March 14, 2019

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

Janet Woodcock, MD
Director
Center for Drug Evaluation and Research
US Food and Drug Administration
10001 New Hampshire Avenue
Hillandale Building, 4th Floor
Silver Spring, MD 20993

Dear Commissioner Gottlieb and Dr. Woodcock,

On behalf of the American Society of Addiction Medicine (ASAM), a national medical specialty society representing more than 6,200 physicians and associated health professionals who specialize in the prevention and treatment of addiction, I am writing to you regarding the need for more medication treatment options for patients with substance use disorder (SUD). Foremost to ASAM’s mission is increasing access to and improving the quality of addiction treatment. Patients with SUD, 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.

Addiction is a complex condition. Clinicians and their patients need access to multiple, nuanced treatment options to meet their unique needs and circumstances. Access to multiple formulations and dosages expands the number of available effective and safe treatment options for SUD.

Therefore, as the FDA considers applications for new products to treat SUD, ASAM hopes that the FDA takes into consideration the need for access to multiple treatment options for clinicians and their patients. Expanding access to safe and effective treatment options for SUD can help advance efforts to address the nation’s opioid overdose epidemic. Please contact Kelly Corredor, Senior Director of Advocacy and Government Relations at kcorredor@asam.org or (301) 547-4111 if you have any questions or would like to discuss this issue further. Thank you for your time and consideration of ASAM’s concerns.
Sincerely,

Kelly Clark, MD, MBA, DFASAM  
President, American Society of Addiction Medicine