SUPPLEMENTARY INFORMATION:

FOR FURTHER INFORMATION CONTACT:

DATES:

SUMMARY:

ACTION:

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

ABBREVIATION: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of a new drug application (NDA) for MERIDIA (sibutramine hydrochloride (HCl)) oral capsules held by Abbott Laboratories, Inc. (Abbott), 100 Abbott Park Rd., Abbott Park, IL 60064. Abbott has voluntarily requested that approval of this application be withdrawn, thereby waiving its opportunity for a hearing.


FOR FURTHER INFORMATION CONTACT:


SUPPLEMENTARY INFORMATION: On October 7, 2010, FDA requested that Abbott voluntarily withdraw MERIDIA (sibutramine HCl) oral capsules from the market, based on FDA’s recent analysis of clinical trial data from the Sibutramine Cardiovascular Outcomes Trial (SCOUT) that indicated that MERIDIA poses an increased risk of heart attack and stroke. In a letter dated October 12, 2010, Abbott requested that FDA withdraw approval of NDA 20–632 for MERIDIA (sibutramine HCl) oral capsules under § 314.150(d) (21 CFR 314.150(d)). In that letter, Abbott also waived its opportunity for a hearing, provided under § 314.150(a). In FDA’s acknowledgment letter of November 1, 2010, the agency stated that based on the review of the SCOUT data and the assessment of the September 15, 2010, meeting of FDA’s Endocrinologic and Metabolic Drugs Advisory Committee at which the SCOUT data were reviewed, we find the benefits of MERIDIA (sibutramine HCl) oral capsules, indicated for the management of obesity, including weight loss and maintenance of weight loss, no longer outweigh the risks in any identifiable patient population. FDA also acknowledged that Abbott waived its opportunity for a hearing.

Therefore, under section 505(e) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(e)), § 314.150(d), and under authority delegated by the Commissioner of Food and Drugs to the Director, Center for Drug Evaluation and Research, approval of NDA 20–632, and all amendments and supplements thereto, is withdrawn (see DATES). Distribution of this product in interstate commerce without an approved application is illegal and subject to regulatory action (see sections 505(a) and 301(d) of the FD&C Act (21 U.S.C. 355(a) and 331(d)).

Dated: December 6, 2010.

Janet Woodcock,

Director, Center for Drug Evaluation and Research.