DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

February 10, 2020

Neal D. Barnard, MD
Physicians Committee for Responsible Medicine
5100 Wisconsin Ave., NW
Suite 400
Washington, DC 20016

Sent via email to: mkennedy@pcrm.org

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting the FDA to require manufacturers to include the following notice on the product packaging and labeling of erectile dysfunction drugs:

> *Erectile dysfunction is caused by artery disease, a condition that this drug will not improve. Artery disease can lead to heart attacks, strokes, and early death. A plant-based diet, moderate exercise, stress management, and lack of smoking can, in combination, improve and often reverse artery disease.*

Your submission was received by this office on 02/10/2020, and it was assigned docket number FDA-2020-P-0698. 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: 2020.02.10 13:01:13 -05'00'

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