http://www.ftc.gov/os/adjpro/d9329/091224commissionopinion.pdf¹, pet. for review den., 2010 WL 5108600 (D.C. Cir. Dec. 10, 2010).

Statements on the immediate container label that document the intended uses of your product include, but are not limited to, the following:

"Ultimate Weight Loss & Metabolism Formula"

"Provides homeopathic support for managing weight along with proper dieting."

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

"Lose 26 lbs in 26 days™ if you follow the HCG Diet Direct ™ weight loss plan as directed."

"Our homeopathic HCG Diet Direct™ weight loss plan in conjunction with the low calorie developed diet, is formulated to encourage extra fat to be mobilized for energy and eliminate the rest."

"HCG Diet Direct™ formula stimulates the body's natural ability to make adjustments to alleviate imbalances."

We recognize that a number of pages on your website contain a disclaimer stating that the products are not intended to diagnose, treat, cure, or prevent any disease. However, notwithstanding this disclaimer, the claims made on your product labeling and website for "HCG Diet Homeopathic Drops" clearly demonstrate that this product is a drug as defined by section 201 (g)(1) of the Act [21 U.S.C. § 321(g)(1)], because it is intended to affect the structure or any function of the body.

Further, "HCG Diet Homeopathic Drops" is a "new drug" within the meaning of section 201(p) of the Act [21 U.S.C. § 321(p)] because there is no evidence that it is generally recognized as safe and effective for its 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 is no FDA-approved application on file for the above product. Therefore, the marketing of "HCG Diet Homeopathic Drops" without an approved application constitutes a violation of these provisions of the Act.

We recognize that labeling identifies this product as a homeopathic drug with active ingredients measured in homeopathic strengths.[1] 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 regulath1.198 2-724 with71.2 ("BDC 28 Tw 20.4tin)4.nctm(supese proviese provi8-6 (tuBDC 0.0)]TJ-6 (tso)

Modernization Act (FDAMA); section 126 of FDAMA amended § 503(b)(4) of the Act to require that the label of a prescription drug must bear the symbol "Rx only."

Page Last Updated: 12/05/2011

Note: If you need help accessing inform