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Inspections, Compliance, Enforcement, and Criminal Investigations

Theoriginalhcgdrops.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

Dr. Gary Arbuckle and Ms. Amy Freeze
 theoriginalhcgdrops.com and resetthebody.com
 400 W 63rd St. 1001
 New York, NY 10069

Dear Dr. Arbuckle and Ms. Freeze:

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 websites at www.theoriginalhcgdrops.com and www.resetthebody.com. Based on our review, "Homeopathic Original HCG" and "Homeopathic HCG" are unapproved new drugs 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 are 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 (11 th 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. 1820, 2009 WL 516000 (F.T.C.), 17-19 (Dec. 24, 2009)

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

Your websites document the intended uses of your products including, but not limited to, the following:

theoriginalhcgdrops.com

- "The Weight Loss Cure"
- "I lost 26 pounds in 38 days! It was the easiest weight loss I've ever done."
- "Lose 20-30 pounds in 30-40 days"
- "Resets your metabolism"
- "HCG has helped me adjust my appetite accordingly and I have lost weight almost everyday I have taken it."

resetthebody.com

- "Typical committed followers of the program report losing 20-30 pounds in 30-40 days. THESE RESULTS ARE TYPICAL."
- "While following our very precise reduced calorie plan, hCG signals the hypothalamus, which in turn directs the body to release fat from its abnormal reserves, commonly known as "trouble spots", the hips, thighs, belly, etc."
- "At the same time hCG is helping the hypothalamus release fat at an astonishing rate...it is also helping to reset our abnormal eating patterns. Not only our waistline, but our HUNGER, our APPETITES, our CRAVINGS, and most importantly our METABOLISM are being reset."

Further, on the Monday, February 21, 2011 airing of the Dr. Oz show, Dr. Gary Arbuckle stated the following in reference to his homeopathic HCG products:

- "I personally lost 35 pounds in 40 days."

We recognize that a number of pages on your website at www.theoriginalhcgdrops.com contain a disclaimer stating that the product is not intended to diagnose, treat, cure, or prevent any disease. However, notwithstanding this disclaimer, the claims made on your websites for "Homeopathic Original HCG" and "Homeopathic HCG" clearly demonstrate that these products are drugs as defined by 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, "Homeopathic Original HCG" and "Homeopathic HCG" 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 is no FDA-approved application on file for "Homeopathic Original HCG" or "Homeopathic HCG." Therefore, the marketing of "Homeopathic Original HCG" and "Homeopathic HCG" without approved applications constitutes a violation of these provisions of the Act.

We recognize that the 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 (HPUS), an addendum to it, or its supplements."

According to your websites, "Homeopathic Original HCG" and "Homeopathic HCG" contain "HCG" (human chorionic gonadotropin) as their 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 "Homeopathic Original HCG" and "Homeopathic HCG" 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 "Homeopathic Original HCG" and "Homeopathic HCG."

"Homeopathic Original HCG" and "Homeopathic HCG" 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 product should be taken in conjunction with a very low calorie diet (VLCD). A VLCD should only be used under proper medical supervision. Because they are subject to section 503(b)(1) of the Act, "Homeopathic Original HCG" and "Homeopathic HCG" 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."¹ Your marketing of these misbranded products 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.

In addition, we have the following comment: Your firm's websites, www.theoriginaldietdrops.com and www.resetthebody.com. make use of the FDA logo. The FDA logo is for the official use of FDA and not for the use of the private sector. To the public, such use would send a message that FDA favors or endorses an organization, its activities, its products, its services, and/or its personnel which it does not and cannot do. Misuse of the FDA logo may violate federal law and subject those responsible to civil and/or criminal liability.

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 Frank Verni, Compliance Officer; U.S. Food & Drug Administration; New York District Office, HFR-NE140; 158-15 Liberty Avenue, Room 4050; Jamaica, NY 11433. If you have questions regarding any issues in this letter, please contact Frank Verni at (718) 662-5702.

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 Richard Cleland at 202-326-3088.

Sincerely,

/s/

Ronald Pace, District Director
New York District Office
Food and Drug Administration

/s/

Mary K. Engle, Associate Director
Division 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

cc: Gary Arbuckle, DC

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Gary Arbuckle and Amy Freeze

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New York State Office of the Professions
State Board for Chiropractic
State Education Building, Second Floor
Albany, NY 12234

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."

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