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August 16, 2013

BY OVERNIGHT MAIL

Division of Dockets Management (HFA-305)
U.S. Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

CITIZEN PETITION

Dear Sir or Madam,

The undersigned submits this petition in quadruplicate pursuant to 21 C.F.R. §§ 10.30 and 314.161, requesting the Commissioner of the Food and Drug Administration to provide a determination whether a listed drug has been withheld from sale for safety or effectiveness reasons, as outlined below.

A. Action Requested

The petitioner requests that the Commissioner of the Food and Drug Administration (FDA) determine that SUBUTEX® (buprenorphine hydrochloride) Sublingual Tablets, EQ. 2 mg and 8 mg Base were not voluntarily withdrawn for safety or efficacy reasons.

B. Statement of Grounds

1. The above-referenced drug products were initially approved under NDA 20-732 on October 8, 2002. (See attached, Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations)

2. At the time of this submission, there is no evidence that the NDA holder is currently marketing SUBUTEX® (buprenorphine hydrochloride) Sublingual Tablets, EQ. 2 mg and 8 mg Base.

3. An abbreviated new drug application (ANDA) seeking approval of a generic formulation of a discontinued reference listed drug must be accompanied by a Citizen Petition for FDA's determination that the discontinued reference listed drug was not voluntarily withdrawn for safety or effectiveness reasons. 21 C.F.R. §§ 314.122, 314.161.

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4. Because there is no apparent commercial distribution of SUBUTEX® (buprenorphine hydrochloride) Sublingual Tablets, EQ. 2 mg and 8 mg Base, it is requested that the FDA determine whether the applicant holder's decision to not market the drug products, as approved under NDA 20-732, was for reasons of safety or effectiveness.

5. Should the NDA holder commence marketing of SUBUTEX® (buprenorphine hydrochloride) Sublingual Tablets, EQ. 2 mg and 8 mg Base after submission of this petition but before an FDA response, Actavis will consider this petition moot and take appropriate action to request its withdrawal.

C. Environmental Impact

Petitioner claims a categorical exclusion from the requirement of an environmental assessment or environmental impact statement pursuant to 21 C.F.R. § 25.31.

D. Economic Impact

Pursuant to 21 C.F.R. § 10.30(b), economic impact information is to be submitted only when requested by the Commissioner following review of this petition.

E. Certification

The undersigned certifies that to the best knowledge and belief of the undersigned, this Citizen Petition includes all information and views upon which the petition relies, and includes representative data and information known to the petitioner which are unfavorable to the petition.

Respectfully submitted,

Actavis Elizabeth LLC.

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