



February 21, 2020

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

Re: 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Drugs, Including Biological Products, under Section 801(d)(1)(B) of the Federal Food, Drug and Cosmetic Act: Draft Guidance for Industry (Docket No. FDA-2019-D-5743)

Dear Madam/Sir:

The American Pharmacists Association (“APhA”) appreciates the opportunity to submit comments in response to the Food and Drug Administration’s (“FDA”), “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Drugs, Including Biological Products, under Section 801(d)(1)(B) of the Federal Food, Drug and Cosmetic Act, Draft Guidance for Industry,” (hereinafter, “Draft Guidance”).¹ Founded in 1852 as the American Pharmaceutical Association, APhA represents nearly 60,000 pharmacists, pharmaceutical scientists, student pharmacists,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, hospitals, long-term care facilities, community health centers, physician offices, ambulatory clinics, managed care organizations, hospice settings, and the uniformed services.

APhA supports efforts to provide Americans access to quality, safe, effective, and affordable prescription drugs. Despite FDA’s good intentions, APhA is concerned the Draft Guidance will cause patient and pharmacy confusion, raises concerns with patient care, and will not meaningfully enhance competition. In addition to raising concerns of potential unintended consequences, we seek additional clarity regarding several components of the Draft Guidance.

I. General Comments

A. Patient and Pharmacy Confusion and Disruptions

APhA understands the intent of providing greater competition and alternatives in the marketplace. However, the introduction of the multi-market approved (“MMA”) versions will create significant chaos and confusion at the pharmacy and could lead to disruptions in patient care.

Identical products in the marketplace with different National Drug Code (“NDC”) numbers and different prices make product selection for patients at the pharmacy complicated and time-consuming. Because patients are on different insurance plans, their co-pay/co-insurance varies depending on their plan and the specific NDC of the dispensed product. Drug pricing in today’s

¹ 84 Federal Register 71961 (December 30, 2019).

marketplace is complex, non-transparent, inequitable, and not predictable. A specific product may be less expensive for one patient compared to another patient. Pharmacy benefit managers (“PBMs”) practices (e.g., spread pricing, pharmacy claw-back fees, etc.) game the drug pricing system to maximize profits without necessarily reducing out-of-pocket expenses for the patient at the pharmacy counter. In addition, due to manufacturer rebates and the lack of drug pricing transparency, a product with a higher list price may garner a higher manufacturer rebate, making it more profitable for the PBM, creating an incentive for the PBM to steer patients to receive the higher list price product. It is likely that a manufacturer of an MMA product will not offer a rebate, resulting in a higher out-of-pocket cost for the patient at the pharmacy counter. The MMA product, with a lower list price, may be preferable for patients who pay cash, such as those who have to meet a high deductible before coverage kicks in or for products that are not covered by insurance. Our members, or their pharmacy technicians, will then have to sort out all of the confusion. A pharmacist will have to run both NDCs through the electronic claims system as separate claims and then reverse (cancel) the claim for the higher priced product. Checking both NDCs and reversing the higher priced NDC takes time. There is also a fee to reverse a claim – adding an unnecessary expense. In addition, patients get frustrated and complain when they have to wait long for their prescription at the pharmacy—adding to disruptions all around.

In order to accommodate the vast scope of patient plans and coverage, pharmacies would need to stock both the original FDA-approved and the MMA product. Shelf space in pharmacies is often limited and they may not be able to stock both. If a pharmacy does not have the MMA version for the patient in stock, the patient will have to either wait until it is in stock or go to another pharmacy. This could create a disruption in patient care, potentially impacting medication adherence if the lack of availability leads the patient to miss a dose or doses or decide not to get the prescription filled at all.

FDA should expect supply disruptions as the marketplace adjusts to demand for one NDC over the other if the market cannot accommodate surges in demand. Therefore, APhA strongly recommends FDA monitor demand and supply issues closely in the marketplace to ensure uninterrupted patient care.

APhA agrees with the statement on lines 313-314 stating that “change to the NDC for the MMA product should not be solely with the package code.” The MMA product should be highly distinguished from the original FDA-approved version. For the reasons stated directly above, product selection is a critical step at the pharmacy to ensure that the patient receives the correct product. A simple change in the package code may not be enough to differentiate the two versions for pharmacy claims purposes.

B. Drug Shortages

APhA appreciates FDA’s recognition in footnote 5 that “[t]he procedures outlined in the draft guidance are not intended to replace existing procedures for temporary importation used to mitigate or prevent drug shortages.” APhA firmly believes that FDA-approval must be the standard for marketing of prescription drugs and biologics in the United States (U.S.). However, we recognize that on rare occasions, in order to address existing or potential shortages where FDA approved versions are not available, FDA does extensive due diligence before allowing temporary, time

limited importation of an unapproved foreign version under enforcement discretion. In these rare and limited occasions, the existing pathway is essential to meet patient needs and should not be compromised.

II. Specific Comments

A. Labeling of an MMA Product

FDA sought comment on specific wording that could be included in the labeling statement to differentiate MMA products from other products and help ensure MMA products are easily identifiable to pharmacists and not confusing to patients. FDA also sought comment on other types of distinguishing characteristics on the carton and container label that would further enable pharmacists to distinguish MMA products from the original FDA-approved version package. It is essential that the MMA products contain a common, uniform statement and other characteristics that make the package highly distinguishable from the original FDA-approved version package. The draft guidance at lines 161-162 states the MMA product “differs from the FDA-approved drug or FDA-licensed biological product only with regard to the labeling statement described in section III.B.” A statement alone is not enough to differentiate one package from another for product selection purposes. The package and container label should differ in other trade dress respects, either by color or other prominent distinguishing markings or graphics that make the MMA package and container label distinguished from the original FDA-approved version. Therefore, APhA recommends FDA establish a common icon that would be placed on a package and container label for all MMA products so pharmacists and patients can easily recognize if a product in the marketplace is an MMA product. Similarly, the MMA statement that is placed on MMA products should be identical for all MMA products to minimize confusion or marketplace gaming due to variable MMA labeling statements. This will also make health care professional and patient education about MMA products clearer and uniform.

B. Attestation for an MMA Product

The Draft Guidance states at lines 231-232 that the attestation should include the applicant’s commitment that the MMA product will continue to meet the quality standards for marketing in the non-U.S. jurisdiction (“originally intended market”). However, if the product is the FDA-approved product, manufactured in accordance with the FDA-approved new drug application (“NDA”), including manufactured, packaged, labeled, and tested in the facility(ies) approved in the NDA, and approved based on an NDA or biologics license application (“BLA”) supplement, then the product should meet the quality standards of the U.S. If finalized, the guidance should make clear that an attestation of continuing to meet the quality standards of the original non-U.S. jurisdiction should not supplant the continuing obligation to meet U.S. quality standards.

The Draft Guidance does not describe the responsibility of the marketing holder to inform FDA if the product is found to fail to conform to the quality standards in the non-U.S. jurisdiction for the MMA, based on information from the marketing holder itself or the regulatory authority in the non-U.S. jurisdiction. Accordingly, if finalized, APhA strongly recommends the guidance provide clarity on this issue.

It is also not clear from the Draft Guidance what the consequences are if information in the attestation is false or misleading. Therefore, if finalized, APhA recommends the guidance should state the statutory violations for a false or misleading attestation and the disposition of the MMA product that is in the marketplace if the attestation is found to be false or misleading.

C. Drug Supply Chain Security Act (DSCSA) Compliance

DSCSA supply chain protections further ensure the security, safety, and integrity of product as it is distributed in the U.S. APhA commends FDA for noting and ensuring that all requirements of the DSCSA apply to MMA products that meet the DSCSA definition of “product,” per section 581(13) of the Federal Food, Drug, and Cosmetic Act. We note that regardless of which market the MMA product was originally intended to be marketed in, the first commercial distribution of the product must be within the U.S. market in order for the DSCSA tracing, verification, identification, and other requirements to adequately assure the product lifecycle distribution protections that DSCSA affords. Thus, if finalized, APhA recommends FDA clarify DSCSA requirements and compliance.

III. Conclusion

Finally, it is not clear when an applicant/manufacture would choose to import an MMA product and undercut its own U.S. price. APhA is not aware of any legal or regulatory requirement that currently exists that would prevent an applicant/manufacture from deciding to apportion a quantity of their existing FDA approved product and package it for market it in the U.S. with a new NDC number at a lower cost now. Though, the significant marketplace operational and logistical issues discussed above remain, whether through re-apportionment with a new NDC or the MMA process. Calling this same FDA-approved product an MMA product and going through the steps to relabel the product adds to the uncertainty if this process will ever be used by an applicant/manufacture. Preparing for and dealing with the confusion and disruption in the marketplace that will accompany MMA products will take more effort and resources than any savings that potentially might be afforded if an applicant/manufacture uses the pathway provided in this guidance. Therefore, APhA strongly urges FDA to carefully consider if the benefits of finalizing this Draft Guidance outweigh the resources, time, effort, confusion, and disruption to the supply chain and potential medication adherence issues for patients that will certainly arise if the Draft Guidance is finalized.

APhA shares FDA’s goal to ensure that patients receive quality, safe, and effective drugs. We look forward to continuing to work with FDA on the implications of drug importation policies on patients and pharmacists and thank you in advance for considering our concerns. If you have any questions, or if we can be of any assistance, please do not hesitate to contact Michael Baxter, Director of Regulatory Affairs, at mbaxter@aphanet.org or by phone at (202) 429-7538.

Sincerely,



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