DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

MAR 20 2014

Edward J. Allera
Buchanan Ingersoll & Rooney PC
1700 K Street N.W., Suite 300
Washington, DC 20006

Re: Docket No. FDA-2013-P-1376

Dear Mr. Allera:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition received on October 21, 2013, and submitted on behalf of Covis Pharma Sàrl (Covis). Your petition requests that the Agency confirm (1) that FDA did not "fully approve" the 0.0625 mg and 0.1875 mg strength Lanoxin tablets on September 30, 1997, when the approval letter for NDA 20405 was issued, (2) that three-year exclusivity was awarded but did not begin to run for the 0.0625 mg and 0.1875 mg tablets on September 30, 1997, and (3) that Petitioner is entitled to three-year exclusivity for the 0.0625 mg and 0.1875 mg tablets beginning on the date of approval of the prior approval supplement (PAS).

FDA has been unable to reach a decision on your petition because it raises significant issues requiring extensive review and analysis by Agency officials. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as we have reached a decision on your request.

Sincerely,

for Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research