DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 021590 / S-015 / S-016

SUPPLEMENT APPROVAL

Azur Pharma
C/O Beckloff Associates
Attention: Gary D. Hindman, PhD, MBA
Director, Managing Consultant
7400 W. 110th Street, Suite 300
Overland Park, KS 66210

Dear Dr. Hindman:

Please refer to your Supplemental New Drug Applications (sNDAs) dated March 20, 2009 and received March 23, 2009 (S-015) and dated March 12, 2010 and received March 15, 2010 (S-016), submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Fazaclo (clozapine) Orally Disintegrating Tablets, 12.5 mg, 25 mg, and 100 mg.

S-015

The March 9, 2010, submission constituted a complete response to our January 7, 2010, action letter.

This Prior Approval supplemental new drug application provides for revisions to the **CLINICAL PHARMACOLOGY – Absorption, Distribution, Metabolism, and Excretion** section of labeling.

We have completed our review of this supplemental application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

S-016

This Chemistry, Manufacturing, and Controls Prior Approval supplemental new drug application proposed the addition of 150 mg and 200 mg tablet strengths.

We have completed our review of this supplemental application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

A 24 month expiry has been granted for the 150 mg and 200 mg strengths, identical to the previously approved 12.5 mg, 25 mg, and 100 mg strengths.

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 to the enclosed labeling (text for the package insert) and include the labeling changes proposed in any pending "Changes Being Effected" (CBE) supplements. 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 from publicly available labeling repositories.

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and container labels that are identical to the carton and immediate container labels submitted on March 12, 2010, as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry titled "Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (June 2008)." Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Carton and Container Labels for approved NDA 021590/S-016.**" Approval of this submission by FDA is not required before the labeling is used.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the package insert(s) to:

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

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the package insert(s), at the time of initial dissemination or publication, accompanied by a Form FDA 2253. 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.

LETTERS TO HEALTH CARE PROFESSIONALS

If you decide to issue a letter communicating important safety-related information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit, at least 24 hours prior to issuing the letter, an electronic copy of the letter to this NDA, to CDERMedWatchSafetyAlerts@fda.hhs.gov, and to the following address:

MedWatch Program
Office of Special Health Issues
Food and Drug Administration
10903 New Hampshire Ave
Building 32, Mail Stop 5353
Silver Spring, MD 20993

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, email Keith Kiedrow, Pharm.D., Senior Regulatory Project Manager, at Keith.Kiedrow@FDA.HHS.GOV.

Sincerely,

{See appended electronic signature page}

Thomas Laughren, M.D.
Director
Division of Psychiatry Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

ENCLOSURES:
Content of Labeling

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-21590	SUPPL-15	AZUR PHARMA INTERNATIONAL III LTD	FAZACLO (CLOZAPINE) ORALLY DISINTEGRATI
NDA-21590	SUPPL-16	AZUR PHARMA INTERNATIONAL III LTD	FAZACLO (CLOZAPINE) ORALLY DISINTEGRATI

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

THOMAS P LAUGHREN
07/09/2010