CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

22-256

RISK ASSESSMENT and RISK MITIGATION REVIEW(S)

10/13/08

Memo to File

Date: October 14, 2008

To: NDA 22-256 Savella™ (milnacipran HCl) Tablets
Applicant: Cypress Bioscience, Inc.
Authorized Agent: Forest Laboratories, Inc

From: Office of Surveillance and Epidemiology (OSE)
Division of Risk Management (DRISK)

Subject: Savella™, (milnacipran HCl Tablets), a Selective Serotonin and Norepinephrine Reuptake Inhibitor, Proposed Risk Evaluation Mitigation Strategy (REMS) submitted October 9, 2008

Background:

On October 8, 2008 there was official email correspondence between FDA Project Manager, Diana Walker, and authorized agent Forest Laboratories, Inc. This Information Request (IR) communication contained rationale and instruction for developing a REMS that includes a Medication Guide and a timetable for assessment.

Material Reviewed:

Memo to File dated October 8, 2008
Proposed REMS submission dated October 9, 2008

Proposed REMS Elements:

Medication Guide
Timetable for Assessment including proposed survey of patients and pharmacists

Conclusion:

DRISK agrees that the Sponsor's proposed REMS for Savella meets the statutory requirements outlined Under 21 CFR 208 and in accordance with 505-1(d).

Recommendation: Approval

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/s/

Mary Dempsey
10/13/2008 03:29:09 PM
DRUG SAFETY OFFICE REVIEWER