

# Questions and Answers on HCG Products for Weight Loss

## **1. What actions are the Food and Drug Administration (FDA) and the Federal Trade Commission (FTC) taking against human chorionic gonadotropin (HCG) drug products marketed for weight loss?**

FDA and FTC are issuing seven joint warning letters to firms marketing over-the-counter (OTC) HCG drug products that are labeled as homeopathic for weight loss. The firms are receiving these letters because they are violating the Federal Food, Drug, and Cosmetic Act and the Federal Trade Commission Act by selling unapproved new drugs and misbranded drugs that make unsubstantiated claims about weight loss.

These unapproved “homeopathic” HCG drug products are marketed OTC on websites and in retail stores, and can be in the form of oral drops, pellets, and sprays. FDA has not evaluated these products for safety or effectiveness.

FDA and FTC will monitor the firms’ responses to the warning letters and take further action as needed. Firms that do not correct the violations may face enforcement action, possible legal penalties, or criminal prosecution.

## **2. What is HCG?**

Human chorionic gonadotropin (HCG) is a hormone produced by the human placenta and found in the urine of pregnant women. HCG is FDA-approved for the treatment of select cases of female infertility and hormone treatment in men. FDA-approved HCG products are only available in injection-form and require a prescription from a licensed medical professional.

There are no FDA-approved HCG products for weight loss.

## **3. Why is FDA concerned about the use of homeopathic HCG drug products marketed for weight loss?**

Currently, there are no FDA-approved HCG drug products for weight loss. HCG has not been demonstrated to be effective therapy in the treatment of obesity. There is no substantial evidence that HCG increases weight loss.

Additionally, the labeling for the “homeopathic” HCG products states that each product should be taken in conjunction with a very low calorie diet (VLCD). Consumers on a VLCD

are at increased risk for side effects including gallstone formation, electrolyte imbalance, and heart arrhythmias. A VLCD should only be used under proper medical supervision.

#### 4. Which homeopathic HCG products and manufacturers/distributors are affected?

The following table provides the products and manufacturers/distributors that are the subjects of this action. This is not an all inclusive list of illegal “homeopathic” HCG products currently on the market. At this time, all drug products claiming to include “homeopathic” HCG are illegally marketed.

Manufacturer/Distributor Name	Product Name
HCG Diet Direct, LLC	HCG Diet Homeopathic Drops
HCG 1234 LLC (The hCG Drops LLC)	Homeopathic HCG
HCG Platinum LLC; RightWay Nutrition	HCG Platinum HCG Platinum X-30 HCG Platinum X-14
Nutri Fusion Systems LLC	HCG Fusion 30 HCG Fusion 43
<a href="http://www.resetthebody.com">www.resetthebody.com</a> ; <a href="http://www.theoriginalhcgdrops.com">www.theoriginalhcgdrops.com</a>	Homeopathic Original HCG Homeopathic HCG
Hcg-miracleweightloss.com	HCG Extra Weight Loss Homeopathic Drops
<a href="#">Natural</a> Medical Supply	Alcohol Free hCG Weight Loss Formula

#### 5. Are prescription HCG products safe and effective for weight loss?

No. FDA-approved uses for prescription HCG products include female fertility and select hormonal treatment in males, and FDA has not approved prescription HCG for any other uses, including weight loss. Current scientific evidence does not support the claim that HCG is safe and effective for weight loss or for the treatment of obesity. In fact, FDA labeling for the approved HCG drug products requires the following statement about the use of HCG for weight loss:

*“HCG has not been demonstrated to be effective adjunctive therapy in the treatment of obesity. There is no substantial evidence that it increases weight loss beyond that resulting from caloric restriction, that it causes a more attractive or ‘normal’ distribution of fat, or that it decreases the hunger and discomfort associated with calorie-restricted diets.”*

FDA is aware that healthcare professionals sometimes prescribe prescription injectable HCG for unapproved uses such as weight loss. FDA understands that sometimes approved products are used to treat conditions that the products were not approved for

(i.e., “off-label” uses). The “off-label” use of products usually presents greater uncertainty about both the risks and benefits because less information is available on safety and effectiveness. Unexpected adverse events may occur in this context. FDA has received reports of serious adverse events associated with the use of HCG injections for weight loss including cases of pulmonary embolism, depression, cerebrovascular issues, cardiac arrest, and death.

## **6. What should consumers do?**

FDA advises consumers who are using “homeopathic” HCG for weight loss to stop using the product, to stop following any labeled dieting instructions, and to discard the product. Consumers who suspect they have experienced adverse effects as a result of the use of HCG drug products for weight loss should contact a licensed health care professional immediately.

FDA urges both health care professionals and consumers to report harmful effects experienced from using HCG for weight loss to the FDA’s MedWatch Adverse Event Reporting program by doing one of the following:

- Complete and submit the report online: [www.fda.gov/MedWatch/report.htm](http://www.fda.gov/MedWatch/report.htm)
- [Download form](#) or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

This FAQ is from the Medication Health Fraud section of the Food and Drug Administration website:

<http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/MedicationHealthFraud/ucm281834.htm>