http://www.ftc.gov/os/adjpro/d9329/091224commissionopinion.pdf[1], pet. for review den., 2010 WL 5108600 (D.C. Cir. Dec. 10, 2010).

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

- ”Lose up to 1 pound a day”
- “Therefore, when you go on a very low calorie diet (VLCD), HCG helps the body make up the difference in the calories it needs to function by using your stored fat as food. The result is rapid weight loss.”
- “Fat burning”
- “Muscle Growth”
- “Blood Flow”
- “Appetite Control”
- “Higher Energy
- “X-30’s key ingredient Irvingia Gabonensis has been clinically proven to promote weight loss, burn fat, reduce LDL cholesterol and improve blood sugar levels.”

The claims made on your product labeling and website for “HCG Platinum,” “HCG Platinum X-30,” and “HCG Platinum X-14” clearly demonstrate that these products are drugs as defined by section

homeopathic active ingredients included in the HPUS or any of the addenda or supplements. Furthermore, to our knowledge, HCG, L-Arginine, Acetyl L-Carnitine, and L-Omithine are not listed in any recognized materia medica containing information on the preparation of homeopathic medicines. Therefore, HCG, L-Arginine, Acetyl L-Carnitine, and L-Omithine are not considered homeopathic drug ingredients and "HCG Platinum" is not considered a homeopathic drug product under the CPG.

"HCG Platinum X-30" and "HCG Platinum X-14" list their active ingredients as "Agnus Castus (Chaste Tree Berry) 3x, 12x, 30x, Angelica sinensis (Dong Quai) 3x, 12x, 30x, Acetyl L-Carnitine 3x, 12x, 30x, Cimicifuga racemosa (Black Cohosh) 3x, 12x, 30x, Dioscorea villosa (Wild Yam) 3x, 12x, 30x, L-Arginine 3x, 12x, 30x, L-Omithine 3x, 12x, 30x." Although, Agnus Castus, Angelica sinensis, Cimicifuga racemosa, and Dioscorea villosa are established homeopathic ingredients listed in the HPUS, Acetyl L-Carnitine, L-Arginine, L-Omithine are not established homeopathic active ingredients included in the HPUS or any of the addenda or supplements. Furthermore, to our knowledge, Acetyl L-Carnitine, L-Arginine, L-Omithine are not listed in any recognized materia medica containing information on the preparation of homeopathic medicines. Therefore, Acetyl L-Carnitine, L-Arginine, L-Omithine are not considered homeopathic drug ingredients and "HCG Platinum X-30" and "HCG Platinum X-14" are not considered homeopathic drug products under the CPG.

Accordingly, the policies set forth in the CPG for the marketing of homeopathic drug products do not apply to "HCG Platinum," "HCG Platinum X-30," and "HCG Platinum X-14."

"HCG Platinum," "HCG Platinum X-30," and "HCG Platinum X-14" are prescription drugs under section 503(b)(1) of the Act [21 U.S.C. § 353(b)(1)]. Section 503(b)(1) of the Act [21 U.S.C. § 353(b)(1)] provides that a drug which "because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug" shall be dispensed only upon a prescription by a practitioner licensed by law to administer such drug. Your labeling provides that your products should be taken in conjunction with a very low calorie diet (VLCD). A VLCD should only be used under proper medical supervision.

Further, "HCG Platinum X-30" is a prescription drug within the meaning of section 503(b)(1) of the Act because it is intended to treat diseases that require diagnosis and treatment by a physician or are intended to provide treatment for symptoms usually caused by an underlying disease process that requires diagnosis and treatment by a physician. For example, your product includes claims for diabetes ("improve blood sugar levels") and heart disease (*e.g.,* "reduce LDL cholesterol levels"). Because they are subject to section 503(b)(1) of the Act, "HCG Platinum," "HCG Platinum X-30," and "HCG Platinum X-14" are misbranded under section 503(b)(4) of the Act [21 U.S.C. § 353(b)(4)] in that their labels fail to bear the symbol, "Rx only."[2] Your marketing of these misbranded products violate sections 301(a) and (k) of the Act [21 U.S.C. §§ 331(a) and (k)].

The issues and violations cited in this letter are not intended to be an all-inclusive statement of violations that exist in connection with your products. You are responsible for investigating and determining the causes of the violations identified above and for preventing their recurrence or the occurrence of other violations. It is your responsibility to assure that your firm complies with all requirements of federal law and FDA regulations.

You should take prompt action to correct the viol