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

May, 24, 2021

Re: Docket No. FDA-2020-P-2236

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 November 25, 2020, and submitted on behalf of the Pharmaceutical Research and Manufacturers of America. Your petition requests that FDA and the U.S. Department of Health and Human Services (HHS):

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 Federal Food, Drug, and Cosmetic Act (FDCA), including section 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 individuals 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.

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
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Carol J. Bennett
Deputy Director
Office of Regulatory Policy
Center for Drug Evaluation and Research