DEPARTMENT OF HEALTH & HUMAN SERVICES

FEB 12 2014

Food and Drug Administration
10903 New Hampshire Avenue
Building #51
Silver Spring, MD 20993

Janak Jadeja, R. Ph.
Director, Regulatory Affairs
Actavis Elizabeth LLC
200 Elmora Avenue
Elizabeth, NJ 07207

Re: Docket No. FDA-2013-P-1055

Dear Dr. Jadeja:

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 20, 2013, and submitted on behalf of Actavis Elizabeth LLC. Your petition requests that the Agency make a determination as to whether SUBUTEX (buprenorphine hydrochloride (HCl) Sublingual Tablets, Equivalent (Eq) 2 milligrams (mg) base and Eq 8 mg base), new drug application (NDA) 20-732, was removed from the market for reasons of safety or effectiveness.

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 request.

Sincerely,

for Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research