U.S. FOOD & DRUG ADMINISTRATION

Jeffrey A. Mattes, M.D.
(b) (6)
[redacted]

June 1, 2023

Re: Docket No. FDA-2022-P-3067

Dear Dr. Mattes:

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 December 6, 2022 (Petition). Your Petition requests that the Agency:

> issue a guidance or a rule to require that any involvement of drug companies with e-prescribing systems, either by way of a "Clinical Decision Support" program or other involvement, in particular if the drug company is paying the EHR [electronic health records] or e-prescribe vendor for a particular action, should be reported to the FDA as promotional, and preferably reviewed by the FDA before implementation.[1]

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: 2023.06.01 09:47:23 -04'00'

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

[1] Petition at 1-2.