DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 22567/S-009

SUPPLEMENT APPROVAL
POSTMARKETING COMMITMENT FULFILLED

Forest Laboratories, Inc.
Attention: Kaity Posada, Pharm.D
Director, Regulatory Affairs
Harborside Financial Center, Plaza V
Jersey City, NJ 07311

Dear Dr. Posada:

Please refer to your Supplemental New Drug Application (sNDA) dated and received on January 31, 2013, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Viibryd (vilazodone hydrochloride) 10 mg, 20 mg, and 40 mg tablets.

We acknowledge receipt of your amendments dated October 30, 2013 and December 9, 2013. We also refer you to the Approval letter dated January 21, 2011.

This "Prior Approval" supplemental new drug application contains final study reports and proposes labeling modifications based upon findings from the following postmarketing commitments (PMC's 1723-9 and 1723-10) as prescribed in the January 21, 2011 Approval letter.

1723-9 Vilazodone is metabolized primarily by CYP3A4. You have not submitted information on the potential effect of CYP3A4 induction on vilazodone exposure. We request that you conduct a drug-drug interaction trial of vilazodone using a CYP3A4 inducer (carbamazepine) in healthy subjects.

1723-10 Vilazodone is extensively metabolized; however, the pharmacokinetics of vilazodone in patients with severe hepatic impairment has not been assessed. We request that you conduct a Phase 1 trial to evaluate the pharmacokinetics of vilazodone in patients with severe hepatic impairment.

We have completed our review of this supplemental application, as amended, and conclude that the above commitments have been fulfilled. Therefore, it is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text. We remind you that there are postmarketing requirements and postmarketing commitments listed in the January 21, 2011 approval letter that are still open.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling (text for the package insert), with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

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.

Also within 14 days, amend all pending supplemental applications that includes labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

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, call Bill Bender, Senior Regulatory Project Manager, at (301) 796-2145.

Sincerely,

{See appended electronic signature page}

Mitchell V. Mathis, M.D.
CAPT, USPHS
Director (acting)
Division of Psychiatry Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

ENCLOSURE(S):
Content of Labeling

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

/s/

MITCHELL V Mathis
12/17/2013