DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-632/S-031

Abbott Laboratories
Attn: Kelly Kaleck-Schlinsog
Manager, Global Pharmaceutical Regulatory Affairs
Dept PA76; Bldg. AP30-1E
200 Abbott Park Road
Abbott Park, IL 60064-6157

Dear Ms. Kaleck-Schlinsog:

Please refer to your supplemental new drug application dated June 30, 2008, received June 30, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Meridia (sibutramine hydrochloride monohydrate) Capsules.

This supplemental new drug application provides for revision of safety information in the following sections of the prescribing information (PI):

ADVERSE EVENTS section

Postmarketing Reports subsection

- The Psychiatric sub-subsection has been revised and updated to add "psychosis" and "mania." It now reads:
  - Cases of depression, psychosis, mania, suicidal ideation and suicide have been reported rarely in patients on sibutramine treatment. However, a relationship has not been established between these events and the use of sibutramine. If any of these events should occur during treatment with sibutramine, discontinuation should be considered.

Other Postmarketing Reported Events subsection

- The Nervous System sub-subsection has been revised to delete "manic reaction" and now reads:
  - abnormal dreams, abnormal gait, amnesia, anger, cerebrovascular accident, concentration impaired, confusion, depression aggravated, Gilles de la Tourette's syndrome, hypesthesia, libido decreased, libido increased, mood changes, nightmares, serotonin syndrome, short term memory loss, speech disorder, transient ischemic attack, tremor, twitch, vertigo.

In addition, this supplement provides for the following changes:

HOW SUPPLIED section.

- This section has been revised to eliminate the 5 mg, 10 mg, and 15 mg Meridia Capsules in bottles of 100 capsules since these packaging presentations have been discontinued.

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

We note that your June 30, 2008, submission included content of labeling in the structured product labeling (SPL) format.

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

MEDWATCH
Food and Drug Administration
Suite 12B05
5600 Fishers Lane
Rockville, MD 20857

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 Pat Madara, Regulatory Project Manager, at (301) 796-1249.

Sincerely,

{See appended electronic signature page}

Mary H. Parks, M.D.
Director
Division of Metabolism and Endocrinology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosure: package insert

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

/s/

Eric Colman

12/24/2008 11:37:12 AM

Eric Colman for Mary Parks