U.S. FOOD & DRUG ADMINISTRATION

D. Tyler Coyle MD, MS, FASAM
University of Colorado School of Medicine
ARTS Westside Center for Change
6303 Wadsworth Bypass
Arvada, CO 80003

February 2, 2023

Re: Docket No. FDA-2022-P-1863

Dear Dr. Coyle:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition received on August 9, 2022. Your petition requests that the Agency:

1) Update language in the labeling of sublingual buprenorphine products approved to treat opioid use disorder (OUD). This [petition] 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.

FDA has been unable to reach a decision on your because it raises complex issues requiring extensive review and analysis by Agency officials. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as we have reached a decision on your request.

Sincerely,

Carol Bennett -S Digitally signed by Carol Bennett -S
Date: 2023.02.01 15:42:18 -05'00'

Carol J. Bennett
Deputy Director
Office of Regulatory Policy
Center for Drug Evaluation and Research

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