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Your website documents the intended uses of your products including, but not limited to, the following:

"If you are looking to lose weight you want our hCG Weight Loss Formula."

"When hCG is taken in women and men the body uses it to mobilize stored fat to use for energy and eliminate the extra as well as the toxins."

"This can pull the fat from the hips, thighs, buttocks, upper arms, chin etc. leaving the healthy tissues alone."

"By following the hCG diet, the excess fat is mobilized for energy and the rest is eliminated."

"Most hCG dieters have reported a loss of one to two pounds a day."

"They help you to not feel as hungry during the first week on the 500 calorie portion of the diet. They also help prepare your body to target the fat cells for weight loss."

We recognize that a number of pages on your website contain a disclaimer stating that the products should not be used to diagnose, treat, cure, or prevent any disease. However, notwithstanding this disclaimer, the claims made on your websites for "Alcohol Free hCG Weight Loss Formula," "hCG Diet Pellets Weight Loss Formula," and "hCG Diet Drops Weight Loss Formula" clearly demonstrate that these products are drugs as defined by section 201(g)(1) of the Act [21 U.S.C. § 321(g)(1)], because they are intended to affect the structure or any function of the body.

Further, "Alcohol Free hCG Weight Loss Formula," "hCG Diet Pellets Weight Loss Formula," and "hCG Diet Drops Weight Loss Formula" are "new drugs" within the meaning of section 201(p) of the Act [21 U.S.C. § 321(p)] because they are not generally recognized as safe and effective for these intended uses.

Under sections 301(d) and 505(a) of the Act [21 U.S.C. §§ 331(d) and 355(a)], a new drug may not be introduced or delivered for introduction into interstate commerce unless an application approved by FDA under either section 505(b) or (j) of the Act [21 U.S.C. § 355(b) or (j)] is in effect for the product. There are no FDA-approved applications on file for the above products. Therefore, the marketing of "Alcohol Free hCG Weight Loss Formula," "hCG Diet Pellets Weight Loss Formula," and "hCG Diet Drops Weight Loss Formula" without approved applications constitutes a violation of these provisions of the Act.

We recognize that labeling identifies these products as homeopathic drugs. The definition of "drug" in section 201(g)(1) of the Act [21 U.S.C. § 321(g)(1)] includes articles recognized in the official Homeopathic Pharmacopeia of the United States (HPUS), or any supplement to it. Homeopathic drugs are subject to the same regulatory requirements as other drugs; nothing in the Act exempts homeopathic drugs from any of the requirements related to adulteration, labeling, misbranding, or approval. We acknowledge that many homeopathic drugs are manufactured and distributed without FDA approval under enforcement policies set out in the Agency's Compliance Policy Guide entitled "Conditions Under Which Homeopathic Drugs May be Marketed (CPG 7132.15)" (the CPG). As its title suggests, the CPG identifies specific conditions under which homeopathic drugs may ordinarily be marketed; thus, in order to fall under the enforcement policies set forth in the CPG, a homeopathic product must meet the conditions set forth in the CPG. The CPG defines a homeopathic drug as: "Any drug labeled as being homeopathic which is listed in the Homeopathic Pharmacopeia of the United States Homeopathic Pharmacopeia of the United States (HPUS), an addendum to it, or its supplements."

According to your website, "Alcohol Free hCG Weight Loss Formula," "hCG Diet Pellets Weight Loss Formula," and "hCG Diet Drops Weight Loss Formula" contain human chorionic gonadotropin (HCG). HCG is not an established homeopathic active ingredients included in the HPUS or any of the addenda or supplements. Furthermore, to our knowledge, HCG is not listed in any recognized materia medica containing information on the preparation of homeopathic medicines. Therefore, HCG is not considered a homeopathic drug ingredient and "Alcohol Free hCG Weight Loss Formula,"





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