U.S. FOOD & DRUG ADMINISTRATION

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November 1, 2024

Re: Docket No. FDA-2024-P-2379

Dear Petitioners:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition received on May 15, 2024. Your petition requests that the Agency

> take action consistent with Congress' enactment of the Federal Food, Drug, and Cosmetic Act ("FDCA") and the Food and Drug Omnibus Reform Act of 2022 ("FDORA") and amend its regulations and guidance documents to clarify the requirements for approval of drugs for the benefit of the regulated community, including the acceptance of data from new alternative methods ("NAMs").

(Petition at 2.)

FDA has been unable to reach a decision on your petition due to the need to address other Agency priorities. 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 possible given the numerous demands on the Agency's resources.

Sincerely,

Carol Bennett -S

Digitally signed by Carol Bennett -S
Date: 2024.11.01 09:44:20 -04'00'

Carol J. Bennett
Acting Director
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Center for Drug Evaluation and Research

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