



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration  
Rockville MD 20855

ANDA 078406/S-014

Aurobindo Pharma USA, Inc.  
Attention: Blessy Johns  
U.S. Agent for Aurobindo Pharma Limited  
2400 Route 130 North  
Dayton, NJ 08810

Dear Madam:

Please refer to your supplemental new drug application dated August 23, 2010, submitted pursuant to 21 CFR 314.70 (c) (6) [Supplement – Changes Being Effected] for Paroxetine Tablets USP, 10 mg, 20 mg, 30 mg, and 40 mg.

This supplemental new drug application provides for a revised package insert to be in accordance with the labeling changes to the reference listed drug, Paxil® (paroxetine hydrochloride) Tablets, NDA 020031/S-059, approved August 7, 2009.

We have completed the review of your application and it is approved. However please further revise your insert labeling to be in accordance with the recently approved RLD labeling, NDA 020031/S-063, approved on October 27, 2010, and submit as a Supplement – Changes Being Effected. To facilitate review of your next submission, and in accordance with 21 CFR 314.94(a)(8)(iv), please provide a side-by-side comparison of your proposed labeling with your last submission with all differences annotated and explained.

We note that if FDA requires a Risk Evaluation & Mitigation Strategy (REMS) for a listed drug, an ANDA citing that listed drug also will be required to have a REMS. See section 505-1(i) of the Act.

**CONTENT OF LABELING**

As soon as possible, but no later than 14 days from the date of this letter, submit, using the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>, that is identical in content to the approved labeling (including the package insert, and any patient package insert and/or Medication Guide that may be required). Information on submitting SPL

files using eLIST may be found in the guidance for industry titled “SPL Standard for Content of Labeling Technical Qs and As” at <http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>.

The SPL will be accessible via publicly available labeling repositories.

### **PROMOTIONAL MATERIALS**

All promotional materials for your drug product that include representations about your drug product must be promptly revised to make it consistent with the labeling changes approved in this supplement, including any new safety information [21 CFR 314.70(a)(4)]. The revisions to your promotional materials should include prominent disclosure of the important new safety information that appears in the revised package labeling. Within 7 days of receipt of this letter, submit your statement of intent to comply with 21 CFR 314.70(a)(4) to the following address or by facsimile at 301-847-8444:

Food and Drug Administration  
Center for Drug Evaluation and Research  
Division of Drug Marketing, Advertising, and Communications  
5901-B Ammendale Road  
Beltsville, MD 20705-1266

In addition, as required under 21 CFR 314.81(b)(3)(i), you must submit your updated final promotional materials, and the package insert(s), at the time of initial dissemination or publication, accompanied by a Form FDA-2253, directly to the above address. For instruction on completing the Form FDA 2253, see page 2 of the Form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see <http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm>.

We remind you that you must comply with the requirements for an approved abbreviated new drug application described in 21 CFR 314.80-81.

The materials submitted are being retained in our files.

Sincerely yours,

*{See appended electronic signature page}*

Wm Peter Rickman  
Director  
Division of Labeling and Program Support  
Office of Generic Drugs  
Center for Drug Evaluation and Research

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**  
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/s/  
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LILLIE D GOLSON  
12/10/2010  
for Wm. Peter Rickman