Amendment to Statistical Review and Evaluation

CLINICAL STUDIES

NDA/Serial Number: 20-632

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 Beaton, 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
Table of Contents

1. COMMENTS .......................................................................................................................................................4
1. **Comment**

The statement in the original review document, should be replaced by

**DISTRIBUTION LIST**

CC:
Archival NDA 20-632

HFD-510/Dr. Colman
HFD-510/Dr. Beaston
HFD-510/Dr. Elekwachi
HFD-700/Dr. Anello
HFD-715/Dr. Nevius
HFD-715/Dr. Wilson
HFD-715/Dr. Sahlroot
HFD-715/Dr. Choudhury

J.Choudhury:x73110: 12/21/04

This review consists of 1 page.
This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/
-----------------------------
Japobrata Choudhury
12/21/04 01:04:35 PM
BIOMETRICS

Todd Sahlroot
12/21/04 01:16:39 PM
BIOMETRICS