Inspections, Compliance, Enforcement, and Criminal Investigations

Nutri Fusion Systems, Inc 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

Mr. Richard Matmer
Nutri Fusion Systems LLC
9854 S. 700 E., Ste 2
Sandy, UT 84070

Dear Mr. Marmer:

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.hcgfusion.com[1]. Based on our review, "HCG Fusion 30" and "H CG Fusion 43" are unapproved new drugs in violation of sections 30 I 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 51 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 products including, but not limited to, the following:

- "After successfully completing the weight loss protocol, the body should have reset its 'set

point' to a new lower weight."

- "HCG Fusion drops allow your body to bum the abnormal fat for energy instead of the food you would typically consume."
- "When a combination of a VLCD and an exact amount of HCG Fusion drops is used, it signals to the body to access and start using and burning the stored fat for energy."
- "Uses ..... Appetite Control & Detox"

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 website for "HCG Fusion 30" and "HCG Fusion 43" 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, "HCG Fusion 30" and "HCG Fusion 43" 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 their 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. The marketing of "HCG Fusion 30" and "HCG Fusion 43" without approved applications constitutes a violation of these provisions of the Act.

We recognize that labeling identifies these products as homeopathic drugs 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 Phmmacopeia 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." The CPG additionally states that "[d]rug products containing homeopathic ingredients in combination with non-homeopathic active ingredients are not homeopathic drug products."

According to your website and package labeling, "HCG Fusion 30" and "HCG Fusion 43" contain "HCG (Human Chorionic Gonadotropin), 6x, l2x, 30x, 60x, Vitamin B12 3x,12x, 30x, Mag Phos cell salt 3x, 12x, 30x, Nat Phos cell salt 3x, 12x, 30x, L-Lysine 3x, 12x, 30x, L-Omathine 3x, l2x, 30x, L-Arginine 3x, 12x, 30x, Acetyl L-Camitine 3x, 12x, 30x." Although Magnesia Phosphorica and Natrum Phosphoricum are established as homeopathic active ingredients in the HPUS, human chorionic gonadotropin (HCG), Vitamin B12, L-Oranthine, L-Arginine, and Acetyl L-Camitine are not established homeopathic active ingredients included in the HPUS or any of the addenda or supplements. Furthermore, to our knowledge, HCG, Vitamin B12, L-Oranthine, LArginine, and Acetyl L-Carnitine are not listed in any recognized materia medica containing information on the preparation of homeopathic medicines. Therefore, HCG,Vitamin B 12, L-Oran thine, L-Arginine, and Acetyl L-Camitine are not considered homeopathic drug ingredients and "HCG Fusion 30" and "HCG Fusion 43" 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 Fusion 30" and "HCG Fusion 43 ."

"HCG Fusion 30" and "HCG Fusion 43" 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)(I) of the Act, "HCG Fusion 30" and "HCG Fusion 43" 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 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 conect the violations cited in this letter. Failure to promptly conect these violations may result in legal action without further notice, including, without limitation, seizure and injunction. Other federal agencies may take this Waming Letter into account when consideling 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 plior 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 website, www.hcgfusion.com[3] makes 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 conect 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 conections. 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 Ms. Nancy Schmidt, Compliance Officer, P.O. Box 25087, Denver, CO 80225-0087. If you have questions regarding any issue in this letter, please contact Ms. Schmidt at (303) 236-3046.

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 Comt 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 concems. If you have any questions regarding compliance with the FTC Act, please contact Mr. Richard Cleland at (202) 326-3088.

Sincerely,

/s/

LaTonya M. Mitchell, District Director
Denver 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

cc: Mr. Richard Marmer
Nutri Fusion Systems LLC
9425 S Union Square, Ste 101
Sandy, UT 84070

[1] For example, the label for HCG Fusion 30 and HCG Fusion 43 includes the ingredients "HCG (Human Chorionic Gonadotropin), 6x, 12x, 30x, 60x, Vitamin B12 3x, 12x, 30x, Mag Phos cell salt 3x, 12x, 30x, Nat Phos cell salt 3x, 12x, 30x, L-Lysine 3x, 12x, 30x, L-Omathine 3x, 12x, 30x, L-Arginine 3x, 12x, 30x, and Acetyl L-Carnitine 3x, 12x, 30x."

[2] 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."

Links on this page:

1. http://www.hcgfusion.com
2. http://www.ftc.gov/os/adjpro/d9329/091224commissionopinion.pdf
3. http://www.hcgfusion.com