

Answers 08/17/1994

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FDA MOVES TO END USE OF BROMOCRIPTINE FOR
POSTPARTUM BREAST ENGORGEMENT

FDA has been receiving inquiries about its intention to withdraw approval of the lactation suppression indication for bromocriptine, marketed in the United States under the trade name Parlodel. The following can be used to answer questions.

FDA is initiating the process to withdraw approval for this use of bromocriptine after receiving reports of serious adverse reactions in women using the drug for that purpose. These reports include 31 women taking bromocriptine who had strokes -- 9 fatal -- and 63 women who had seizures. Of those reporting these two events, 40 percent reported no other cause of the events. FDA has received seven reports of women who experienced myocardial infarction, one fatal. An additional 16 patients were hospitalized for reasons other than stroke, myocardial infarction or seizure: 7 for headaches with severe hypertension, 2 for headaches without hypertension and 7 with a variety of other conditions.

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Page 2, T94-37, Bromocriptine

These reports to FDA, and similar reports in the medical literature, indicate that hypertension, seizure, stroke and myocardial infarction can occur in some patients treated with bromocriptine for lactation suppression, although the rate of these adverse events is unknown. Furthermore, lactation suppression can be managed effectively -- and more safely -- by the use of cold packs, compression bandages and pain medication, as needed.

FDA's Fertility and Maternal Health Drugs Advisory Committee has said it believes that the possibility that bromocriptine may cause serious adverse events in some patients outweighs the limited benefits for its use in a temporary condition that can be managed by more conservative treatment. After a risk/benefit assessment based on currently available data, the agency has therefore initiated the action needed to withdraw approval for this indication.

Before the approval for this indication can be withdrawn, the manufacturer, Sandoz Pharmaceutical Corp. of East Hanover, N.J., will have the opportunity to request a public hearing to present evidence to demonstrate bromocriptine's safety for this indication.

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