August 9, 2022

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Sent via email to: tyler.coyle@cuanschutz.edu

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting that FDA take the following two actions described below:

1) Update language in the labeling of sublingual buprenorphine products approved to treat opioid use disorder (OUD). This CP requests that labeling include the following statement:

> Following initiation, buprenorphine dose should be titrated based on the prescriber's clinical judgment to alleviate symptoms enough to enable patients to maintain discontinuation of illicit opioid use. Evidence suggests that 16mg per day or more may reduce risk of overdose death more effectively than lower doses. Some patients may require a higher than average dose due to significant inter-patient variability in opioid tolerance, drug absorption, and drug metabolism such as during pregnancy.

2) Issue a drug safety communication (DSC) to providers highlighting the potential clinical benefit of sublingual buprenorphine doses >16mg/day in patients with OUD.

This petition was received by this office and processed under CFR 10.30 on 08/09/2022 and it was assigned docket number FDA-2022-P-1863. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note, the acceptance of the petition for filing is a procedural matter and in no way reflects the Agency's decision on the substantive merits of the petition.

Sincerely,

Karen P. Malvin -S

Digitally signed by Karen P. Malvin -S
Date: 2022.08.10 08:34:48 -04'00'

Karen Malvin
Acting Director
Dockets Management Staff
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