Depo Provera Linked to Bone Density Loss (2004)

DEPO-PROVERA LABELED:
LINKED TO BONE DENSITY LOSS

The U.S. Food and Drug Administration (FDA) has issued a "black box warning" -- the strongest possible FDA warning issued -- to the labeling of the Depo-Provera drug, noting that extended use of this injectabel contraceptive can cause "significant bone density loss." [Right to Life, www.cincinnatirighttolife.org. Cincinnati Right to Life, April 2008]

November 17, 2004

Consumer Inquiries: 888-INFO-FDA

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. [November 17, 2004 - Talk Paper - FDA]

CDER News Items 2004

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www.fda.gov/cder/previous_news2004.htm - 01-03-2008 -

November 18, 2004

* FDA announces 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. MedWatch Safety Info.

Depo-Provera (medroxyprogesterone acetate injectable suspension)

FDA and Pfizer notified healthcare professionals of the addition of a BOXED WARNING along with revisions to the WARNINGS, INDICATIONS AND USAGE, PRECAUTIONS and POSTMARKETING EXPERIENCE sections of the prescribing information to include information on the loss of significant bone mineral density.

Depo-Provera Contraceptive Injection is indicated only for the prevention of pregnancy in women of child-bearing potential. Bone loss is greater with increasing duration of use and may not be completely reversible. Depo-Provera Contraceptive should be used as a long-term birth control method (eg, longer than 2 years) only if other birth control methods are inadequate.

[November 18, 2004 - Dear Healthcare Professional Letter - Pfizer] Adobe Acrobat [pdf] file

[November 18, 2004 - Dear Healthcare Organization Leader Letter - Pfizer] Adobe Acrobat [pdf] file

[November, 2004 - Label - Pfizer] Adobe Acrobat [pdf] file - http://www.fda.gov/medwatch/SAFETY/2004/DepoProvera_Label.pdf

[http://www.fda.gov/cder/previous_news2004.htm]