DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

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November 15, 2013

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 require all ANDA sponsors of 0.0625 mg and 0.1875 mg Digoxin tablet dosage strengths that rely upon Covis' Lanoxin tablets as the RLD to conduct and pass the same validation testing that Covis conducted, was received by this office on 10/21/2013. It was assigned docket number FDA-2013-P-1377/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)