August 23, 2023

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RE: Docket No. FDA-2023-P-0660

Dear Mr. Mendoza and Dr. Morten,

This is an interim response to the Citizen Petition (FDA-2023-P-0660) (“petition”) that you filed with Food and Drug Administration (FDA) on February 27, 2023.

Your petition requests that the Commissioner take the following actions:

1. Order and organize offices to increase enforcement of 42 U.S.C. § 282(j), issuing more Pre-Notices and Notices of Noncompliance, and imposing civil money penalties when appropriate;
2. Order the drafting and issuance of a new guidance document which explains how FDA will focus its enforcement efforts. This guidance should clearly outline a prioritization framework for the enforcement of 42 U.S.C. § 282(j); and
3. Create a public dashboard of Pre-Notices sent by FDA.

FDA will require additional time to issue its final response to your petition because of the complexity of issues raised. FDA intends to respond to your citizen petition once our review is complete. 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 requests.

Sincerely,

Lauren Roth
Associate Commissioner for Policy

U.S. Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20903
www.fda.gov
cc:

The Honorable Xavier Becerra, Secretary
U.S. Department of Health and Human Services

Lawrence A. Tabak, DDS, PhD, Acting Director
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