DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

FILE COPY

December 13, 2013

Rakesh Grover, Ph.D.
President & Chief Operating Officer
Sigmapharm Laboratories, LLC
3375 Progress Drive
Bensalem, PA 19020

Dear Dr. Grover:

Your petition to the Food and Drug Administration requesting the Agency to refuse to receive ("RTR") any Abbreviated New Drug Application ("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 and that the filing acceptance date of any ANDA for Asenapine Sublingual Tablets, for purposes of determining eligibilty for 180 day exclusivity, be based on the date that the application first contained the results of a bioequivalence study performed in accordance with the Agency's June 2013 bioequivalence guidance, was received by this office on 12/9/2013. It was assigned docket number FDA-2013-P-1623/CP1, and it was filed on 12/13/2013. 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

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