CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:
NDA 20-632/S014

Trade Name: Meridia

Generic Name: sibutramine hydrochloride monohydrate

Sponsor: Abbott Laboratories, Inc.

Approval Date: August 8, 2002

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:
NDA 20-632/014

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CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 20-632/S014

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-632/S-014

Abbott Laboratories, Inc.
Attention: Todd Chermak,
Associate Director, Regulatory Affairs
200 Abbott Park Road
D-491, AP30-1E
Abbott Park, IL 60064-6157

Dear Mr. Chermak:

Please refer to your supplemental new drug application submitted March 13, 2002, received March 15, 2002, under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Meridia® (sibutramine hydrochloride monohydrate) Capsules.

This "Changes Being Effected in 30 Days" supplemental new drug application provides for a 30-count sample presentation, and for a smaller size bottle and cap than that for the currently approved 100-count bottle.

We acknowledge receipt of your submission dated March 21, 2002, to amend the supplement by providing only for physician samples. We also acknowledge receipt of your amendment dated July 31, 2002.

We have completed the review of this supplemental application as amended, and it is approved.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call James Cross, Regulatory Project Manager, at (301) 827-6381.

Sincerely,

{See appended electronic signature page}

Sheldon Markofsky, Ph.D.
Acting Chemistry Team Leader I, DNDC II for the
Division of Metabolic and Endocrine Drug Products,
(HFD-510)
Office of New Drug Chemistry
Center for Drug Evaluation and Research

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/s/

Sheldon Markofsky
8/7/02 10:43:22 AM

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

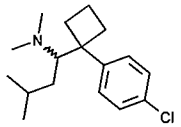
NDA 20-632/S014

CHEMISTRY REVIEW(S)

CHEMIST'S REVIEW	1.ORGANIZATION	2. NDA NUMBER
	DMEDP, HFD-510	**20-632**

3. NAME AND ADDRESS OF APPLICANT	4. SUPPLEMENT NUMBER,DATE
Abbott Laboratories 200 Abbott Park Road Abbott Park, IL (847) 937-5531	SCP-014, 3/13/02
5. NAME OF THE DRUG / 6. NONPROPRIETARY NAME	User Fee Date, 9/15/02
Meridia / sibutramine HCl monohydrate	CBE-30
	8. AMENDMENTS/REPORT,DATE
7. SUPPLEMENT PROVIDES FOR:	
A 30-count sample presentation and a smaller size bottle and cap.	Amendment, 3/21/02 Amendment, 7/31/02
9. PHARMACOLOGICAL CATEGORY / 10. HOW DISPENSED	11. RELATED IND/NDA/DMF
Anti-obesity / Oral	
12. DOSAGE FORM / 13. POTENCY	DMF 1016, 4544
Capsules / 5, 10, and 15 mg	
14. CHEMICAL NAME AND STRUCTURE.	

Cyclobutanemethanamine, 1-(4-chlorophenyl)-
N,N-dimethyl-(2-methylpropyl)- hydrochloride, monohydrate (±)



15. COMMENTS

This CBE-30 days supplement provides for a 30-count sample presentation in addition to the approved 100-count presentation and for a smaller size bottle and cap . The 3/21/02 Amendment provides for removal of the provision for It will be used for physician samples only.

The 7/31/02 Amendment provides a dimensional drawing of the new container closure. For specific chemistry comments, see Review Notes.

16. CONCLUSION AND RECOMMENDATION

The CMC information provided is satisfactory. Issue an **Approval** letter.

17. REVIEWER NAME	18. REVIEWER SIGNATURE	19. DATE COMPLETED
Martin Haber, Ph.D.		August 1, 2002

AP DISTRIBUTION: ORIGINAL JACKET J. Cross M. Haber

R/D Init by: Dr. Shelton Markofsky, Acting Chemistry Team Leader

4 Page(s) Withheld

1 § 552(b)(4) Trade Secret / Confidential

_____ § 552(b)(4) Draft Labeling

_____ § 552(b)(5) Deliberative Process

Withheld Track Number: Chemistry- 20-632 / 5014

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/s/

Martin Haber
8/1/02 09:49:41 AM
CHEMIST

recommends approval

Sheldon Markofsky
8/1/02 10:31:19 AM
CHEMIST

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 20-632/S014

ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-632/S-014

CBE-30 SUPPLEMENT

Abbott Laboratories
Attention: Todd Chermak
Associate Director, Regulatory Affairs
200 Abbott Park Road
D-491, AP30-1E
Abbott Park, IL 60064-6157

Dear Mr. Chermak:

We have received your supplemental drug application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Meridia® (sibutramine hydrochloride monohydrate) Capsules. Please note the following information:

NDA Number/Supplement:	20-632/S-014
Date of Supplement:	March 13, 2002
Date of Receipt:	March 15, 2002
Filing Date:	May 14, 2002

This supplemental application was submitted as a "Changes Being Effected (CBE) in 30 Days" supplement and provides for the following changes:

1. The addition of a 30-count bottle for use as a physician sample package.
2. A change in bottle and cap commodities to accommodate the proposed 30-count package

[redacted]

Unless we notify you within 60 days of our receipt date that the application is not sufficiently complete to permit a substantive review, this application will be filed under section 505(b) of the Act on May 14, 2002 in accordance with 21 CFR 314.101(a). If the application is filed, the user fee goal date will be September 15, 2002.

Please cite the application number listed above at the top of the first page of any communications concerning this application. All communications concerning this supplemental application should be addressed as follows:

U.S. Postal/Courier/Overnight Mail:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Metabolic and Endocrine Drug Products, HFD-510
Attention: Division Document Room
5600 Fishers Lane, 14B19
Rockville, MD 20857

If you have any questions, call me at 301-827-6381.

Sincerely,

{See appended electronic signature page}

James T. Cross
Regulatory Project Manager
Division of Metabolic and Endocrine Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

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/s/

James Cross
4/24/02 03:03:45 PM