



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring MD 20993

April 5, 2019

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Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration is requesting to immediately impose a moratorium on all future approvals of new drug applications (NDAs) for new opioids or new opioid formulations was received by this office on 04/05/2019.

It was assigned docket number FDA-2019-P-1643. 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)