Indiana State Department of Health
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Governor

Gregory N. Larkin, M.D., F.A.A.F.P.
State Health Commissioner

DATE: October 11, 2010

TO: All Local Health Departments
Attn: Chief Food Inspection Officer

FROM: A. Scott Gilliam, MBA, CP-FS
Director, Food Protection Program
ASG

SUBJECT: FDA News Release Abbott Laboratories

SUGGESTED ACTION: **FDA Advisory; Obesity drug Meridia (sibutramine) from the U.S. market because of clinical trial data indicating an increased risk of heart attack and stroke; Information provided in case of consumer inquiry.**

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FDA NEWS RELEASE

For Immediate Release: Oct. 8, 2010
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Abbott Laboratories agrees to withdraw its obesity drug Meridia

Abbott Laboratories has agreed to voluntarily withdraw its obesity drug Meridia (sibutramine) from the U.S. market because of clinical trial data indicating an increased risk of heart attack and stroke, the U.S. Food and Drug Administration announced today.

"Meridia's continued availability is not justified when you compare the very modest weight loss that people achieve on this drug to their risk of heart attack or stroke," said John Jenkins, M.D., director of the Office of New Drugs in the FDA's Center for Drug Evaluation and Research (CDER). "Physicians are advised to stop prescribing Meridia to their patients and patients should stop taking this medication. Patients should talk to their health care provider about alternative weight loss and weight loss maintenance programs."

Meridia was approved by the FDA in November 1997 for weight loss and maintenance of weight loss in obese people, as well as in certain overweight people with other risks for heart disease. The approval was based on clinical data showing that more people receiving sibutramine lost at least 5 percent of their body weight than people on placebo who relied on diet and exercise alone.

The FDA requested the market withdrawal after reviewing data from the Sibutramine Cardiovascular Outcomes Trial (SCOUT). SCOUT was initiated as part of a postmarket requirement to look at cardiovascular safety of sibutramine after the European approval of this drug. The trial demonstrated a 16 percent increase in the risk of serious heart events, including non-fatal heart attack, non-fatal stroke, the need to be resuscitated once the heart stopped, and death, in a group of patients given sibutramine and another given placebo. There was a small difference in weight loss between the placebo group and the group that received sibutramine.

"The patients in the European SCOUT trial did not have the same characteristics as the patients for the approved indication in the United States; however, these results, combined with other available safety data raised serious questions about Meridia's safety for all patient groups," said Gerald Dal Pan, M.D., M.H.S., director of the Office of Surveillance and Epidemiology in CDER.

The agency's analysis of SCOUT was the subject of the FDA's Endocrinologic and Metabolic Drugs Advisory Committee meeting on Sept. 15.

For more information:

Drug Safety Communication: FDA Recommends against the Continued Use of Meridia (sibutramine)
http://www.fda.gov/Drugs/DrugSafety/ucm228746.htm

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