DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Silver Spring MD 20993

November 27, 2020

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

Dear Petitioner:

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

1. Discontinue section 804(j) implementation efforts, including withdraw HHS and FDA's "Request for Proposals Regarding Waivers for Individual Drug Importation Plans" and refrain from approving any Individual Waiver Importation Plans; or

2. Refrain from granting waivers to authorize personal importation pursuant to section 804(j)(2) unless and until HHS;

    a. Certifies to Congress, after an appropriate notice-and-comment proceeding, that the implementation of section 804 of the FDCA, including 804(j), poses no additional risk to the public's health and safety and results in a significant reduction in the cost of covered products to the American consumer;
    b. Publishes a final guidance document in accordance with FDA's Good Guidance Practices that describes the circumstances under which the Secretary will grant case-by-case waivers prior to issuing any waiver pursuant to section 804(j)(2);
    c. Grants case-by-case waivers to indidivuals solely in compliance with statutory requirements applicable to personal importation under the FDCA;
    d. Follows the appropriate due process procedures for informal adjudications under the Administrative Procedure Act; and
    e. Publishes notice of any approvals of any individual drug importation plans or grants of case-by-case waivers immediately upon issuance.

Your submission was received by this office on 11/25/2020. It was assigned docket number FDA-2020-P-2236. 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: 2020.11.27 11:00:26 -05'00'

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