FDA U.S. FOOD & DRUG ADMINISTRATION

Michael C. Barnes
Chairman of the Board
Center for Lawful Access and Abuse Deterrence
1000 Potomac Street NW, Suite 150-A
Washington, DC 20007

DEC 2 8 2017

Re: Docket No. FDA-2017-P-4039

Dear Mr. Barnes:

I am writing to inform you that the Food and Drug Administration (FDA or the Agency) has not yet resolved the issues raised in your citizen petition received July 3, 2017, and submitted on behalf of the Center for Lawful Access sand Abuse Deterrence. Your petition requests that FDA take certain actions to foster a transition to opioid analgesics with abuse-deterrent labeling (ADOs). Specifically, you ask FDA to require that, once three oral immediate-release or three oral extended-release/long-acting (ER/LA) ADOs with the same active moiety, all oral opioids without abuse-deterrent properties with that same active moiety and release profile either be converted to ADOs within three years of the approval date of the third ADO or else be removed from the market. You further request that, given that FDA has already approved abuse-deterrent labeling for three oral ER/LA morphine and oxycodone analgesics, FDA require manufacturers of oral non-abuse-deterrent ER/LA morphine and oxycodone analgesics to convert those products to ADOs or else remove them from the market on July 3, 2020.

FDA has been unable to reach a decision on your petition 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 requests.

Sincerely,

Carol Bennett

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

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov