November 26, 2013

SigmaPharm
LABORATORIES

VIA FEDERAL EXPRESS

Division of Dockets Management (HFA-305)
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Dear Sir or Madam,

Sigmapharm Laboratories, LLC ("Sigmapharm") submitted to the FDA a Citizen Petition dated October 30, 2013. The Citizen Petition was submitted to consider incomplete and refuse to receive any ANDA for Asenapine Maleate Sublingual Tablets that does not contain the results of a bioequivalence study performed in accordance with the Agency's June, 2013 product-specific bioequivalence guidance for this drug product.

The submitted Citizen Petition was received by the FDA on October 31, 2013 and was assigned a docket number FDA-2013-P-1399/CP1, and was filed on 11/19/2013.

On November 26, 2013 Sigmapharm received a call from the FDA in reference to the above mentioned Citizen Petition to revise the "Certification" section of the Citizen Petition in accordance with 505(q) (1) (H) of Federal Food, Drug and Cosmetic Act.

We are therefore hereby submitting the revised Citizen Petition and requesting withdrawal of Citizen Petition dated October 30, 2013.

We sincerely apologize for the inconvenience caused. In case of any questions please direct correspondence to me per the contact information shown in the signature line.

Sincerely,

Rakesh Grover, Ph.D.
President & Chief Operating Officer,
Sigmapharm Laboratories, LLC
Telephone: (215) 352-6636
Fax: (215) 352-6644
E-mail: rgrover@sigmapharm.com

FDA-2013-P-1554

2013-9947
CP