



U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Pharmacoepidemiology and Statistical Science
Office of Biostatistics

Amendment to Statistical Review and Evaluation CLINICAL STUDIES

NDA/Serial Number: 20-632, (b) (4) 21

Drug Name: Meridia [®] (sibutramine hydrochloride monohydrate) Oral Capsule

Indication(s): Obesity

Applicant: Abbott Laboratories

Date(s): Submitted June 21, 2004
User fee goal date: December 20, 2004

Review Priority: Priority

Biometrics Division: DOB II

Statistical Reviewer: Japobrata Choudhury, Ph.D. (HFD-715)

Concurring Reviewers: Todd Sahlroot, Ph.D. (HFD-715)

Medical Division: Division of Metabolic and Endocrine Drug Products

Clinical Team: Patricia Beaston, M.D. (HFD-510), Eric Colman, M.D. (HFD-510)

Project Manager: Oluchi Elekwachi, Pharm.D., M.P.H.

Keywords: Clinical studies, NDA review, pediatric exclusivity

APPEARS THIS WAY ON ORIGINAL



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1. COMMENTS4

1. **Comment**

The statement in the original review document, [REDACTED] (b) (4)

should be replaced by

[REDACTED] (b) (4)

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J.Choudhury:x73110: 12/21/04

This review consists of 1 page.

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/s/

Japobrata Choudhury
12/21/04 01:04:35 PM
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Todd Sahlroot
12/21/04 01:16:39 PM
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