



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

August 21, 2019

Errol Gould, Ph.D.
Global Head of Clinical Development
and Medical Affairs
Persion Pharmaceuticals LLC
10 North Park Place
Suite 201
Morristown, NJ 07960

Sent via email to: egould@nalpropion.com

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting to take certain actions with respect to generic Hydrocodone Bitartrate Extended-Release Capsules to protect the safety of patients with hepatic impairment was received by this office on 08/20/2019.

It was assigned docket number FDA-2019-P-3946. 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
Dockets Management Staff
FDA/Office of Operations (OO)

CC: Sally Y. Choe, Ph.D.