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FDA issues Warning Letter to makers of "Viagra Coffee"

Latest step in FDA's decade-long crackdown on so-called "dietary supplements" designed and marketed to treat erectile dysfunction and enhance sexual performance

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John J. Richardson

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Recently, INZ Distributors, Inc./Magic Power Coffee, Inc (Magic Power) came under FDA scrutiny for the marketing of its Magic Power Coffee product, a product available only through online sales. The company claims its product is a "100% natural" dietary supplement that can enhance sexual performance. Despite being labeled as an all-natural dietary supplement, a laboratory investigation conducted by the FDA revealed that at least one batch of the coffee product also contained hydroxythiohomosildenafil, a similar compound of the drug sildenafil, the active ingredient in Pfizer's Viagra.

This undisclosed inclusion of a pharmaceutical component prompted the FDA to warn consumers on June 19, 2010 to avoid the product and to report any adverse health effects to the FDA. Despite a mass voluntary recall of all production dates up to May 8, 2010, the FDA then issued a Warning Letter to Magic Power on August 23, 2010, notifying the company that the current marketing and distribution of the Magic Power Coffee product was in violation of multiple provisions of the Federal Food, Drug and Cosmetic Act (the Act).

Why did the FDA issue a warning letter to INZ Distributors, Inc./Magic Power Coffee, Inc.?

Since 2004, the FDA has been monitoring the online marketing of so-called "dietary supplements" that claim to treat erectile dysfunction and enhance sexual performance. Despite being presented as all-natural alternatives to prescription drugs like Viagra, Levitra and Cialis, the FDA has found that some of these unapproved products actually contain undisclosed amounts of the same pharmaceutical ingredients present in these FDA-approved drugs.

FDA approval is required for these types of drugs because of the serious risks of harm that they pose to certain classes of consumers. Specifically, these drugs (known as PDE 5 inhibitors) may interact with nitrates, commonly taken by consumers with diabetes, high blood pressure, high cholesterol or heart disease, to cause blood pressure to drop to unsafe levels. The FDA's concern is that consumers who are unable to obtain prescriptions for Viagra, Levitra or Cialis may be using alternative products such as Magic Power Coffee, unaware of the serious risks and consequences that they pose.

The FDA Warning Letter notified the company that the current marketing and distribution of the Magic Power Coffee product without an FDA approved application was violating multiple provisions of the Federal Food, Drug and Cosmetic Act.

Specifically, the inclusion of hydroxythiohomosildenafil meant that the product could not be properly marketed as either a dietary supplement or as a conventional food as its labeling suggested. The drug's presence, along with claims such as "*Serving Passion One Cup at a Time*" and "*for best results, use*

approximately 30-45 minutes prior to engaging in sexual intercourse," led the FDA to find that Magic Power Coffee qualified as a "drug" under the Act as the product was intended to affect the structure or function of the body.

More specifically, the FDA found that the product constituted a "new drug" under the Act because it was "not generally recognized as safe and effective for use under the conditions proscribed, recommended, or suggested in the labeling thereof." The introduction and delivery of a new drug into interstate commerce without an FDA approved application violates sections 301(d) and 505(a) of the Act.

The Warning Letter further states that the Magic Power Coffee product was misbranded under the Act in three respects.

1. The agency found Magic Power Coffee to be misbranded under section 502(f)(1) of the Act, which provides that a drug is misbranded if it fails to bear adequate directions for its intended use. The Warning Letter states that Magic Power Coffee is a prescription drug because, like all other PDE 5 inhibitors that the FDA had previously approved, its potentially harmful effects render it unsafe for use except under the supervision of a licensed practitioner. Because prescription drugs can only be used safely under the supervision of a licensed practitioner, it is the FDA's position that it is impossible to write adequate directions for consumer use only.
2. The FDA also found that the undisclosed presence of hydroxythiohomosidenafil caused the product to be misbranded under sections 502(a) and 502(f)(2) of the Act. A drug is misbranded under 502(a) if "its labeling is false or misleading in any particular," and under 502(f)(2) if its labeling lacks adequate warnings for the protection of users based on the risks associated with the consumption of the product. As noted, the product's labeling neither warned consumers of the presence of hydroxythiohomosildenafil nor of its potentially dangerous side effects.
3. The FDA also determined that the introduction and delivery into interstate commerce of the misbranded Magic Power Coffee violated Section 301(a) of the Act.

What is an FDA Warning Letter?

Initially, it is important to note that ongoing or promised corrective action, such as the company's voluntary recall in the case of Magic Power Coffee, will not necessarily preclude the issuance of a Warning Letter.

An FDA Warning Letter is an informal and advisory correspondence that provides notification to companies and individuals that their products, practices, processes or other activities have been observed to be in violation of the Federal Food, Drug and Cosmetic Act. The FDA Regulatory Procedures Manual describes the Warning Letter as the "agency's principal means of achieving prompt voluntary compliance with the [Act]."

Despite having no obligation to issue Warning Letters to companies and individuals observed to be in violation of the Act, the FDA does so with the expectation that these companies and individuals will promptly and voluntarily come into compliance once notified.

Warning Letters are only issued for violations of regulatory significance, *i.e.*, those violations that may ultimately lead to enforcement action if not promptly and adequately corrected. In this sense, they serve to ensure that the seriousness and scope of the observed violations are understood by top management so that the appropriate response can be made by the affected industry in order to correct violations and to prevent recurrence.

Are FDA Warning Letters legally binding?

Despite the serious nature of the Warning Letter, they are not binding upon either the affected industry or the FDA. They serve the purpose of communicating the FDA's position on a very specific matter, but do not

commit the FDA to take any further enforcement action against the industry. As such, the FDA does not consider the Warning Letter to constitute final action upon which the agency can be sued.

Warning Letters do, however, serve the additional purpose of being the FDA's primary means of establishing prior notice. It is the FDA's policy to afford individuals and firms an opportunity to take voluntary corrective action prior to the initiation of an enforcement action. However, if that voluntary action is not achieved to the satisfaction of the FDA, documentation of prior notice strengthens the FDA's position in future enforcement actions by establishing that responsible individuals continued violating the law despite having been previously warned.

What should a manufacturer do if it receives an FDA Warning Letter?

Generally, Warning Letters give the party in violation 15 days to respond, in writing, to inform the office issuing the letter of the specific steps that have been taken to correct the stated violations and to ensure that similar violations will not recur. As discussed, FDA Warning letters are non-binding and compliance is purely voluntary. Further, the issuance thereof does not necessarily indicate that an enforcement action will follow.

However, the Warning Letter will serve as prior notice to the company or individual in violation, which strengthens the agency's position in any future enforcement action. Therefore, upon receipt of an FDA Warning Letter the targeted individual or company should promptly respond with the allotted 15 day period.

- The individual or company should first consult either inside and/or counsel familiar with FDA compliance issues in order to establish a working plan to make an appropriate response.
- The individual or company should contact the listed FDA contact if any aspect of the letter is unclear. It may also be appropriate in some circumstances to schedule a meeting with the FDA contact.
- A typical response should first acknowledge the company and or individual's obligation to implement whatever measures are necessary to ensure that their products are in compliance with the law.
- The response should then state what corrective action is being taken on the company's behalf and what corrective action, if any, has already been taken.
- The response should be as specific as possible in communicating to the FDA a relative time table of when future corrective action will take place.
- A thorough response letter should also refer to any changes that are being made in company practice/policy to keep abreast of changes in the law and to ensure future compliance with the Act.

A response letter could articulate any reasons that the company has for disagreeing with the FDA's position on a particular matter, but again, the FDA uses the Warning Letter as a means of facilitating prompt and voluntary compliance with the Act and as its chief means of providing prior notice. Failure to take corrective action despite being notified could subject affected individuals and companies to harsh FDA enforcement action, where the FDA's position would be strengthened by virtue of the prior notice that was established through the issuance of the Warning Letter.

Nicholas Godfrey assisted the author with the article. Godfrey is a student at Duquesne University School of Law and is currently serving a legal internship in Dinsmore & Shohl's Pittsburgh office.