DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-632/S-019 and S-020

Abbott Laboratories
Attention: Rebecca McSwine, Ph.D.
Associate Director, Regulatory Affairs
200 Abbott Park Road
D-491, AP30-1E
Abbott Park, Illinois 60064-6157

Dear Dr. McSwine:

Please refer to your supplemental new drug applications (NDA) dated May 26, and June 11, 2004, received May 27, June 14, 2004, respectively, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Meridia (Sibutramine HCL Monohydrate) Capsules for supplements -020 and -019, respectively.

We acknowledge receipt of your submissions dated September 30, and October 27, 2004.

The June 11, 2004, submission constituted a complete response to our June 1, 2004, action letter for supplement -019.

These supplemental new drug applications provide for (1) the addition of a new 30-count commercial package for the Meridia 5 mg dosage strength (S-019) and (2) modifications in the package insert (PI) and the patient information insert (PPI) in regard to a risk management program for Meridia (S-020).

We completed our review of these applications, as amended, and they are 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 the patient package insert submitted May 26, 2004, and September 30, 2004, respectively. Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and unapproved new drugs.

In addition, submit the content of labeling in electronic format as described in 21 CFR 314.50(l)(5) and in the format described at the following website: http://www.fda.gov/oc/datacouncil/spl.html. For administrative purposes, designate these submissions "**FPL for approved NDA 20-632**." Approval of this submission by FDA is not required before the labeling is used.

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 Oluchi Elekwachi, PharmD, MPH , Regulatory Project Manager, at (301) 827-6381.

Sincerely,

{See appended electronic signature page}

David G. Orloff, MD
Director
Division of Metabolic and Endocrine Drug Products, HFD-510

Enclosure: PI and PPI Labeling

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

/s/

David Orloff

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