Memo to File

Date: October 14, 2008

To: NDA 22-256 Savella\textsuperscript{TM} (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\textsuperscript{TM}, (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