CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

22-256/S010

Trade Name: SAVELLA®

Generic Name: MILNACIPRAN HYDROCHLORIDE

Sponsor: CYPRESS BIOSCIENCE

Approval Date: 4/26/2011

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APPROVAL LETTER

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

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OTHER REVIEW(S)

Risk Evaluation and Mitigation Strategy (REMS) Memorandum
REMS Elimination

U.S. FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH
OFFICE OF NEW DRUGS II
DIVISION OF ANESTHESIA, ANALGESIA, AND ADDICTION PRODUCTS

NDA/BLA #s:	022256
Products:	Savella® (milnacipran HCl) Tablets 12.5/50/100 mg
APPLICANT:	Forest Laboratories, Inc.
FROM:	Laura Governale, Pharm.D., MBA, Acting Deputy Director for Safety
DATE:	April 26, 2011

A REMS for Savella® (milnacipran HCl) Tablets was approved on January 14, 2009, and the most recent REMS modification was approved on February 2, 2010, to ensure the benefits of the drug outweighed the risks of serious psychiatric symptoms, including suicidal ideation, particularly in patients with depression. The REMS consists of a Medication Guide and a timetable for submission of assessments of the REMS.

On April 8, 2011, Forest Laboratories submitted a proposed REMS modification to release the requirement for the REMS. The REMS modification referenced a REMS assessment dated July 14, 2010.

After consultations between the Office of New Drugs (OND) and the Office of Surveillance and Epidemiology (OSE), we have determined that a REMS for Savella® (milnacipran HCl) Tablets is no longer necessary to ensure the benefits of the drug outweigh the risks described above because labeling is adequate to describe the risks. The Medication Guide will continue to be part of the approved labeling in accordance with 21 CFR 208. Like other labeling, Medication Guides are subject to the safety labeling change provisions of section 505(o)(4) of the FDCA.

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/s/

LAURA A GOVERNALE
04/26/2011

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ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

NDA 022256/S-010

ACKNOWLEDGEMENT --
PRIOR APPROVAL SUPPLEMENT

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 New Drug Application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for the following

Name of Drug Product: Savella (milnacipran HCl) Tablets

NDA Number: 022256

Supplement number: S-010

This REMS Modification and Assessment Prior Approval supplemental application proposes the elimination of the approved Savella (milnacipran HCl) Medication Guide-only REMS.

Unless we notify you within 60 days of the receipt date that the application is not sufficiently complete to permit a substantive review, we will file the application on June 7, 2011, in accordance with 21 CFR 314.101(a).

SUBMISSION REQUIREMENTS

Cite the application number listed above at the top of the first page of all submissions to this application. Send all submissions, electronic or paper, including those sent by overnight mail or courier, to the following address:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Anesthesia, Analgesia, and Addiction Products
5901-B Ammendale Road
Beltsville, MD 20705-1266

All regulatory documents submitted in paper should be three-hole punched on the left side of the page and bound. The left margin should be at least three-fourths of an inch to assure text is not obscured in the fastened area. Standard paper size (8-1/2 by 11 inches) should be used; however, it may occasionally be necessary to use individual pages larger than standard paper size. Non-standard, large pages should be folded and mounted to allow the page to be opened for review without disassembling the jacket and refolded without damage when the volume is shelved. Shipping unbound documents may result in the loss of portions of the submission or an unnecessary delay in processing which could have an adverse impact on the review of the submission. For additional information, see http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/DrugMasterFilesDMFs/ucm073080.htm.

If you have any questions, call me at (301) 796-4029.

Sincerely,

{See appended electronic signature page}

Diana L. Walker, Ph.D.
Regulatory Project Manager
Division of Anesthesia, Analgesia,
and Addiction Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

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/s/

DIANA L WALKER
04/12/2011