

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

August 28, 2024

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

Dear Ms. Vantrees:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition received on March 1, 2024, and submitted on behalf of Aimed Alliance. Your petition requests that the Agency "issue a guidance document, as outlined in 21 CFR 10.115, pertaining to third-party companies that partner with employer-sponsored health plans to import prescription drugs from outside the United States, also known as alternative funding programs."

FDA has been unable to reach a decision on your petition because it raises complex issues requiring extensive review and analysis by Agency officials. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as we have reached a decision on your request.

Sincerely,

Carol Bennett - Digitally signed by Carol Bennett - Date: 2024.08.28 10:56:36

Carol J. Bennett Acting Director Office of Regulatory Policy Center for Drug Evaluation and Research