



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring MD 20993

April 8, 2019

Scott M. Lassman
Goodwin Procter LLP
901 New York Avenue, NW
Washington, DC 20001

Sent via email to: SLassman@goodwinlaw.com

Dear Petitioner:

Your petition to the Food and Drug Administration requesting that the Commissioner revoke orphan drug designation for Sublocade (buprenorphine extended-release) injection for treatment of opiate addiction in opiate users, currently referred to as opioid use disorder was received by this office on 04/05/2019.

It was assigned docket number FDA-2019-P-1679. 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)