



Filed electronically at <https://www.regulations.gov>

February 21, 2020

Lowell J. Schiller
Principal Associate Commissioner for Policy
Food and Drug Administration
Department of Health and Human Services
10903 New Hampshire Avenue
Silver Spring, MD 20993

Re: Docket No. FDA-2019-D-5743, 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

Dear Principal Associate Schiller:

The Academy of Managed Care Pharmacy (AMCP) thanks the Food and Drug Administration (FDA) for the opportunity to provide comments in response to its new Draft Guidance, [“Importation of Certain FDA-Approved Human Prescription Drugs, Including Biological Products, under Section 801\(d\)\(1\)\(B\) of the Federal Food, Drug, and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 \[FDA-2019-D-5743\]”](#) published in the Federal Register on December 23, 2019. We appreciate the opportunity to leverage our members’ expertise in offering feedback on this guidance. As an organization representing health care professionals, AMCP has a number of significant concerns regarding the commercial importation of prescription drugs for sale in the United States and cannot support FDA’s guidance until such time as sufficient resources have been devoted to both study the impact of the proposal on consumer access to medications, and on ensuring that the quality and safety of the drug supply chain has not been compromised. We discuss these issues below.

AMCP is the nation’s leading professional association dedicated to increasing patient access to affordable medicines, improving health outcomes and ensuring the wise use of healthcare dollars. Through evidence and value-based strategies and practices, the Academy’s 8,000 pharmacists, physicians, nurses and other practitioners manage medication therapies for the 270 million Americans served by health plans, pharmacy benefit management firms, emerging care models and government.

AMCP supports the goals of improving access to prescription drugs at lower prices and reducing overall health care costs but we remain concerned that the Draft Guidance does not specifically address the issue of affordability for all stakeholders, including patients, pharmacies, and payers.

While it is possible that importation could allow consumers to purchase drugs at a lower cost, the anticipated savings generated through importation programs remains uncertain and is subject to many presently unknown factors that could impact actual cost reductions. For example, while certain brand-name products sold in other countries, such as Canada, have been shown to be priced considerably lower than in the United States, the price differential on other drugs, particularly generics, are minimal. Additionally, patient and health system savings may not be fully realized because of the additional costs manufacturers must assume for significant importation, including registration fees, transportation of products, and technology investments to secure the supply chain. If past precedent is a guide, there is no guarantee that manufacturers importing multi-market approved products will offer such products at a lower net cost to purchasers and consumers. As part of FDA's review of applications, the agency should evaluate how the introduction of a new a multi-market approved National Drug Code (NDC) will impact patient affordability.

To this end, AMCP does not yet believe there is sufficient evidence to allow for the importation of generic or biosimilar products, given the lower costs of these products and the possibility for unintended consequences. First, price competition is already strong among oral solid generics, and the flexibility to re-price by generic manufacturers means there is little need for importation. While biosimilars lack the historical experience of generics, we are concerned the importation of biosimilars could have the unintended consequence of slowing down the introduction of new biosimilars in the marketplace.

AMCP is also concerned about the lack of coordination with FDA's other Health and Human Services (HHS) partner agencies, including the Centers for Medicare & Medicaid Services (CMS) and the Department of Veterans Affairs (VA), in assessing the impact on price reporting. As FDA is well aware, granting a unique NDC to a product can have a number of downstream impacts on government price reporting, impacting additional programs including: the Medicaid Drug Rebate Program, the 340B Drug Pricing Program, Medicare Part B's Average Sales Price and National Average Drug Acquisition Cost program, and the Veterans Health Administration's Federal Ceiling Price. While we appreciate and understand FDA's desire to defer to its partner agencies on matters outside of its jurisdiction, given the inevitable impacts of this policy proposal on the drug pricing chain as a whole, we urge FDA to review and reconsider its Draft Guidance following consultation with its partner agencies.

While AMCP is generally opposed to the commercial importation of prescription drug sales in the United States until such time as adequate resources and studies can ensure that their quality and safety have not been compromised, if FDA moves forward with its Draft Guidance, we encourage the agency to limit the applicability of the Guidance to only the narrow set of brand drugs to which it was initially proposed. In particular, under the Draft Guidance, controlled substances, biological products, infused drugs, intravenously injected drugs, drugs inhaled during surgery, intrathecally or intraocularly injected drugs, and drugs subject to REMS would be excluded from potential importation. Given AMCP's overarching concerns about patient safety and product integrity, we support the exclusion of these higher-risk products from importation. We further urge FDA to clarify that post-marketing compliance obligations will apply to any multi-market approved products, to the extent applicable, in order to protect the safety and integrity of the U.S. drug supply chain.

FDA should also clarify in the Final Guidance the degree to which a multi-market approved product may differ from the U.S. approved product, and still be available for importation, including the extent to which manufacturing processes, inactive ingredients, and pill size and shape can differ.

Additionally, consumers, payers, and healthcare providers should be able to clearly identify a multi-market approved product from its U.S. counterpart, including in instances in which a multi-market approved product is repackaged. As part of the Final Guidance, we encourage FDA to require labeling informing the public that the product is not the FDA-approved product but is identical to the FDA-approved product.

Finally, the drug industry is facing an impending shortage of NDCs and AMCP is concerned that the Draft Guidance will exacerbate and accelerate the looming shortage. As the FDA noted in 2018, at some point in the next 10-15 years, NDC formatting will need to be updated to accommodate longer NDCs because of the increasing number of new labelers entering the U.S. drug market.¹ NDCs play a vital role in the workflow of pharmacists and other health care providers, who rely on the codes to prescribe electronically, to bill health plans, and to verify prescriptions. Changes to the NDC formatting will require industry investment, including updating, reconfiguring, or purchasing new systems. Any changes to the NDC formatting must be done deliberately and carefully, with ample time for all stakeholders to make necessary updates to comply. AMCP appreciates the efforts FDA has already undertaken to begin addressing the upcoming shortage of NDCs and we urge FDA to evaluate the impact the Draft Guidance and the importation of multi-market approved products will have on this issue.

Conclusion

AMCP appreciates the opportunity to comment on FDA-2019-D-5743: 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. We are committed to being a valuable resource to FDA on improving access to prescription drugs at lower costs and on the challenges surrounding drug importation. If you have any questions regarding AMCP's comments or would like further information, please contact me at 703-684-2600 or scantrell@amcp.org.

Sincerely,



Susan A. Cantrell, RPh, CAE
Chief Executive Officer

¹ FDA-2018-N-2610 (<https://www.regulations.gov/document?D=FDA-2018-N-2610-0001>)