



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-632/S-030

NDA 20-381/S-032

Abbott Laboratories
Attention: Nancy Aiello
Regulatory Affairs Manager
200 Abbott Park Road
Department PA71/Bldg. AP30-1E
Abbott Park, IL 60064-6157

Dear Ms. Aiello:

Please refer to your supplemental new drug applications dated February 21, 2007 (20-632/S-030) and May 7, 2007 (20-381/S-032), submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Meridia (sibutramine HCl) Capsules and Niaspan (Niacin extended-release tablets) respectively.

These supplemental new drug applications provide for revised bottle labels and cartons to harmonize across the Abbott product line.

We completed our review of these applications. These applications 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 immediate container and carton labels).

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).

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If you have any questions, call Kati Johnson, Regulatory Project Manager, at (301) 796-1234.

Sincerely,

{See appended electronic signature page}

Mary H. Parks, MD

Director

Division of Metabolism and Endocrinology Products

Office of Drug Evaluation II

Center for Drug Evaluation and Research

Enclosure:

Meridia Labeling-5 mg

30-count bottle label: DN1106V2

30-count carton label: DN1107V2

90-count (3 X 30-count) carton label: DN1108V2

Meridia Labeling-10 mg

30-count bottle label: DN1109V2

30-count carton label: DN1110V2

90-count (3 X 30-count) carton label: DN1111V2

Meridia Labeling-15 mg

30-count bottle label: DN1103V2

30-count carton label: DN1104V2

Niaspan Labeling

500 mg (100-ount) bottle label: 04-A006/R1

750 mg (100-count) bottle label: 04-A007/R1

1000 mg (100-count) bottle label: 04-A008/R1

**This is a representation of an electronic record that was signed electronically and
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/s/

Eric Colman
5/29/2008 08:59:32 AM
Eric Colman for Mary Parks