



Ashira Vantrees
Aimed Alliance
1455 Pennsylvania Avenue NW, Suite 400
Washington, DC 20004

Re: Docket No. FDA-2024-P-1058

Dear Ms. Vantrees:

This letter responds to the citizen petition submitted on behalf of Aimed Alliance and received by the Food and Drug Administration (FDA or the Agency) on March 1, 2024 (Petition).

The Petition requests that FDA “issue a guidance document that offers both an interpretation and a clear position statement concerning importation activities conducted by alternative funding programs.”¹ The Petition requests that the proposed guidance:

. . . differentiate the legality of personal importation and FDA-approved state importation programs, from the prescription drug importation practices conducted by third-party companies importing prescription drugs on behalf of consumers with employer-sponsored health insurance.²

Specifically, the Petition requests that the proposed guidance address (1) “whether third-party companies that partner with employer-sponsored health plans can legally require employees to import their prescription drugs from outside the United States” and (2) “whether third-party companies that partner with employer-sponsored health plans can import prescription drugs on behalf of consumers enrolled in an alternative funding program.”³ The Petition additionally requests that the proposed guidance include “an explanation of the existing reporting pathways available for individuals and organizations to promptly notify the FDA of instances where entities engage in such practices.”⁴

FDA has carefully considered the Petition and the comments submitted to the docket. For the reasons below, the Petition is denied.

¹ Petition at 2.

² Petition at 2.

³ Petition at 1 and 10.

⁴ Petition at 1, 2, and 10.

I. BACKGROUND

FDA protects public health by promoting supply chain integrity and working to ensure medicines imported into the United States comply with applicable legal requirements. FDA examines and analyzes samples of imported drugs to ensure they meet the Agency’s standards for quality, safety, and effectiveness, and comply with labeling requirements. FDA refuses admission of drugs and other articles if they appear to be adulterated, misbranded, or in violation of pre-market approval requirements in section 505 of the Federal Food, Drug, and Cosmetic Act (FD&C Act).⁵ Introduction or delivery for introduction into interstate commerce of a drug that is adulterated, misbranded, or in violation of section 505 of the FD&C Act, is also subject to serious penalties.⁶

FDA recognizes that the cost of prescription drugs, many of which are needed to treat life-threatening and serious conditions, is a serious concern for many Americans and can impact patients’ ability to cope with their illnesses. Although FDA does not have statutory authority to control the prices charged for marketed drugs, FDA has developed a pathway under section 804 of the FD&C Act to allow importation of certain prescription drugs from Canada to reduce the cost of these drugs to the American consumer without imposing additional risk to public health and safety. FDA’s regulations limit this importation to Section 804 Importation Programs (SIPs), which are sponsored by States and Indian Tribes and which are submitted to FDA for review and authorization.⁷ Absent authorization from FDA, importation under section 804 of the FD&C Act is not permissible. In January 2024, FDA authorized Florida’s Agency for Health Care Administration’s SIP proposal, the first step toward Florida facilitating importation of certain prescription drugs from Canada.⁸

II. DISCUSSION

The Petition addresses “alternative funding programs” or “specialty medication programs” that the Petition describes as designed to help employer-sponsored health plans lower prescription drug spending by sourcing prescription drugs from outside the conventional health plan framework.⁹ The Petition states that a health plan excludes specific high-cost drugs from its covered drug formulary.¹⁰ To obtain those medications, patients are directed to enroll in an alternative funding program, managed by a third-party vendor, or bear the full cost of a drug.¹¹

⁵ Section 801 of the FD&C Act.

⁶ See sections 301 and 303 of the FD&C Act.

⁷ 21 CFR part 251. Under 21 CFR 251.2, it is possible for FDA to allow a pharmacist or wholesaler to sponsor a SIP instead of a State or Indian Tribe if certain conditions are met. To date, these conditions have not been satisfied and, as such, all SIP sponsors must be either a State or Indian Tribe.

⁸ FDA has also issued a guidance for industry *Importation of Certain FDA-Approved Human Prescription Drugs, Including Biological Products, and Combination Products under Section 801(d)(1)(B) of the Federal Food, Drug, and Cosmetic Act* (September 2020), that describes procedures drug manufacturers can follow to facilitate importation of prescription drugs, including biological products, that are FDA-approved, manufactured abroad, authorized for sale in any foreign country, and originally intended for sale in that foreign country. We update guidances periodically. For the most recent version of a guidance, check the FDA guidance web page at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>.

⁹ Petition at 3.

¹⁰ Id.

¹¹ Id.

The alternative funding program assesses options such as international importation, commercial copay assistance programs, and charitable and patient assistance programs.¹² The Petition “asks the FDA to solely address the use of *international importation* by alternative funding programs.”¹³ According to the Petition, alternative funding programs coordinate the fulfillment of prescription drugs through a foreign pharmacy, which directly deliver the medications to the plan beneficiary in the United States.¹⁴

The Petition argues that “drug importation methods” utilized by alternative funding programs are not authorized by the FD&C Act, including section 804 of the FD&C Act, and “are not within the scope of . . . FDA’s personal importation policy.”¹⁵ The Petition states that despite warning letters from FDA, alternative funding programs refer to FDA policies regarding personal importation and importation of prescription drugs from Canada as support for the legality of their importation practices.¹⁶ The Petition states that patients are compelled to import medication from outside the United States, potentially exposing them to unapproved and misbranded drugs.¹⁷ The Petition states that even though FDA has issued a “clear warning letter,” there is “a lack of explicit guidance and action by the FDA regarding the importation of prescription drugs by alternative funding programs,” and as a result “these programs perpetuate without accountability or oversight.”¹⁸ The Petition also states that it is critical to ensure that FDA’s authorization of Florida’s section 804 importation program “does not inadvertently contribute to misconceptions surrounding international importation practices.”¹⁹ The Petition states that new guidance from FDA would clarify what importation practices are permissible, foster accountability, and deter “actors looking to exploit perceived ambiguities within FDA regulations.”²⁰ The Petition also states that new guidance would empower employers and better equip patients to make informed decisions about their healthcare, brokers, and health plan contracts.²¹ The Petition further states that clarification about reporting pathways for individuals and organizations to notify FDA of unauthorized practices would add accountability.²² Overall, the Petition claims, the proposed new guidance would help safeguard consumers from dangers associated with illegally imported unapproved or misbranded prescription drugs.²³

FDA shares your concerns about risks posed by unapproved new drugs and misbranded drugs.²⁴ FDA’s regulation and oversight of the drug approval process protects consumers by requiring rigorous scientific standards for new drug approval, labeling review for accuracy and

¹² Id.

¹³ Id. at footnote 13 (emphasis in original).

¹⁴ Id.

¹⁵ Petition at 2 and 5.

¹⁶ Petition at 8-10.

¹⁷ Petition at 7-8.

¹⁸ Petition at 8.

¹⁹ Petition at 9.

²⁰ Petition at 10.

²¹ Id.

²² Id.

²³ Id.

²⁴ As noted in the Petition, FDA previously responded to a letter from Aimerd Alliance regarding practices that the organization said were violating the FDA’s policies and federal regulations, including certain companies’ practice of partnering with health plans to implement “alternative funding programs” under which plan enrollees’ prescription medications are imported into the United States.

completeness, and manufacturing procedures and testing performed under closely controlled conditions at FDA-registered and inspected facilities. Substitution of FDA-approved prescription drugs with unapproved drugs and misbranded drugs poses significant health risks to U.S. consumers. Unapproved new drugs do not carry the same assurances of safety and effectiveness as FDA-approved drug products. Drugs that have circumvented regulatory safeguards may be contaminated, counterfeit, contain varying amounts of active ingredients, or contain different ingredients altogether. Imported drugs must meet FDA's standards for safety, effectiveness, and quality. Drug products imported or offered for import into the United States must comply with all applicable requirements under the FD&C Act, including requirements related to registration, listing, approval, drug labeling, and drug current good manufacturing practice (CGMP). Under section 801 of the FD&C Act, articles that appear adulterated or misbranded, or that appear to be unapproved new drugs in violation of section 505 of the FD&C Act, are subject to refusal of admission.

FDA believes that the guidance offering an "interpretation" and a "clear position statement" proposed in the Petition is not warranted at this time.²⁵ FDA maintains information about human drug importation on its web site.²⁶ There is information about personal importation of FDA-regulated products, including unapproved drugs on FDA's Personal Importation web page²⁷ and in FDA's Regulatory Procedures Manual.²⁸ FDA has repeatedly made clear that, in most circumstances, it is illegal for individuals to import drugs into the United States for personal use. Such drugs from other countries often have not been approved by FDA for use and sale in the United States. If a drug is approved outside the United States but has not been approved by FDA, it is an unapproved drug in the United States. Prescription medicines that are approved for use in the United States have been reviewed by FDA for safety, effectiveness, and quality and are subject to FDA-regulated manufacturing controls and FDA inspections of manufacturing facilities. Generally, prescription medicines purchased from foreign sources are not the FDA-approved versions and FDA cannot ensure their safety, effectiveness, or quality. Further, drugs promoted as being from Canada or approved in Canada that are offered to U.S. citizens in many instances are not actually from Canada and not approved in Canada. Instead, these drugs are obtained from ever-evolving illicit sources of supply. Because of these many risks, in contrast, FDA's implementation of section 804(b)-(h) of the FD&C Act applies only to specific sponsors (e.g., States and Indian Tribes) and includes a variety of safeguards such as drug sourcing oversight, drug quality testing, supply chain tracing, and safety reporting and recalls associated with imported drugs.

FDA's Regulatory Procedures Manual, chapter 9-2, provides operating procedures for the coverage of personal-use quantities of FDA-regulated imported products in baggage and mail. These procedures clarify how FDA may best protect the public with a reasonable expenditure of resources. Commercial and promotional shipments, as described in the Regulatory Procedures Manual, are not subject to these procedures. In accordance with the Regulatory Procedures

²⁵ FDA's development and issuance of guidance document is governed by good guidance practices set forth in section 701 of the Federal Food, Drug, and Cosmetic Act and in 21 CFR 10.115.

²⁶ See, e.g., <https://www.fda.gov/drugs/guidance-compliance-regulatory-information/human-drug-imports>.

²⁷ <https://www.fda.gov/industry/import-basics/personal-importation>.

²⁸ Available at <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-manuals/regulatory-procedures-manual>.

Manual, FDA personnel evaluate drugs imported in personal-use quantities on a case-by-case basis. The Regulatory Procedures Manual explains that one consideration is whether effective treatment is available domestically either through commercial or clinical means.²⁹ The Regulatory Procedures Manual does not state that the cost of an FDA-approved prescription drug is a consideration for FDA personnel.

As discussed above, FDA has also addressed importation of certain prescription drugs from Canada under section 804(b)-(h) of the FD&C Act. On October 1, 2020, FDA published a final rule entitled *Importation of Prescription Drugs* (85 FR 62094), which allows FDA-authorized programs to import certain prescription drugs from Canada under specific conditions that ensure that the importation poses no additional risk to the public's health and safety while achieving a significant reduction in the cost of covered products to the American consumer. Under the final rule, time-limited SIPs will be authorized by FDA and managed by States or Indian Tribes.³⁰ In May of 2022, FDA published the final guidance *Importation of Prescription Drugs Final Rule Questions and Answers; Small Entity Compliance Guide*, to help small entities better understand the final rule. FDA has made additional information about the section 804(b)-(h) importation program available on its website.³¹ FDA has authorized only one drug importation program under section 804(b)-(h), for Florida's Agency for Health Care Administration. Alternative funding programs as described in the Petition are not permitted to import drugs under section 804. FDA's final rule notes that an article that is imported or offered for import into the United States in violation of section 804 or FDA's implementing regulations is subject to refusal, and the importation of a prescription drug in violation of section 804 or any other violation of FDA's implementing regulations is a prohibited act subject to serious penalties.

In addition, FDA has taken steps to address the distribution of unapproved new drugs and misbranded drugs to U.S. consumers in situations similar to those described in the Petition. FDA has placed a firm on Import Alert 66-57, which identifies distributors, including online pharmacies, of foreign unapproved prescription drugs to U.S. patients.³² In addition, as recognized in the Petition, FDA sent a Warning Letter in March 2023 to a firm that facilitated the dispensing of prescription drugs by foreign pharmacies to employees in the United States.³³ FDA also sent a separate Warning Letter in February 2019 to a firm engaged in similar activities.³⁴

²⁹ Id.

³⁰ As noted above, under 21 CFR 251.2, it is possible for FDA to allow a pharmacist or wholesaler to sponsor a SIP instead of a State or Indian Tribe if certain conditions are met. To date, these conditions have not been satisfied and, as such, all SIP sponsors must be either a State or Indian Tribe.

³¹ The Importation Program under Section 804 of the FD&C Act web page is available at <https://www.fda.gov/about-fda/reports/importation-program-under-section-804-fdc-act>.

³² See PriceMDs.com, Inc (published April 19, 2021), available at https://www.accessdata.fda.gov/cms_ia/importalert_197.html.

³³ Warning Letter in March 2023 to ElectRx and Health Solutions, LLC, MARCS-CMS 61425, available at <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/electrx-and-health-solutions-llc-614251-03022023>.

³⁴ Warning Letter in February 2019 to CanaRx Services Inc, MARCS-CMS 554740, available at <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/canarx-services-inc-554740-02262019>.

Finally, regarding your question about how to notify FDA of suspected unauthorized importation practices, our website provides this information. You can contact FDA's Office of Inspections and Investigations, Office of Import Operations at FDAImportsInquiry@fda.hhs.gov for general import operational and policy questions,³⁵ or CDER staff at CDERImports@fda.hhs.gov with questions about human drug importation.³⁶

In light of the available information described above, at this time it would not be an efficient use of FDA's limited resources to issue the guidance proposed in the Petition regarding importation of drugs by alternative funding programs. If we do decide to develop policies or procedures about this issue in the future, you may comment through any appropriate mechanism at that time.

III. CONCLUSION

For the reasons described above, the Petition is denied.

Sincerely,

Michael Davis, M.D., Ph.D.
Deputy Director
Center for Drug Evaluation and Research
Food and Drug Administration

³⁵ More information about how to contact the FDA Import Program is available at <https://www.fda.gov/industry/import-program-food-and-drug-administration-fda/contact-fda-import-program>. We take complaints seriously and appreciate the information that you have provided. However, to the extent you are asking FDA to initiate an enforcement action, such actions are not within the scope of FDA's citizen petition procedures (see 21 CFR 10.30(k)).

³⁶ As noted above, more information about human drug imports is available at <https://www.fda.gov/drugs/guidance-compliance-regulatory-information/human-drug-imports>.