April 27, 2023

Michael A. Carome, M.D., Director
Public Citizen's Health Research Group
1600 20th Street, N.W.
Washington, DC 20009

Sent via email to: mcarome@citizen.org

Dear Petitioner:

Your submission requesting that the Commissioner of Food and Drug to promptly initiate the regulatory process to amend, through notice and comment rulemaking, FDA regulations at 21 C.F.R. § 216.24 — the list of drug products that were withdrawn or removed from the market for reasons of safety or effectiveness and that therefore may not be compounded under the exemptions provided by section 503A(a) or section 503B(a) of the FDCA — to include hydroxyprogesterone caproate injection for prevention of preterm birth was received and processed under CFR 10.30 by this office on 04/27/2023.

It was assigned docket number FDA-2023-P-1660. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note, the acceptance of the petition for filing is a procedural matter and in no way reflects the Agency's decision on the substantive merits of the petition.

Sincerely,

Karen Malvin

Karen Malvin
Acting Director
Dockets Management Staff
FDA/Office of Operations (OO)

cc: swolfe@citizen.org