DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
300 S. Riverside Plaza, Suite 550 South Chicago, IL 60606 (312) 353-5863 Fax:(312) 886-3280	03/21/2002 - 04/03/2002*
	FEI NUMBER 3002025546

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
TO: John D. Wolfinger, D.V.P., Corp. Reg. & Qual. Science

FIRM NAME	STREET ADDRESS
Abbott Laboratories	100 Abbott Park Road
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Abbott Park, IL 60064	Pharmaceutical Manufacturer

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

OBSERVATION 1

Records relating to all adverse drug experiences known to you, including raw data and any correspondence, have not been maintained for the required year period.

Specifically: All raw data for cases reported for deaths associated with Meridia was not available for review. Data and stored electronically on the and/or computer database systems could be reprinted, and some original reports were located but the complete case files containing any documentation as to follow-up investigations conducted and information obtained therein were missing.

OBSERVATION 2

Adverse drug experience information has not been reported to FDA.

Specifically death associated with Meridia was not reported, and several records reviewed showed that the adverse drug information reported to FDA was either not accurate, not supported by source data, or was missing additional information found in the source data. For example:

a) report documents that a patient who died several weeks after stopping Meridia was reported to the contract research organization (formerly by a sales representative on 11/10/2000, however this adverse event was not reported to FDA. This reported was located only after a query for all "deaths" related to Meridia stored on the computer system was requested to be performed during the inspection. Abbott had not performed this type of query prior to the inspection.

b) reported the death of a in with a history of and on Meridia for weight loss. The had a mild increase after one month of Meridia therapy, and physician started on the patient died the next day. A source document reports that the physician at first thought it may have been a action to the , but an autopsy did not reveal anything other than the The MedWatch initial and follow-up reports, dated 8/4/98 and 4/7/99, reported only that the physician thought it might have been an allergic reaction to and that additional information was unavailable. The autopsy finding was not reported. The Updated supplemental review of sibutramine adverse events, February 1998 to 08 March 2002, reported to FDA that the patient had been taking sibutramine for an unknown period of time when was prescribed or management of The reporting physician thought it may have been an allergic reaction to the No autopsy was performed.

c) dated 11/22/00, reports the death of taking Meridia who had adverse events of and A source document reports that the was in early and was not known to have any type of This information was not reported in the MedWatch report. The as reported as unknown.

d) reported the death of a in with a history of and who was brought to an emergency room The MedWatch, dated 5/22/98, reported the duration of Meridia therapy as day. The Updated supplemental review of sibutramine adverse events, February 1998 to 08 March

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2002 reported that the patient was hospitalized with a following a single dose of sibutramine therapy. There is no source data documenting that the patient only took a single dose of Meridia.

e) ed 1/18/99, reports the death of a patient taking Meridia who had adverse events of . A follow-up MedWatch report, dated 4/8/99, states that further information is unavailable. However, source records document that attempts to obtain the autopsy report were discontinued per instructions from the legal department.

f) dated 9/16/98, reports that patient with initiated Meridia for weight loss, was transferred to the hospital with (date unknown), and subsequently died. In a MedWatch report, dated 4/7/99, the sponsor stated that it is likely that the patient expired due to complications of underlying however, the original report indicates that the patient's preexisting conditions were unknown, and there is no source data documenting that the patient had preexisting prior to initiating Meridia therapy.

g) dated 10/21/98, reports the death of a patient taking Meridia who had adverse events, including and the does not attribute the death to Meridia. There is no documentation of how or from whom this information was obtained. This information was reported in MedWatch follow-up report #5, dated 3/26/99. record dated 3/22/99 stated that the patient developed

OBSERVATION 3

Adverse drug experience information obtained or otherwise received from any source was not reviewed, including information from postmarketing clinical investigations.

Specifically, is an adverse event report of a patient who was in a blinded sibutramine vs. study from 9/23/98 until 2/21/01 and died suddenly on 2/22/01. The initial study, serious adverse event form reported the causality as unrelated. The form stated post mortem/ autopsy report to follow. The review and evaluation of this event did not include documented attempts to obtain a copy of the autopsy report. The case was closed on 1/2/02. The blind was broken, and the patient had received sibutramine therapy.

OBSERVATION 4

Written procedures have not been developed for the evaluation of postmarketing adverse drug experiences.

Specifically, written procedures for postmarketing product safety literature reporting do not require the documentation of the individual responsible for reviewing literature abstracts/articles involving products with approved applications (e.g. Meridia) for reportability and the date the review is performed.

*** DATES OF INSPECTION:**
03/21/2002(Thu), 03/22/2002(Fri), 03/25/2002(Mon), 03/26/2002(Tue), 03/27/2002(Wed), 03/29/2002(Fri), 04/02/2002(Tue), 04/03/2002(Wed)

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FDA EMPLOYEES' NAMES, TITLES, AND SIGNATURES:

David G. Perkins, Investigator

Lisa Hayka, Investigator

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