DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

NDA 022256/S-010

SUPPLEMENT APPROVAL
RELEASE REMS REQUIREMENT

Cypress Bioscience, Inc.
c/o Forest Laboratories, Inc.
Harborside Financial Center
Plaza V, Suite 1900
Jersey City, NJ 07311

Attention: Debleena Sengupta, PhD, RAC
Senior Manager, Regulatory Affairs

Dear Dr. Sengupta:

Please refer to your supplemental New Drug Application (sNDA) dated and received April 8, 2011, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Savella® (milnacipran HCl) Tablets, 12.5 mg, 50 mg, and 100 mg.

We also acknowledge receipt of your risk evaluation and mitigation strategy (REMS) assessment, dated July 14, 2010.

This supplemental new drug application provides for elimination of the approved REMS.

RISK EVALUATION AND MITIGATION STRATEGY REQUIREMENTS

The REMS for Savella® (milnacipran HCl) was originally approved on January 14, 2009, and the most recent REMS modification was approved on February 2, 2010. 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 Savella® (milnacipran HCl).

We have determined it is no longer necessary to include the Medication Guide as an element of the approved REMS, and that a REMS is no longer necessary to ensure that the benefits of Savella® (milnacipran HCl) outweigh its risks. Therefore, a Medication Guide is no longer required as part of the REMS, and we agree with your proposal that a REMS for Savella® (milnacipran HCl) 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, call Diana Walker, Regulatory Health Project Manager, at (301)796-4029.

Sincerely,

{See appended electronic signature page}

Laura Governale, Pharm.D., M.B.A.
Acting Deputy Director for Safety
Division of Anesthesia, Analgesia,
and Addiction Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

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/s/

LAURA A GOVERNALE
04/26/2011