Inspections, Compliance, Enforcement, and Criminal Investigations

Hcg-miracleweightloss.com 11/28/11

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION
BUREAU OF CONSUMER PROTECTION
WASHINGTON, D.C. 20580

DEPARTMENT OF HEALTH
AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
SILVER SPRING, MD 20993

WARNING LETTER

November 28,2011

In reply refer to Warning Letter SEA 12-08

Mr. Greg Grimshaw
hcg-miracleweightloss.com
3264 Upper Fords Creek Rd.
Orofino,Idaho 83544

Dear Mr. Grimshaw:

This letter is to advise you that the United States Food and Drug Administration (FDA) and the United States Federal Trade Commission (FTC) have reviewed your firm's product labeling and your website at www.hcg-miracleweightloss.com[1]. Based on our review, "HCG Extra Weight Loss Homeopathic Drops" is an unapproved new drug in violation of sections 301 and 505 of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. §§ 331 and 355] and is misbranded in violation of sections 503 and 301 of the Act [21 U.S.C. §§ 353 and 331].

In addition, it is unlawful under the FTC Act, 15 U.S.C. § 41 et seq., to advertise that a product can prevent, treat, or cure human disease unless you possess competent and reliable scientific evidence, including, when appropriate, well-controlled human clinical studies, substantiating that the claims are true at the time they are made. *See FTC v. Direct Mktg. Concepts*, 569 F. Supp. 2d 285, 300, 303 (D. Mass. 2008), *aff'd*, 624 F.3d 1 (1st Cir. 2010); *FTC* v. *Nat'l Urological Group, Inc.*, 645 F. Supp. 2d 1167, 1190, 1202 (N.D. Ga. 2008), *aff'd,* 356 Fed. Appx. 358 (11th Cir. 2009); FTC v. *Natural Solution, Inc.,* No. CV 06-6112-JFW, 2007-2 Trade Cas. (CCH) P75,866, 2007 U.S. Dist. LEXIS 60783, at *11-12 (C.D. Cal. Aug. 7, 2007). More generally, to make or exaggerate such claims, whether directly or indirectly, through the use of a product name, website name, metatags, or other means, without rigorous scientific evidence sufficient to substantiate the claims, violates the FTC Act. *See In re Daniel Chapter One*, No. 9239, slip op. 18-20, 2009 WL 516000 (F.T.C.), 17-19 (Dec. 24, 2009) http://www.ftc.gov/os/adjpro/d9329/091224commissionopinion.pdf[2], pet. for review den., 2010 WL 5108600 (D.C. Cir. Dec. 10, 2010).

Your website documents the intended uses of your product including, but not limited to, the

following:

- "Lose up to 30 lbs in 30 days!"
- "HCG resets your hypothalamus gland so you do not gain the weight back."
- "You lose fat and the weight loss comes directly from this fat loss and does not strip the body of muscle or bone mass."

The claims made on your website for "HCG Extra Weight Loss 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 Extra Weight Loss Homeopathic Drops" is a "new drug" within the meaning of section 201(p) of the Act [21 U.S.C. § 321(p)] because it is 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 is no FDA-approved application on file for the above product. Therefore, the marketing of "HCG Extra Weight Loss 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. 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 (HPUS), an addendum to it, or its supplements."

According to your website and container label, "HCG Extra Weight Loss Homeopathic Drops" contains HCG (human chorionic gonadotropin) as its active ingredient. HCG is not an established homeopathic active ingredient 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 "HCG Extra Weight Loss Homeopathic Drops" is not considered a homeopathic drug product under the CPG. Accordingly, the policies set forth in the CPG for the marketing of homeopathic drug products do not apply to "HCG Extra Weight Loss Homeopathic Drops."

"HCG Extra Weight Loss Homeopathic Drops" is a prescription drug 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 product should be taken in conjunction with a very low calorie diet (VLCD). A VLCD should only be used under proper medical supervision. Because it is subject to section 503(b)(1) of the Act, "HCG Extra Weight Loss Homeopathic Drops" is misbranded under section 503(b)(4) of the Act [21 U.S.C. § 353(b)(4)] in that its label fail to bear the symbol, "Rx only."[1] Your marketing of this misbranded product violates 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 violations cited in this letter. Failure to promptly correct these violations may result in legal action without further notice, including, without limitation, seizure and injunction. Other federal agencies may take this Warning Letter into account when considering the award of contracts.

We note that under section 201(ff)(3)(B) of the Act [21 U.S.C. § 321 (ff)(3)(B)], dietary supplements cannot contain an article that is approved as a new drug under section 505, which was not marketed as a dietary supplement or food prior to FDA approval of such drug. FDA approved Pregnyl, which contains HCG as the active ingredient, as a new drug on October 20, 1976. To FDA's knowledge there is no evidence that HCG was marketed as a dietary supplement or food prior to FDA approval of Pregnyl. As such, a product containing HCG could not be a dietary supplement.

Within fifteen working days of receipt of this letter, please notify this office in writing of the specific steps that you have taken to correct violations. Include an explanation of each step being taken to prevent the recurrence of violations, as well as copies of related documentation. If you cannot complete corrective action within fifteen working days, state the reason for the delay and the time within which you will complete the corrections. Furthermore, please advise this office of what actions you will take to address product that you have already distributed.

Your reply should be directed to the attention of Mr. Peter Chow, Compliance Officer, 22201 23rd Dr. S.E., Bothell, WA 98021. If you have questions regarding any issue in this letter, please contact Mr. Chow at 425-483-4766.

FTC strongly urges you to review all claims for your products and ensure that those claims are supported by competent and reliable scientific evidence. Violations of the FTC Act may result in legal action seeking a Federal District Court injunction or an Administrative Cease and Desist Order. An order also may require that you pay back money to consumers. Please notify FTC via electronic mail at healthproducts@ftc.gov, within fifteen working days of receipt of this letter, of the specific actions you have taken to address FTC's concerns. If you have any questions regarding compliance with the FTC Act, please contact Mr. Richard Cleland at 202-326-3088.

Sincerely,

/s/

Charles M Breen, District Director
Seattle District Office
Food and Drug Administration

/s/

Mary K. Engle, Associate Director
Division of Advertising Practices
Federal Trade Commission

/s/

Ilisa B.G. Bernstein, Pharm. D.. J.D.
Acting Director, Office of Compliance
Center for Drug Evaluation and Research
Food and Drug Administration

[1] The Agency's guidance, "Conditions Under Which Homeopathic Drugs May be Marketed (CPG 7132.15)," states that, in accordance with§ 503(b)(1) of the Act, homeopathic drug products offered for conditions that require diagnosis or treatment by a licensed practitioner must bear the prescription legend, "Caution: Federal law prohibits dispensing without prescription." This guidance was issued by the agency in 1988. In 1997, Congress enacted the Food and Drug Administration 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."

Close Out Letter

- Hcg-miracleweightloss.com - Close Out Letter 4/16/12[3]

Page Last Updated: 04/26/2012
Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

Links on this page:

1. http://www.hcg-miracleweightloss.com
2. http://www.ftc.gov/os/adjpro/d9329/091224commissionopinion.pdf
3. /ICECI/EnforcementActions/WarningLetters/2011/ucm300974.htm