PERSION™
PHARMACEUTICALS LLC

August 29, 2019

VIA ELECTRONIC SUBMISSION

Division of Dockets Management
Department of Health and Human Services
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

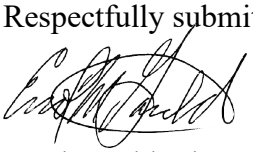
Re: Docket No. FDA-2019-P-3946; Withdrawal of Citizen Petition

Dear Sir or Madam:

On behalf of Persion Pharmaceuticals LLC ("Persion"), the undersigned hereby withdraws pursuant to 21 C.F.R. § 10.30(g) the above-identified Citizen Petition (Docket No. FDA-2019-P-3946) requesting the Commissioner of Food and Drugs to take certain actions with respect to generic hydrocodone bitartrate extended-release capsules to protect the health and safety of patients with hepatic impairment. This withdrawal is being made without prejudice to resubmission.

I certify that, to my best knowledge and belief: (a) I have not intentionally delayed submission of this document or its contents; and (b) the information upon which I have based the action requested herein first became known to me on or about August 29, 2019. If I received or expect to receive payments, including cash and other forms of consideration, to file this information or its contents, I received or expect to receive those payments from the following persons or organizations: Persion Pharmaceuticals LLC. I verify under penalty of perjury that the foregoing is true and correct as of the date of the submission of this document.

Respectfully submitted,



Errol Gould, PhD
Global Head of Clinical Development
and Medical Affairs
Nalpropion Pharmaceuticals, Inc. (an affiliate of
Persion Pharmaceuticals LLC)
T: 215-704-0475 Email: egould@nalpropion.com