

FDA NEWS RELEASE

For Immediate Release: December 6, 2011

Media Inquiries: Shelly Burgess 301-796-4651, shelly.burgess@fda.hhs.gov or Tamara Ward 301-796-7567, Tamara.Ward@fda.hhs.gov

Consumer Inquiries: 888-INFO-FDA

FDA, FTC act to remove “homeopathic” HCG weight loss products from the market. *Joint action is first step in halting sale of the products*

The U.S. Food and Drug Administration and the Federal Trade Commission (FTC) today issued seven Warning Letters to companies marketing over-the counter (OTC) HCG products that are labeled as “homeopathic” for weight loss.

Human chorionic gonadotropin (HCG) is a hormone produced by the human placenta and found in the urine of pregnant women. HCG is FDA-approved as an injectable prescription drug for the treatment of some cases of female infertility and other medical conditions.

The letters warn the companies that they are violating federal law by selling drugs that have not been approved, and by making unsupported claims for the substances. There are no FDA-approved HCG drug products for weight loss.

The joint action is the first step in keeping the unproven and potentially unsafe products from being marketed online and in retail outlets as oral drops, pellets, and sprays.

The labeling for the “homeopathic” HCG products states that each product should be taken in conjunction with a very low calorie diet. There is no substantial evidence HCG increases weight loss beyond that resulting from the recommended caloric restriction. Consumers on a very low calorie diet are at increased risk for side effects including gallstone formation, electrolyte imbalance, and heart arrhythmias.

“These HCG products marketed over-the-counter are unproven to help with weight loss and are potentially dangerous even if taken as directed,” said Ilisa Bernstein, acting director of the Office of Compliance in FDA’s Center for Drug Evaluation and Research. “And a very low calorie diet should only be used under proper medical supervision.”

“Deceptive advertising about weight loss products is one of the most prevalent types of fraud,” said David Vladeck, director of the FTC’s Bureau of Consumer Protection. “Any advertiser who makes health claims about a product is required by federal law to back them up with competent and reliable scientific evidence, so consumers have the accurate information they need to make good decisions.”

According to the Warning Letters, the companies have 15 days to notify the FDA of the steps they have taken to correct the violations cited. Failure to do so may result in legal action, including seizure and injunction, or criminal prosecution.

Consumers and health care professionals are encouraged to report adverse events (side effects) that may be related to the use of these products to MedWatch, the FDA's voluntary reporting program, by calling 800-FDA-1088, or electronically at www.fda.gov/medwatch/report.htm.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation’s food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

#