DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

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September 5, 2013

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

Dear Dr. Jadeja:

Your petition to the Food and Drug Administration requesting the Agency to provide a determination that SUBUTEX® (buprenorphine hydrochloride) Sublingual Tablets, EQ. 2 mg and 8 mg Base were not voluntarily withdrawn for safety or efficacy reasons, was received by this office on 8/20/2013. It was assigned docket number FDA-2013-P-1055/CP1 and it was filed on 8/20/2013. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an Agency decision on the substantive merits of the petition.

Sincerely,

Karen Kennard
Director
Division of Dockets Management
FDA/Office of the Executive Secretariat (OES)