DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

June 16, 2020

Francis E. O'Donnell, Jr., MD
(b) (6)

Sent via email to: (b) (6)

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting the FDA to:

1. Amend current black box warnings on all opioid analgesics to include:

WARNING: In order to reduce the risk of addiction and death due to overdose, prescribers of opioid analgesics in patients who have achieved adequate pain control should seek the patient's cooperation with a program of gradual reduction in dosing and discontinuation if possible. (See Dosage and Administration General Principles)

2. Require that package inserts for all opioids include the recommendation that patients with adequately controlled pain on a stable dose of opioids should be engaged by prescribers about their willingness to titrate down their daily dosage and ultimately discontinue opioids if possible (please see suggested insert for inclusion in section of package insert on Dosage and Administration General Principles).

Your petition was received by this office on 06/16/2020 and assigned docket number FDA-2020-P-1575. 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 and in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Dynna Gorham-bigby -S

Digitally signed by Dynna Gorham-bigby -S
Date: 2020.06.17 11:05:17 -04'00'

Dynna Bigby
Supervisory Administrative Proceedings Officer
Dockets Management Staff
FDA/Office of Operations (OO)