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July 6, 2021

Re: Docket No. FDA-2021-P-0034

Dear Dr. Dohm, Ms. Karetnick, and Ms. Wood:

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 January 8, 2021, and submitted on behalf of the Pharmaceutical Research and Manufacturers of America, the Partnership for Safe Medicines, and the Council for Affordable Health Coverage. Your petition requests that the Agency refrain from authorizing the State of Florida's Section 804 Importation Program Proposal for the Importation of Prescription Drugs from Canada and disclose the identities of Foreign Sellers for public comment.

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 -S

Digitally signed by Carol Bennett -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Carol Bennett -S, 0.9.2342.19200300.100.1.1=2000004958
Date: 2021.07.06 14:36:47 -04'00'

Carol J. Bennett
Deputy Director
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