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/

Links on this page:

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