DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 022567/S-001

SUPPLEMENT APPROVAL

Forest Laboratories, Inc.
Attention: Kimberly Fabrizio
Vice President Regulatory Affairs
Harborside Financial Center
Plaza V, Suite 1900
Jersey City, NJ 07311

Dear Ms. Fabrizio:

Please refer to your Supplemental New Drug Application (sNDA) dated April 29, 2011 (NDA 022567/S-001), 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 also acknowledge receipt of your amendment dated May 2, 2011.

This "Changes Being Effected" labeling supplemental new drug application provides for general editorial revisions that include information to reflect Forest as the distributor of Viibryd.

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 as communicated in an email dated June 24, 2011 between yourself and Bill Bender, of this Agency.

CONTENT OF LABELING

Within 14 days, amend all pending supplemental applications 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, Regulatory Project Manager, at (301) 796-2145.

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

ENCLOSURE: Content of Labeling (package insert and Medication Guide)

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
09/21/2011