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December 30, 2022

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

Dear Dr. Dohm:

This letter responds to your citizen petition (Petition) received by the Food and Drug Administration (FDA or the Agency) 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]

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

(2) Refrain from granting waivers to authorize personal importation pursuant to section 804(j)(2) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 384(j)(2)), unless and until HHS:

   a. Certifies to Congress, after an appropriate notice-and-comment proceeding, that the implementation of section 804 of FD&C Act, 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 FD&C Act

[1] Petition at 1-2.

d. Follows the appropriate due process procedures for informal adjudications under the Administrative Procedure Act (APA)

e. Publishes notice of any approvals of any individual drug importation plans, or grants of case-by-case waivers, immediately upon issuance

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, HHS issued the Personal Importation 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 Importation" (January Notice)[2] and a revised version of the Personal Importation RFP. The Personal Importation RFP and associated FAQs described a process for pharmacies or other private sector entities to submit IWIPs for HHS authorization. These plans were intended to allow individuals who obtain a waiver from the Secretary to purchase prescription drugs imported from certain countries and regions. The drugs would have been dispensed to the individuals by authorized State-licensed pharmacies specified in the plan. The Personal Importation RFP cited section 804(j)(2) of the FD&C Act for the authority to grant to individuals a waiver of the prohibition on importation of prescription drugs or devices.

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

[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.

Your Petition is largely based on your assertion that the Personal Importation RFP and IWIP program constitute a significant departure from the requirements of both the FD&C Act and the APA.[5] In support of your requests in the Petition:

(1) You assert that HHS is proceeding to implement section 804(j)(2) of the FD&C Act through the IWIP program without having met the threshold requirements of section 804.[6]

(2) You argue that the IWIP program impermissibly conflates personal importation with commercial importation.[7]

(3) You allege that products that would be subject to an IWIP would be unapproved, misbranded, and likely adulterated.[8]

(4) You assert that HHS must issue guidance describing the circumstances in which it intends to grant case-by-case waivers of the prohibition of importation before it can approve any IWIPs.[9]

(5) You allege that, in the past, HHS and FDA have described significant safety and cost concerns associated with personal importation and that HHS has not explained how the IWIP program will address those concerns.[10]

(6) You further assert that each approval of an IWIP or other grant of a case by-case-waiver is an informal adjudication under the APA which, you assert, gives interested persons the right to notice and an opportunity to provide input.[11]

In light of the Withdrawal Notice, we are dismissing as moot your request that we withdraw the Personal Importation RFP and refrain from approving any IWIPs.

We also are denying your requests that FDA adopt or follow certain processes and procedures with regard to implementing section 804(j). Many of these requests are that FDA comply with what you assert are legal requirements, such as that FDA: "grant[] case-by-case waivers to individuals solely in compliance with statutory requirements applicable to personal importation under the [FD&C Act];" and "follow[] the appropriate due process procedures for informal

[5] Petition at 2.

[6] Id.

[7] Id.

[8] Petition at 3.

[9] Petition at 3 & 18.

[10] Id.

[11] Id.

adjudications under the [APA]." Requests that FDA abide by legal requirements 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, the Personal Importation RFP has been withdrawn, neither HHS nor FDA is engaged in any other implementation of section 804(j), and, as you note in your petition, section 804(j) is not in effect, because the Secretary has not made the section 804(*l*) certification to Congress with regard to personal importation. Given these facts, considering what policies and procedures FDA should adopt and follow with regard to implementing section 804(j) would not be an efficient use of FDA's limited resources at this time. If we do decide to implement section 804(j) 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 Personal Importation RFP and for FDA to refrain from approving any IWIPs 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 10:22:21

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