



Healthcare Distribution Alliance

PATIENTS MOVE US.

February 20, 2020

BY ELECTRONIC FILING

<http://www.regulations.gov>, Dkt. No. FDA-2019-D-5743

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RE: Draft Guidance for Industry, Importation of Certain FDA-Approved Human Prescription Drugs, Including Biological Products, under Section 801(d)(1)(B) of the Federal Food, Drug, and Cosmetic Act, Docket No. FDA-2019-D-5743. [84 Fed. Reg. 71961 (Dec. 30, 2019)].

Dear Ms. Hennessey and Mr. Ripley:

The Healthcare Distribution Alliance (HDA) appreciates this opportunity to provide comments to the Food and Drug Administration (FDA) regarding the draft guidance titled: “[*Importation of Certain FDA-Approved Human Prescription Drugs, Including Biological Products, under Section 801\(d\)\(1\)\(B\) of the Federal Food, Drug, and Cosmetic Act*](#)” (“draft guidance” or “guidance”) Docket No. FDA-2019-D-5743. [84 Fed. Reg. 71961 (Dec. 30, 2019)].

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.

Background

HDA joins FDA in its commitment to assuring that the U.S. pharmaceutical supply chain remains safe and secure. We also share FDA’s commitment to expanding Americans’ access to high-quality, safe and effective, affordable medicines. The guidance, if finalized as drafted, is intended to facilitate

manufacturers' importation into the U.S. of their "multi-market approved products" or "MMA products."

For discussion of the specific processes and procedures set forth in the draft guidance, HDA defers to the public comments we anticipate will be provided by other stakeholders, including drug and biologic manufacturers, and those entities who represent them.

HDA's comments below primarily focus upon our strong support for Section VI of the draft guidance which provides that MMA products falling within the purview of the Drug Supply Chain Security Act (DSCSA) are subject to all applicable DSCSA requirements. We also briefly discuss additional hurdles to importation that may be posed by other legal requirements beyond those arising under the federal Food, Drug and Cosmetic Act (FD&C Act) and FDA's implementing regulations.

HDA supports the draft guidance's provision that MMA products must meet applicable DSCSA requirements

HDA offers its strong support for FDA's application of the DSCSA's requirements to MMA products. The draft guidance states:

An MMA product offered for import that meets the DSCSA definition of a "product" is subject to all applicable requirements of section 582 of the FD&C Act (21 U.S.C. 360eee-1).¹

HDA agrees with this statement.

To protect the American pharmaceutical supply chain, wholesale distributors and their trading partners supported the DSCSA's enactment and have worked diligently to implement this complex law. That difficult, costly work is ongoing. The DSCSA is intended to build an electronic, interoperable system for the identification and tracing of prescription drugs as they are distributed in the United States. Traceability will aid in protecting patients from drugs that may be counterfeit, stolen, contaminated, or otherwise unfit for distribution. The DSCSA is intended to improve the ability of FDA and industry to detect and remove dangerous products from the supply chain.

We believe that subjecting *all* DSCSA-covered products to the statute's requirements, regardless of whether they are MMA products, is essential to continued assurance that the U.S. pharmaceutical supply chain remains safe and secure and that products can be traced. We would not wish to see the DSCSA's important security advances weakened by exempting MMA products imported under this guidance. A lax application of the DSCSA's requirements to any covered drugs, including MMA products, would undermine the law's security protections and potentially open up a channel for the introduction of counterfeit or other substandard drug products into the U.S. supply chain. Ultimately, the effect could be to undermine the DSCSA's fundamental goals and purpose -- to the detriment of the provision of vital medicines and healthcare to patients.

¹ Draft Guidance at lines 330-331.

Moreover, as the draft guidance recognizes, wholesale distributors depend upon their trading partners meeting their own DSCSA requirements. For example, if a manufacturer does not fulfill its DSCSA obligations, wholesale distributors would not be able to accept ownership of, or be able to resell, an MMA product. As the draft guidance states:

if the manufacturer transfers ownership of a DSCSA-covered MMA product to a wholesale distributor, **the wholesale distributor generally shall not accept ownership of a product** unless the manufacturer has... provided the transaction history, transaction information, and a transaction statement for the product.²
(Emphasis supplied)

DSCSA-covered MMA product may not (and should not) move downstream in the supply chain to wholesale distributors and ultimately to dispensers and patients unless the supplying manufacturers meet their applicable DSCSA requirements. If MMA products and their importing manufacturers are not in compliance the DSCSA, patients will never receive the benefit of lower cost MMA products because their downstream trading partners will not be able to accept, buy, sell, or dispense them. The goal of the draft guidance to enable the safe, secure importation of less expensive drug products into the U.S. is effectively nullified.

HDA recommends that FDA add that drugs imported under this guidance are subject to applicable DSCSA-implementing final guidances and regulations, and that FDA will rigorously review any requests for waivers, exceptions and exemptions for MMA drugs from DSCSA requirements

HDA has additional recommendations regarding the draft guidance's DSCSA discussion to help assure the protection and security of the U.S. pharmaceutical supply chain.

First, HDA recommends that FDA strengthen its DSCSA discussion by including a short statement to the effect that in addition to meeting statutory requirements, imported MMA products should also comply with applicable final implementing DSCSA-related guidances and regulations. We believe this could be accomplished by adding a brief insert at the beginning of Section VI, in lines 330 – 332, as follows (suggested insert shown in **blue bold** type font):

An MMA product offered for import that meets the DSCSA definition of a “product” is subject to all applicable requirements of section 582 of the FD&C Act (21 U.S.C. 360eee-1), **DSCSA-implementing final regulations and, where appropriate, final guidances.**

Second, HDA notes that the DSCSA contains provisions for requesting waivers, exceptions and exemptions from compliance with its requirements.³ We urge a close and searching examination of

² *Draft Guidance* at lines 359-363.

³ Generally speaking, “waivers” would be based on economic challenges or emergency medical situations, “exceptions” refers to situations where there is insufficient space on a product package to place a product identifier, and “exemptions” are a “catch all” for any other reason why DSCSA provisions couldn't be met. See: § 582(a)(3)(A).

any request for a waiver, exception or exemption from a DSCSA requirement otherwise applicable to an MMA product under this guidance. We further recommend that the Agency subject the request to the same rigorous evaluation and decision criteria that FDA would apply to such requests for the equivalent domestic drug products.

Third, HDA urges particular caution if the Agency is asked to waive DSCSA requirements related to MMA products due to financial considerations or “an undue economic hardship.”⁴ Protecting the U.S. supply chain requires financial investment and we urge searching and critical evaluation of any potential effort to circumvent the DSCSA’s protections with arguments that it is too costly or inconvenient for MMA products to comply. Nor do we believe it equitable if MMA products were able to avoid, on the basis of cost, compliance requirements that the equivalent domestic products must meet.

A rigorous review is crucial to supporting the DSCSA’s goals of enhancing the safety and security of the supply chain. As we noted above, relaxing its application may open up the supply chain to unsafe practices and products. The attendant risks may well outweigh the benefit of a patient’s cost reduction by also subjecting those same patients to the risk of encountering counterfeit and/or other substandard products.

We recommend that FDA consider including a reference to the forthcoming final FDA guidance on waivers, exceptions, and exemptions.⁵ We also encourage noting in the final importation guidance that, as a general matter, FDA would not consider importation-related costs as adequate justification for a finding of “an undue economic hardship” in support of a DSCSA-waiver request.

Our suggestion is to insert into the final guidance an explanation of the above by adding the following, or similar, language into a third subsection of the DSCSA discussion (Section VI.C.):

C. Requests for Waivers, Exceptions, and Exemptions from the DSCSA for Imported Products

Requests for waivers, exceptions and exemptions from the DSCSA’s requirements pertaining to products intended for importation under this guidance will be subject to the procedures outlined in FDA’s forthcoming final guidance “*Waivers, Exceptions, and Exemptions from the Requirements of Section 582 of the Federal Food, Drug and Cosmetic Act, Guidance for Industry.*” Generally, it is not anticipated that expenses related to the processes, procedures and other activities associated with importing a drug under this guidance would constitute sufficient justification for a waiver request based upon “an undue economic hardship” under Section 582(a)(3)(A)(i).

⁴ § 582(a)(3)(i) states: “an authorized manufacturer, repackager, wholesale distributor, or dispenser may request a waiver from any of the requirements set forth in [§ 582] . . . if the Secretary determines that such requirements would result in **an undue economic hardship**”. (Emphasis supplied.)

⁵ It is our understanding that FDA is currently preparing a final version of the guidance on waivers, exceptions and exemptions. See: 83 Fed. Reg. 21297 (May 9, 2018) and the [draft guidance](#).

HDA suggests consideration of applicable legal requirements beyond those arising under the FD&C Act and implementing regulations

HDA also notes that such imported drugs may be subject to additional legal requirements beyond those arising under the FD&C Act.

The Consumer Product Safety Improvement Act (CPSIA) and the Poison Prevention Packaging Act (PPPA), administered by the Consumer Product Safety Commission (CPSC) are one example. These statutes require testing and documentation of the packaging used for a variety of consumer products including certain drug products.

We recommend that consideration be given to other applicable legal requirements that could pose hurdles to a manufacturer's intended importation of an MMA product.

* * *

Conclusion

HDA and its members are committed to continuing efforts to enhance the safety and security of the U.S. pharmaceutical supply chain while also assuring that Americans have access to the medicines they need.

HDA reiterates its support for including in the final guidance the explanation, preferably augmented by the additional clarifications recommended above, that the DSCSA's requirements would apply to the drug products under consideration for importation under this guidance.

If you have any questions, please feel free to contact me at aducca@hda.org or 703-885-0240. Thank you.

Sincerely,



Anita T. Ducca
Senior Vice President, Regulatory Affairs