DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 22567/S-002

SUPPLEMENTAL APPROVAL
RELEASE REMS REQUIREMENT

Forest Laboratories, Inc.
Attention: Kimberly Fabrizio
Vice President, Regulatory Affairs
Five Science Park
New Haven, CT 06511

Dear Ms. Fabrizio:

Please refer to your Supplemental New Drug Applications (sNDA) dated May 16, 2011 (S-002), submitted pursuant to section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Viibryd (vilazodone hydrochloride) Tablets 10 mg, 20 mg, and 40 mg .

We acknowledge receipt of your risk evaluation and mitigation strategy (REMS) assessment dated June 8, 2011.

This supplement (S-002) proposes to eliminate the requirement for the approved Viibryd (vilazodone hydrochloride) Tablets REMS.

We have completed our review of this supplemental application. It is approved, effective on the date of this letter.

RISK EVALUATION AND MITIGATION STRATEGY REQUIREMENTS

The REMS for Viibryd (vilazodone hydrochloride) Tablets was originally approved on January 21, 2011. The REMS consists of a Medication Guide and a timetable for submission of assessments of the REMS.

You propose that FDA no longer require a REMS for Viibryd (vilazodone hydrochloride) Tablets.

We have determined that maintaining the Medication Guide as part of the approved labeling is adequate to address the serious and significant public health concern and meets the standard in 21 CFR 208.1. Therefore, it is no longer necessary to include the Medication Guide as an element of the approved REMS to ensure that the benefits of Viibryd (vilazodone hydrochloride) Tablets outweigh its risks.

Therefore, we agree with your proposal and a REMS for Viibryd (vilazodone hydrochloride) Tablets is no longer required.

We remind you that the Medication Guide will continue to be part of the approved labeling in accordance with 21 CFR 208.

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, please email CDR Bill Bender, Senior Regulatory Project Manager, at william.bender@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

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
06/29/2011