DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

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November 19, 2013

Rakesh Grover, Ph.D.
President & Chief Operating Officer
Sigmapharm Laboratories, LLC
3375 Progress Drive
Bensalem, PA 19120

Dear Petitioner:

Your petition to the Food and Drug Administration requesting the Agency 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, was received by this office on 10/31/2013. It was assigned docket number FDA-2013-P-1399/CP1, and it was filed on 11/19/2013. 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)