DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-632/S-026

Abbott Laboratories
Attn: Kelly Kaleck-Schlinsog
Manager, Global Pharmaceutical Regulatory Affairs
Dept RA76; 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 February 22, 2006, received February 23, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Meridia (sibutramine hydrochloride monohydrate) Capsules.

We acknowledge receipt of your submission dated August 16, 2006.

This supplemental new drug application provides for labeling changes to incorporate additional information regarding drug interactions with Meridia. Information related to the concomitant use of Meridia with simvastatin, omeprazole, olanzapine, or lorazepam has been added to the **Pharmacokinetics** subsection of the **CLINICAL PHARMACOLOGY** section. In addition, the information describing Meridia's interaction with ketoconazole, erythromycin, cimetidine, and drugs highly bound to plasma proteins has been moved from the **Drug Interactions** subsection of the **PRECAUTIONS** section to the **Pharmacokinetics** subsection.

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

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert and patient package insert).

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 20-632/S-026**." Approval of this submission by FDA is not required before the labeling is used.

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
5515 Security Lane
HFD-001, Suite 5100
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
patient 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/

Mary Parks

8/23/2006 05:18:56 PM