



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring MD 20993

March 21, 2019

Sidney M. Wolfe, M.D. et. al.
Founder and Senior Adviser
Public Citizen's Health Research Group
1600 20th Street NW
Washington DC 20009

Sent via email to: swolfe@citizen.org

Dear Petitioner:

Your petition to the Food and Drug Administration requesting that the Commissioner impose a moratorium on approval of all NDAs for new opioids or new opioid formulations was received by this office on 3/21/2019.

It was assigned docket number FDA-2019-P-1364. 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
Supervisory Administrative Proceedings Specialist
Division of Dockets Management
FDA/Office of the Executive Secretariat (OES)