



NDA 20-632/S-017

Rebecca McSwine, R.Ph., Ph.D.  
Associate Director, PPD Regulatory Affairs  
200 Abbott Park Road  
D-491/AP30-1E  
Abbott Park, IL 60064-6157

Dear Dr. McSwine:

Please refer to your supplemental new drug application dated December 16, 2002, received December 17, 2002, 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 to the PRECAUTIONS and ADVERSE REACTIONS sections of the package insert (PI), to reflect data analyzed and submitted to the European Committee for Proprietary Medicinal Products (CPMP). The patient package insert (PPI) has also been revised to be consistent with safety information included in the PI.

We completed our review of this application. This application is approved, effective on the date of this letter, for use as recommended in the labeling submitted on December 16, 2002.

The final printed labeling (FPL) must be identical to the submitted labeling (package insert and patient package insert, submitted December 16, 2002).

Please submit the FPL electronically 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, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20-632/S-017." 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, HFD-410  
FDA  
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).

We remind you that you must submit patent information on form FDA 3542, *Patent Information Submitted Upon and After Approval of an NDA or Supplement*, within 30 days of the date of this letter as required by 21 CFR 314.53(c)(2)(ii) and 314.53(d)(2) at the address provided by 21 CFR 314.53(d)(4). The form may be obtained at <http://www.fda.gov/opacom/morechoices/fdaforms/cder.html>. To expedite review of this patent declaration form, we request you submit an additional copy of the form to the Center for Drug Evaluation and Research "Orange Book" staff at

Food and Drug Administration  
Office of Generic Drugs, HFD-610  
Orange Book Staff  
7500 Standish Place  
Metro Park North II  
Rockville, MD 20855-2773

If you have any questions, call Oluchi Elekwachi, Pharm.D., M.P.H., Regulatory Project Manager, at (301) 827-6381.

Sincerely,

{See appended electronic signature page}

David G. Orloff, M.D.  
Director  
Division of Metabolic and Endocrine Drug Products  
Office of Drug Evaluation II  
Center for Drug Evaluation and Research

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

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David Orloff

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