FDA Talk Paper

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Black Box Warning Added Concerning Long-Term Use of Depo-Provera Contraceptive Injection

The Food and Drug Administration (FDA) announced today that a "black box" warning, highlighting prolonged use may result in the loss of bone density, will be added to the labeling of Depo-Provera Contraceptive Injection, an established injectable drug approved for use in women to prevent pregnancy.

Although Depo-Provera Contraceptive Injection has been used for decades for birth control throughout the world and remains a safe and effective contraceptive, FDA and Pfizer, the drug's manufacturer, are taking this action to ensure that physicians and patients have access to this important information.

The black box warning for Depo-Provera highlights that prolonged use of the drug may result in significant loss of bone density, and that the loss is greater the longer the drug is administered. This bone density loss may not be completely reversible after discontinuation of the drug. Thus the warning states that a woman should only use Depo-Provera Contraceptive Injection as a long-term birth control method (for example, longer than two years) if other birth control methods are inadequate for her.

Black box warnings are designed to highlight special problems, particularly those that are serious, and to give health care professionals a clear understanding of a potential medical complication associated with a drug. Black box warnings provide physicians with important insights as to how to prescribe a drug that may be associated with serious side effects in a way that maximizes its benefits and minimizes its risks.

The addition of the black box warning came as a result of the drug manufacturer's and FDA's analysis of data that clarified the drug's long-term effects on bone density.

In addition to the black box warning on the labeling, the drug's manufacturer will issue a "Dear Health Care Practitioner" letter regarding the effect of long-term treatment on bone mineral density to prescribers likely to prescribe the drug, and will incorporate the new information in the patient information sheet distributed with the drug.

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Dear Healthcare Professional Letter (Pfizer Inc.) (PDF)
Dear Healthcare Organization Leader Letter (Pfizer Inc.) (PDF)
Label (Pfizer Inc.) (PDF)