



HCG Marketers Face Hot Pursuit by FDA, FTC

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Putting a snag in New Year's resolutions for pound-shedding, the FDA and the FTC recently sent out warning letters to several companies that sell HCG-based diet products online. (These companies include Nutri-Fusion Systems LLC, Natural Medical Supply, HCG Platinum, LLC, theoriginalhcgdrops.com, HCG Diet Direct, LLC, and Hcg-miracleweightloss.com.)

The warning letters, which came at the outset of the holiday season (and just before the January windfall for the diet industry, which the government may or may not have had in mind), allege that the companies are in violation of federal law (1) for selling unapproved and misbranded new drugs and (2) for advertising the health benefits of products without sufficient back-up research.

The products at issue, generally liquid drops, contain the human chorionic gonadotropin (HCG) hormone, which comes from human placenta and is extracted from pregnant women's urine. HCG has been popular for weight loss since the 1950s, when a British doctor published a study that the hormone aided dramatic weight loss (of up to a pound a day) by mobilizing fat stores without affecting muscle or normal/structural fat. The popularity of HCG-based diet products escalated in 2007 when the notorious infomercial man, Kevin Trudeau, published a diet book on HCG.

Responding to the increased demand, in came many enterprising online marketers. But there's an issue with selling these products – government



regulation. HCG is FDA-approved, but only as a prescription drug and only for certain medical conditions, which do not include weight loss.

To get around this government roadblock, companies have marketed their HCG products as “homeopathic.” The FDA allows for the manufacture and distribution – without FDA approval – of homeopathic drugs provided those drugs meet criteria [set out in the agency’s Compliance Policy Guide](#) under “Conditions Under Which Homeopathic Drugs May be Marketed (CPG 7132.15).”

But according to the FDA’s warning letters [such as this one](#), the HCG products marketed by these companies don’t meet the Compliance Policy Guide criteria. The biggest issue, which companies are going to have a hard (read impossible) time getting around is that HCG is not an established homeopathic active ingredient. And if a product has any non-homeopathic active ingredients, it falls out of the homeopathic exceptions under the CPG. Since HCG is a regulated drug (several states, including California and New York, list it as a Schedule III controlled substance) and can’t fall under the homeopathic exception, companies marketing HCG-based products are subject to a host of FDA regulations that require FDA involvement and approval. As these companies operated outside the FDA’s purview, they now find themselves in hot water.

The FDA isn’t the only government agency barking up these marketers’ money trees. The FTC joined the investigation and incorporated their allegations into the warning letters. The letters note that the companies’ websites make a host of claims that the government alleges are unsubstantiated. Any advertisement that includes health claims requires “competent and reliable scientific evidence,” such as human clinical studies.



The letters give the companies 15 days to take corrective measures and notify the government of those measures. If you go on these companies' sites today, you'll notice a lot of "coming soon" and "products currently being improved"-type language. And this all takes place during the New Year's resolution timeframe, when these companies could be raking it in.

A few takeaways from the warning letters: (1) If you are going to invest time and money into a product being marketed purely through a regulatory loophole, make sure you satisfy all the criteria to meet that exception. (2) Don't go where Kevin Trudeau has gone. This is meant to be partially glib, but the fact of the matter is that Trudeau is an FTC pet peeve. You can be sure of FTC involvement if you trek the same path he has. (3) Disclaimers are not enough to avoid the FDA. A couple of the HCG marketers to whom warning letters were issued had included disclaimers on their websites that the products are not intended to treat, cure or prevent disease. Such disclaimers, according to the FDA, could not overcome other health claims and language on the sites. (4) At the end of the day, if the government wants to give you a hard time, there is little you can do about it. Other warning letters issued by the FDA regarding homeopathic products noted that *"that there may be circumstances where a product that otherwise may meet the conditions set forth in the CPG may nevertheless be subject to enforcement action."* With this last pointer, all we can say is, *do a cost-benefit risk analysis.*

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