GBS
Group Benefit Services

Compliance Alert

October 25, 2010

FDA Asks Abbott to Withdrawal Drug

This Alert is to inform you of new, important information regarding Abbott's weight loss drug Meridia (Sibutramine). On October 8, 2010, Abbott announced that, at the request of the U.S. Food and Drug Administration (FDA), it is voluntarily withdrawing Meridia from the U.S. prescription market. This decision was primarily based on a review of results for the SCOUT study Sibutramine Cardiovascular OUTcomes Trial) which showed a 16% increased risk of heart attacks and strokes in patients taking the drug versus those given placebo. FDA's guidance for physicians is as follows:

- Stop prescribing and dispensing Meridia
- Contact patients currently taking Meridia and ask them to stop taking the medication.
- Inform patients of the risks associated with Meridia therapy and discuss alternative weight management strategies.
- Be aware of the possible risk of major adverse cardiovascular events with patients taking Meridia and assess patients for these events if they present with any signs or symptoms of cardiovascular disease.

- Adverse events should be reported to FDA's MedWatch reporting system online (www.accessdata.fda.gov/scripts/medwatch/), by phone (1-800-FDA-1088), by facsimile (1-800-FDA-0178) or by email using the MedWatch Form FDA 3500 (FDA Medical Products Reporting Program, 5600 Fishers Lane, Rockville, MD 20852-9787).

Additional information regarding this market withdrawal can be directed to Abbott's Medical Information Line at 1-866-257-8909 or visit www.sibutramine.com.

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