DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 22256/S-002 **SUPPLEMENT APPROVAL**

Cypress Bioscience, Inc.
c/o Forest Laboratories, Inc.
Harborside Financial Center
Plaza III, Suite 602
Jersey City, NJ 07311

Attention: Michael K. Olchaskey, PharmD
Director, Regulatory Affairs

Dear Dr. Olchaskey:

Please refer to your supplemental new drug application dated and received June 30, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Savella (milnacipran HCl) 12.5 mg, 25 mg, 50 mg, and 100 mg Tablets.

This "Changes Being Effected" supplemental new drug application provides for the implementation of class labeling for all SSRI/SNRI products with information about the risk of Neuroleptic Malignant Syndrome (NMS) or NMS-like Reactions associated with the use of these drug products.

We also refer to our email correspondence dated December 16, 2009, requesting additional revisions to the label in order to update and reorganize the Drug Interactions section, and to your submission via email dated December 21, 2009, of draft labeling and concurrence with these revisions.

We have completed our review of this application. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the labeling enclosed in this letter.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)(1)(i)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the enclosed labeling (text for the package insert). For administrative purposes, please designate this submission "**SPL for approved supplement NDA 22-256/S-002.**" Approval of this submission by FDA is not required before the labeling is used.

Marketing the product with final printed labeling that is not identical to the approved labeling text and in the required format may render the product misbranded and an unapproved new drug.

LETTERS TO HEALTH CARE PROFESSIONALS

If you issue a letter communicating important safety related information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit an electronic copy of the letter to both this NDA and to the following address:

MedWatch
Food and Drug Administration
5600 Fishers Lane, Room 12B05
Rockville, MD 20857

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, contact Diana Walker, Ph.D., Regulatory Project Manager, at (301) 796-4029.

Sincerely,

{See appended electronic signature page}

Larissa Lapteva, M.D.
Deputy Director for Safety
Division of Anesthesia, Analgesia
and Rheumatology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosure:
Package Insert Labeling

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-22256	SUPPL-2	CYPRESS BIOSCIENCE INC	SAVELLA TABLETS

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

LARISSA LAPTEVA
02/01/2010