U.S. FOOD & DRUG ADMINISTRATION
OFFICE OF REGULATORY AFFAIRS

April 14, 2023

VIA EMAIL

Ashira Vantrees, Counsel
Aimed Alliance
1455 Pennsylvania Ave., NW, Suite 400
Washington, DC 20004
(954) 608-0912

www.aimedalliance.org

Dear Ms. Vantrees,

This letter responds to your email of February 25, 2023, to the Food and Drug Administration (FDA or Agency), submitted on behalf of Aimed Alliance, regarding practices of importing prescription drugs that you say are violating the FDA's policies and federal regulations. Specifically, you have concerns about certain companies partnering with health plans to implement "alternative funding programs" whereby plan enrollees' prescription medications are imported into the United States.

FDA shares your concerns about risks posed by unapproved new drugs and misbranded drugs. 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.

Drug products imported or offered for import into the United States must comply with all applicable requirements under the Federal Food, Drug, and Cosmetic Act ("FD&C Act"). Imported drugs must meet the FDA's standards for quality, safety, and effectiveness. At the time of import, the FDA will verify compliance with 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.

In most circumstances, it is illegal for individuals to import unapproved new drugs into the U.S. for personal use because such drugs have not been approved by the FDA. The FDA's Regulatory Procedures Manual (RPM) Chapter 9-2 "Coverage of Personal Importations" provides FDA field offices with information to consider in reviewing an unapproved new drug imported for personal use.

The FDA and the Department of Health and Human Services have provided two pathways to allow importation of certain prescription drugs that were originally intended for foreign markets. These pathways include a final rule to implement section 804 of the FD&C Act and a final guidance for industry 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. For further information,

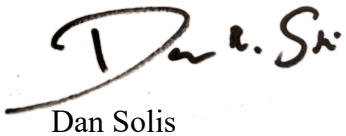
please visit the Importation of Drugs Originally Intended for Foreign Markets page.

FDA utilizes its import authorities under section 801(a) of the FD&C Act to examine drug products being imported or offered for import into the U.S., and, when appropriate, to refuse admission of drug products that appear to be violative, such as unapproved new drug products. FDA will continue to use its authority under the FD&C Act to address noncompliant products, including unapproved new drug products.

We appreciate your support of our compliance and enforcement actions, including for imported products. We will continue to use our resources to find and take action against those companies that import or offer for import illegal products.

This letter serves as FDA's response to Aimed Alliance's requests noted above and FDA considers this matter closed. We appreciate you bringing this matter to our attention. If you have any questions, please let us know at FDAImportsInquiry@fda.hhs.gov.

Sincerely,



Dan Solis
Assistant Commissioner for Import Operations
Office of Import Operations

cc:

S. Leigh Verbois
Director, Office of Drug Security, Integrity, and Response
Center for Drug Evaluation and Research