



DEPARTMENT OF HEALTH & HUMAN SERVICES

---

Food and Drug Administration  
Rockville, MD 20857

September 5, 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](mailto: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 08/29/2019.

It was assigned docket number FDA-2019-P-4140. 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.