Julie Dohm, J.D., Ph.D.
Covington & Burling LLP
One CityCenter
850 Tenth Street, NW
Washington, DC 20001-4956

June 15, 2021

Re: Docket No. FDA-2020-P-2322

Dear Dr. Dohm:

I am writing to inform you that the Food and Drug Administration (FDA or the Agency) has not yet resolved the issues raised in your citizen petition received on December 17, 2020, and submitted on behalf of the Pharmaceutical Research and Manufacturers of America. Your petition requests that FDA:

1. Withdraw the Request for Proposals Regarding Insulin Reimportation Programs issued on September 24, 2020.

2. Refrain from authorizing reimportation of insulin under section 801(d)(2) unless insulin is in shortage as a result of a medical emergency.

3. Establish a process by which the drug manufacturer has notice and an opportunity to participate in the decision-making process with respect to an application for reimportation of its drug product under section 801(d)(2).

4. Provide the public with notice whenever an application for drug reimportation under section 801(d)(2) has been approved.

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,

Elizabeth R. Jungman -S

Digitally signed by Elizabeth R. Jungman -S
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Date: 2021.06.14 12:05:37 -04'00'

Elizabeth Jungman
Director
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