April 3, 2020

Meena Aladdin, M.S., Ph.D
Public Citizen
1600 20th Street, NW
Washington, DC 20009

Re: Docket No. FDA-2019-P-4683

Dear Dr. Aladdin:

I am writing to inform you that the Food and Drug Administration (FDA or Agency) has not yet resolved the issues raised in your citizen petition, submitted on behalf of Public Citizen, received on October 8, 2019. Your petition requests that FDA (1) immediately withdraw approval of all medications containing hydroxyprogesterone caproate (HPC), which you state is currently marketed under the brand name Makena and multiple generic formulations; and (2) immediately place HPC on the list of drug products that have been withdrawn or removed from the market for reasons of safety or effectiveness and therefore may not be compounded under the exemptions provided by sections 503(A)(a) or 503B(a) of the Food, Drug, and Cosmetic Act.

FDA has been unable to reach a decision on your petition because it raises complex issues requiring extensive review and analysis by Agency officials. 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 request.

Sincerely,

Carol Bennett -S

Digitally signed by Carol Bennett -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Carol Bennett -S, 0.9.2342.19200300.100.1.1=2000004958
Date: 2020.04.03 09:47:54 -04'00'

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