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

December 30, 2022

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

Dear Dr. Dohm:

This letter responds to your citizen petition (Petition) received by the Food and Drug Administration (FDA or the Agency) on December 17, 2020, and submitted on behalf of the Pharmaceutical Research and Manufacturers of America. Your Petition requests that FDA:[1]

(1) Withdraw the Request for Proposals (RFP) Regarding Insulin Reimportation Programs (Insulin Reimportation RFP)

(2) Refrain from authorizing reimportation of insulin under section 801(d)(2) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 381(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) of the FD&C Act

(4) Provide the public with notice whenever an application for drug reimportation under section 801(d)(2) of the FD&C Act has been approved

We have carefully reviewed your Petition and other information available to the Agency. For the reasons explained below, your Petition is dismissed in part and denied in part.

On September 24, 2020, pursuant to Executive Order 13938, the U.S. Department of Health and Human Services (HHS) issued the Insulin Reimportation RFP and an accompanying frequently asked questions document (FAQs). In January 2021, HHS issued a *Federal Register* notice entitled "Requests for Proposals for Insulin Reimportation and Personal Prescription Drug

[1] Petition at 1.

Importation" (January Notice)[2] and a revised version of the Insulin Reimportation RFP. The Insulin Reimportation RFP and associated FAQs described a process whereby FDA-approved insulin products manufactured in the United States and exported to a foreign country could be reimported back into the United States by a person other than the manufacturer. The Insulin Reimportation RFP cited section 801(d)(2) of the FD&C Act, which allows reimportation of drugs by entities other than the manufacturer if the drugs are required for emergency medical care.

As described in a *Federal Register* notice published July 9, 2021 (Withdrawal Notice), HHS withdrew the January Notice, the Insulin Reimportation RFP, and the FAQs.[3] HHS is not aware that any proposals were received, before publication of the Withdrawal Notice, in response to the January Notice or Insulin Reimportation RFP, and proposals submitted to HHS or FDA in response to the Insulin Reimportation RFP on or after publication of the Withdrawal Notice will not be considered.[4]

Your Petition is largely based on your assertion that the Insulin Reimportation RFP is flawed both legally and factually.[5] In support of your requests in the Petition:

(1) You assert that the Insulin Reimportation RFP ignores significant risks to patient safety posed by reimported insulin and fails to consider factors FDA has identified as relevant to determining whether a drug is "required for emergency medical care."[6]

(2) You argue that the Insulin Reimportation RFP relies on an improper reading of the "required for emergency medical care" provision under section 801(d)(2) of the FD&C Act.[7]

(3) You allege that the Insulin Reimportation RFP is also plagued by several additional legal flaws.[8]

(4) You further assert that FDA should establish a process for manufacturers to participate in FDA's consideration of any request by another entity under section 801(d)(2) of the

[2] 86 FR 6343 (Jan. 21, 2021), available at https://www.federalregister.gov/documents/2021/01/21/2021-01125/requests-for-proposals-for-insulin-reimportation-and-personal-prescription-drug-importation.

[3] 86 FR 36283 (July 9, 2021), available at https://www.federalregister.gov/documents/2021/07/09/2021-14637/requests-for-proposals-for-insulin-reimportation-and-personal-prescription-drug-importation.

[4] Id.

[5] Petition at 20.

[6] Petition at 1.

[7] Id.

[8] Petition at 2.

FD&C Act to reimport that manufacturer's specific drugs and that the public should be made aware of any decision to authorize reimportation.[9]

In light of the Withdrawal Notice, we are dismissing as moot your first request, for the withdrawal of the Insulin Reimportation RFP.

We also are denying your requests that FDA adopt or follow certain processes or procedures for the Agency's review of applications for drug reimportation under section 801(d)(2) of the FD&C Act. To the extent that you request that FDA comply with what you assert are legal requirements, such as that FDA comply with section 801(d)(2)'s "required for emergency medical care" provision, which you assert "is properly interpreted to allow reimportation of a drug only when a shortage of that drug arises as the result of a medical emergency," these are not requests to "take or refrain from taking" an administrative action, and so are not the appropriate subject of a citizen petition (see 21 CFR § 10.25(a)).

In addition, as noted in your Petition, FDA promulgated regulations implementing section 801(d)(2) in 1999.[10] Section 801(d)(2) has limited applicability, because a drug must be "required for emergency medical care" for FDA to authorize its reimportation. Given this, considering the development of any new processes or procedures for the Agency's review of applications for drug reimportation under section 801(d)(2) would not be an efficient use of FDA's limited resources at this time. If we do decide to develop new processes or procedures for the Agency's review of applications for drug reimportation in the future, you could submit a new citizen petition and/or comment through any appropriate mechanism at that time.

For the reasons set forth above, your request for withdrawal of the Insulin Reimportation RFP is dismissed as moot. The remaining requests in your Petition are denied.

Sincerely,

Jacqueline A. Corrigan-curay -S

Digitally signed by Jacqueline A. Corrigan-curay -S
Date: 2022.12.30 10:19:38 -05'00'

Patrizia Cavazzoni, M.D.
Director
Center for Drug Evaluation and Research

[9] Id.

[10] Prescription Drug Marketing Act of 1987; Prescription Drug Amendments of 1992; Policies, Requirements, and Administrative Procedures, 64 FR 67720 (Dec. 3, 1999) (promulgating 21 CFR §§ 203.10-203.12).