DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

November 15, 2013

FILE COPY

Edward J. Allera
Counsel to Covis Pharma Sarl
Buchanan Ingersoll & Rooney PC
1700 K Street NW, Suite 300
Washington, D.C. 20006

Dear Mr. Allera:

Your petition to the Food and Drug Administration requesting the Agency to confirm that the 0.0625 mg and 0.1875 mg tablets on September 30, 1997 in NDA 20-405 was not fully approved, was received by this office on 10/21/2013. It was assigned docket number FDA-2013-P-1376/CP1, and it was filed on 11/15/2013. 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)