DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

October 8, 2019

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

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting that the FDA;

1. Immediately withdraw approval of all medications containing hydroxyprogesterone caproate (hereafter referred to as hydroxyprogesterone), which is currently marketed under the brand name Makena and multiple generic formulations.

2. Immediately place hydroxyprogesterone on the list of drug products that have been withdrawn or removed from the market for reasons of safety or effectiveness and therefore may not be compounded under the exemptions provided by sections 503A(a) or 503B(a) of the FDCA was received by this office on 10/08/2019.

It was assigned docket number FDA-2019-P-4683. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Dynna Bigby Digitally signed by Dynna Bigby Date: 2019.10.08 13:15:56 -04'00'

Dynna Bigby
Supervisory Administrative Proceedings Officer
Dockets Management Staff
FDA/Office of Operations (OO)