



July 9, 2018

[Submitted electronically to <http://www.regulations.gov>]

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville MD, 20852

RE: Waivers, Exceptions, and Exemptions from the Requirements of Section 582 of the Federal Food, Drug, and Cosmetic Act (FDA-2018-D-1434)

Dear Sir/Madam:

The American Pharmacists Association (“APhA”) appreciates the opportunity to provide a response to the Food & Drug Administration’s (“FDA”) Draft Guidance, Waivers, Exceptions, and Exemptions from the Requirements of Section 582 of the Federal Food, Drug, and Cosmetic Act (hereinafter “Draft Guidance”). APhA, founded in 1852 as the American Pharmaceutical Association, represents 62,000 pharmacists, pharmaceutical scientists, student pharmacists, pharmacy technicians, and others interested in improving medication use and advancing patient care. APhA members provide care in all practice settings, including community pharmacies, physicians’ offices, hospitals, long-term care facilities, community health centers, managed care organizations, hospice settings and the uniformed services.

APhA is committed to working with FDA and other health professionals and stakeholders to enhance the safety and security of the pharmaceutical distribution supply chain. APhA appreciates FDA’s efforts to clarify the waivers, exceptions and exemptions process. Because of the potential negative impacts to patient care, APhA believes FDA needs to simplify, ease and clarify the process to request a waiver and exemption for supply chain participants, especially dispensers who do not have compliance or legal staff.

I. Ease of Requesting a Waiver or Exemptions

APhA is concerned the Draft Guidance sets up a waiver and exemption framework that is not intuitive or user-friendly. According to the Draft Guidance, each request should include, “the requirements of section 582 of the FD&C Act to which the proposed waiver, exception, or exemption would apply” and a “detailed statement of the reasons why FDA should grant the proposed waiver, exception or exemption, including pertinent supporting documentation.” As FDA is aware, small dispensers have limited resources and therefore, may not have staff or be able to afford an attorney who can identify the specific components of section 582 that require a waiver or exemption. Often, pharmacists are made aware of new requirements to comply with DSCSA from their wholesale distributor, professional association or buying group. As a result,

many dispensers may not be familiar with each DSCSA requirement and their downstream implications. Therefore, APhA anticipates dispensers seeking a waiver or exemption will have difficulty effectively satisfying this portion of the request.

APhA encourages FDA to provide additional resources, such as an FAQ, helpline or FDA contact to help dispensers complete such requests. Given FDA's ability to deny requests that lack sufficient information, APhA believes dispensers' infrequent communications with FDA and awareness of DSCSA will make them particularly vulnerable to request denials unless additional resources are provided. Also, instead of immediately denying waiver or exemption requests from dispensers, FDA could contact dispensers in advance of a denial to help resolve the issue associated with the application or the dispensers' request and use such information in creating educational resources for dispensers.

II. Request Tracking

The Draft Guidance indicates FDA will, upon receipt of a request, issue an acknowledgement to the trading partner or stakeholder that submitted the request. However, no information regarding anticipated wait times or follow-up is provided. Requests may be time sensitive from compliance, planning or patient need perspectives. APhA encourages FDA to identify a mechanism for dispensers to more carefully track the status of their request and for FDA to provide more information regarding anticipated review times.

III. Meaningful Opportunity to Comply

Should FDA decline to grant a waiver or exemption, APhA requests dispensers be given a meaningful opportunity to comply with the law before being penalized for noncompliance. A dispenser's decision to file a waiver or exemption request should not serve as a means for FDA or other enforcement bodies to identify dispensers in non-compliance and should generally not be used against dispensers as proof of non-compliance, especially when no meaningful opportunity to comply is provided.

IV. Notice and Coordination with States

The Draft Guidance does not indicate how FDA intends to provide notice to states regarding a pending, granted or denied request for a waiver or exemption. Such information may be relevant when a pharmacy is being inspected and questions related to DSCSA compliance are raised. APhA requests FDA indicate how it will communicate and coordinate waivers and exemptions with state enforcement authorities. In addition, APhA requests FDA clarify state authority regarding these waivers and exemptions. For example, may states also grant a waiver or exemption? Can states expand the scope of a waiver or exemption? Are states able to request a waiver, exception or exemption? As stated above, dispensers should not be penalized by federal or state enforcement entities immediately upon denial of a waiver or exemption.

V. Downstream Implications

Should a waiver, exception or exemption be granted, it will likely have compliance implications for other trading partners and, potentially, the supply chain more broadly. However, the Draft Guidance does not make clear how other trading partners' compliance activities will be

impacted, or how they will know a waiver, exception or exemption has been granted. Given FDA's Estimated Annual Reporting Burden, only 20 requests of a waiver, exception, or exemption are anticipated, there may be an opportunity to more carefully address downstream trading partners and consider their compliance strategies. While APhA does not believe trading partners should need to verify waivers, exceptions or exemptions, we do recognize supply chain security can be enhanced by effectively communicating with trading partners when a waiver, exception or exemption is granted.

VI. Education

APhA requests FDA provide additional education to dispensers regarding DSCSA compliance and the waivers, exceptions and exemptions process. APhA appreciates FDA's recent webinar regarding DSCSA compliance for pharmacists and encourages the agency to continue, and build upon, this effort by providing subsequent webinars and answers to Frequently Asked Questions. Specific to the Draft Guidance, APhA encourages FDA's educational efforts to include examples regarding different scenarios where a dispenser may consider requesting a waiver or exemption, and to also provide examples of information that would support such applications.

APhA appreciates FDA's efforts to secure the drug supply chain by providing guidance regarding waivers, exception and exemptions under DSCSA. We look forward to supporting FDA's efforts and working to improve the safety and security of the drug supply chain using practical and feasible implementation approaches. If you have any questions please contact, Jenna Ventresca, Director, Health Policy, by email jventresca@aphanet.org or phone (202) 558-2727.

Sincerely,



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Executive Vice President and CEO

cc: Stacie Maass, BSPHarm, JD, Senior Vice President, Pharmacy Practice and Government Affairs