DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Silver Spring MD 20993

December 22, 2020

Julie Dohm, J.D., Ph.D.
Covington & Burling LLP
800 Tenth Street, NW
Washington, DC 20001

Sent via email to: jdohm@cov.com

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting the FDA:

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

Your submission was received by this office on 12/17/2020. It was assigned docket number FDA-2020-P-2322. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter and in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Dynna Gorham-bigby -S
Digitally signed by Dynna Gorham-bigby -S
Date: 2020.12.22 15:16:40 -05'00'

Dynna Bigby
Supervisory Administrative Proceedings Officer
Dockets Management Staff
FDA/Office of Operations (OO)

CC: jperez@cov.com