completion of such period). Clarity and predictability is critical to the efficient distribution of product, and delayed determinations on important requests can leave even the most well-intentioned organizations at risk of noncompliance.
- 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 a request. As mentioned, this level of clarity and predictability is critical, and will facilitate submission by requestors of all information the Agency needs in order to make an informed decision. We specifically encourage the Agency to consider the following factors when reviewing the merits of an exemption request:
    - The level of security risk associated with product or transaction sought to be exempted.
    - The cost burden, compared to the related benefit, of compliance with Section 582.
    - The impact of compliance with Section 582 on public health and product movement and/or availability.
    - The scope of the request and the estimated volume of products or transactions that would be subject to the exemption.[1]
- For each exemption the Agency receives, the Agency should categorize the exemption request as either:
    A. An exemption that (if granted) is generally applicable to, and can be relied upon by, multiple or all organizations in the supply chain ,[2] or
    B. An exemption that (if granted) is unique and can only be relied upon by the requestor.

  The Agency should solicit public comment on exemption requests that fall into category A, above, because organizations other than the requestor may rely on the proposed exemption. Such exemptions will have a broad impact on many stakeholders, and accordingly, the Agency should seek input from those stakeholders. In contrast, a public comment process is not necessary for those exemption requests that fall into category B and on which only the requestor may rely because far fewer organizations would be impacted by the exemption. The public comment process should be streamlined to the maximum extent possible to expedite Agency decisions.
- When requesting public comments, FDA's notice should explicitly state that it is considering making the exemption broadly applicable. Similarly, final decisions should

[1] The exemption process should be used to review and grant new exemptions for products or transactions not already exempt under the statute. The exemption process should not be used to request a determination that a given product or transaction is within the scope of an existing statutory exemption (*e.g.*, whether a specific product is considered an intravenous product used to maintain the equilibrium of water and minerals in the body, pursuant to Section 581(24)(B)(xv)).

[2] A request to exempt charitable donations from the definition of "transaction" is an example of the generally applicable type of request that would fall into this category.

also explicitly state whether the exemption may be relied upon by entities other than the requester.

- The Agency should publish all granted and denied exemption requests, unless circumstances call for confidentiality.[3] Published denials should include a brief explanation of the reason for the denial and should not identify the requestor. Published approvals should include a brief explanation of the decision, and should identify the requestor and any trading partner that is also exempt, if the exemption is limited to identifiable organizations. Approvals should clearly state whether organizations other than the requestor may rely upon the exemption. Agency decisions should be published for multiple reasons:
    - As noted above, other organizations may be allowed to rely on the exemptions.
    - Transparency is critical to the successful implementation of the DSCSA. Transparency of Agency determinations—both approvals and denials—will allow stakeholders to better understand the Agency's thinking and allow regulators and regulated organizations to remain aligned in implementation of the DSCSA's requirements.
    - Publication of exemption decisions maintains a level playing field. If only the requestor, or some other limited set of organizations, has access to an exemption decision, the requestor and those limited organizations may be able to leverage that information to gain an unfair competitive advantage.
    - Downstream trading partners need to know—with certainty—whether there is an applicable exemption. The movement of product and patient access to product could be significantly impeded if downstream trading partners face uncertainty as to whether an exemption has been granted. This is particularly true of downstream trading partners who may purchase similar products from, or engage in similar transactions with, multiple upstream trading partners. Those downstream trading partners will be left in a precarious situation if only certain upstream trading partners have knowledge of an exemption.
    - Publication will save the Agency the burden of reviewing repetitive requests. Industry is currently considering exemption requests for multiple types of products and transactions. Absent publication of approvals and denials, the Agency could receive, and have to respond to, requests for such products and transactions dozens (or more) of times.
- The Agency should set forth a process by which it will keep grants and denials of exemptions confidential when circumstances require confidentiality. Such circumstances should be rare and may include:
    - Exemptions related to products for which an NDA/ANDA/BLA is still under FDA review.
    - Exemptions for which publication would create legitimate security risks.
    - Exemptions that involve proprietary business information and cannot be drafted in a general non-business-specific manner.
- 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.

[3] Exemptions related to specific products could present increased security risks, as publication of such exemptions could result in targeting of those products. We encourage the Agency to carefully consider whether such exemptions should remain confidential pursuant to the process noted.

We believe these recommendations will assist in the development of an efficient, reliable mechanism for receiving, reviewing, and granting or denying exemption requests.

Waivers

Section 582(a)(3)(i) requires the Secretary to "by guidance establish a process by which an authorized manufacturer, repackager, wholesale distributor, or dispenser may request a waiver from any of the requirements set forth in [section 582], which the Secretary may grant if the Secretary determines that such requirements would result in an undue economic hardship or for emergency medical reasons, including a public health emergency declaration . . . ."

Unlike exemptions—most of which apply to types of products or transactions across all trading partners—a waiver applies to one specific, individual trading partner. For this reason, different considerations must be taken into account.

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

- The Agency should identify the types of information it expects to see in a waiver application. In particular, applicants seeking a waiver due to undue economic hardship should be required to establish and provide evidence of specific economic hardship that would result if the applicant were required to comply with section 582.
- Waiver applicants should be required to specify the specific requirements in section 582 from which it is seeking a waiver.
- The Agency should establish a clear review and/or appeal process for denied waiver applications. Such process could be modeled after, or incorporated into, existing review and appeal processes.
- As we have explained in previous correspondence, certain trading partners may not be able or legally required to meet the licensure or registration requirements for authorized status.[4] Aside from those and similar situations, the FDA should not waive the authorized trading partner requirement of sections 582(b)(3), (c)(3), (d)(3), and (e)(3). The authorized trading partner provisions are critical to supply chain security because they restrict the supply chain to only those trading partners that are properly licensed or registered. Furthermore, the burden of complying with the authorized trading partner requirements is minimal and should be part of all good business practices. Accordingly, PDSA cannot contemplate a situation in which the burden of complying with the authorized trading partner provisions would outweigh the security benefits those provisions provide to the supply chain and patients.
- When evaluating a waiver application, the Agency should consider the impact, benefits, and risks of the waiver to (i) the applicant, (ii) the rest of the supply chain, and (iii) patients. A waiver will significantly affect all three categories of stakeholders. The requirements in section 582 were carefully drawn to provide proper protections to the supply chain and patients. A waiver from those requirements would remove those protections—albeit in

[4] *See* October 29, 2014 letter from PDSA to Dr. Ilisa Bernstein regarding Pharmaceutical Distribution Security Alliance Questions and Answers Regarding the Drug Supply Chain Security Act (Q&A #14), and December 4, 2014 letter from PDSA to Dr. Ilisa Bernstein regarding Pharmaceutical Distribution Security Alliance Questions and Answers Regarding the Drug Supply Chain Security Act (Q&A #15).

very narrow instances—and the Agency should carefully weigh the benefits and risks of doing so.

- The Agency should publish all waivers in a manner that is accessible only to legitimate supply chain participants. Similar to an exemption, a waiver will significantly impact downstream trading partners. The requirements of section 582 leverage the interconnected nature of the supply chain, and waiving those requirements with regard to one organization will impact the obligations of other trading partners. However, a waiver has the potential to create a more significant security risk because, unlike an exemption, the determination as to whether a waiver is granted is more likely to focus on the burden to the requestor and less likely to focus on the risk profile of the products handled by the requestor. Broad publication of a waiver could allow bad actors to target waived organizations and attempt to introduce illegitimate product into the supply chain through those waived organizations. Therefore, publication should be limited to legitimate trading partners.
- When the Agency grants and publishes a waiver, the Agency should provide direction for complying with their obligations under section 582 to the waived organization's trading partners. For example, if an organization receives a waiver from the obligation to pass or receive the transaction information (TI), transaction history (TH), and transaction statement (TS), the Agency should instruct that organization's trading partners as to how they should account for the waived entity in subsequent TI, TH, and TS.

We believe these recommendations will assist in the development of a waiver process that appropriately balances the need for waivers in limited circumstances with the potential risks associated with such waivers while also minimizing disruption in the supply chain.

Exceptions and Grandfathering

PDSA is actively considering recommendations regarding grandfathering and an effective process for receiving, consider, and granting exceptions. We look forward to sharing those recommendations with the Agency very soon.

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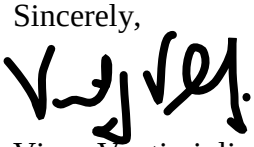
PDSA appreciates the FDA's continued efforts in implementation of the DSCSA. We look forward to reviewing the Agency's draft guidance on this topic and providing additional comments at that time. We welcome the opportunity to discuss this important topic or provide any other assistance that would be valuable to the Agency.

Sincerely,



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