



August 23, 2023

Justin Mendoza, admin@essentialmedicine.org
Interim Executive Director
Universities Allied for Essential Medicines North America
1380 Monroe Street, NW, #218
Washington, DC 20010

Christopher J. Morten, J.D., Ph.D.
Director, Science, Health & Information Clinic
Morningside Heights Legal Services, Inc.
Columbia Law School
435 West 116th Street
New York, NY 10027

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



cc:

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

Lawrence A. Tabak, DDS, PhD, Acting Director
National Institutes of Health

Megan Curtin
curtinemegan@gmail.com
Member, Transparency Team,
UAEM North America

Ted Malpass
teddymalpass@gmail.com
Member, Transparency Team,
UAEM North America

Navya Dasari
nd2199@nyu.edu
Member, Transparency Team,
UAEM North America

Lauren Baron
Student Attorney, Science, Health &
Information Clinic, Columbia Law School
Legal representative of UAEM

Davis Gonsalves-DeDobbelaere
Student Attorney, Science, Health & Information
Clinic, Columbia Law School
Legal representative of UAEM

Amy Chun
Student Attorney, Science, Health &
Information Clinic, Columbia Law School
Legal representative of UAEM

Nancy Lu
Student Attorney, Science, Health & Information
Clinic, Columbia Law School
Legal representative of UAEM

Kasey Clarke
Student Attorney, Science, Health &
Information Clinic, Columbia Law School
Legal representative of UAEM

Wisdom Onwuchekwa-Banogu
Student Attorney, Science, Health & Information
Clinic, Columbia Law School
Legal representative of UAEM

Ari Wugalter, Ph.D.
Student Attorney, Science, Health &
Information Clinic, Columbia Law School
Legal representative of UAEM

Mica Standing Soldier
Student Attorney, Science, Health & Information
Clinic, Columbia Law School
Legal representative of UAEM