



October 16, 2017

Scott Gottlieb, MD
Acting Commissioner
US Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Re: FDA-2017-N-4977

Dear Dr. Gottlieb,

The Coalition to Stop Opioid Overdose (CSOO) is pleased to have the opportunity to comment on the new drug application (NDA) 209819, buprenorphine subcutaneous injection, submitted by Indivior Pharmaceuticals, Inc. for the proposed indication of maintenance treatment of opioid dependence.

CSOO is a coalition of health care and social service providers, criminal justice professionals, patients and family advocates, and allied organizations united around common policy goals that will lead to meaningful and comprehensive policies to promote opioid addiction prevention, treatment, and recovery.

We support a comprehensive approach to addressing the opioid misuse and overdose epidemic including increasing access to and improving the quality of opioid addiction treatment. The introduction of novel addiction pharmacotherapies supports this goal. Addiction patients, like all patients, should have available to them a robust and varied array of treatment options as no one treatment modality is appropriate or therapeutic for everyone.

Buprenorphine has been shown to be safe and effective for the treatment of opioid dependence. Unlike the oral buprenorphine formulations, this once-monthly subcutaneous injection has the potential to decrease risk of diversion.

CSOO supports the development and manufacturing of medications that aid in the treatment of addiction and applauds the efforts of manufacturers to minimize the risks of diversion, accidental exposure and/or overdose associated with potentially addictive pharmaceuticals. Both are necessary to improve the care of people with addiction and to advance the field of treatment but, independent of similar efforts to advance prevention, education and recovery support services, not sufficient to fully address the causes and consequences of addiction.



CSOO looks forward to a continued collaboration with your agency to promote advances in and increased access to opioid addiction treatment. Again, the CSOO thanks the FDA for the opportunity to share our comments with the Psychopharmacologic Drugs Advisory Committee.

Sincerely,

Coalition To Stop Opioid Overdose
<http://www.stopopioidoverdose.org/>