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DEPARTMENT OF HEALTH & HUMAN SERVICES

New York District

Food & Drug Administration
158-15 Liberty Avenue
Jamaica, NY 11430

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Ayoula Dublin
120 Greenwich Street, Suite #3A
New York, New York 10006

July 22, 2003

NYK-2003-30

Dear Ms. Dublin:

This letter is in reference to your marketing and distribution of the product "Lipostabil." Examples of the claims for this product found on your Internet website, www.geocities.com/lipodissolve, include:

"A Quick Fix: Burn Fat Away With An Injection" ... "How its supposed to work: An enzyme called phosphadidyl choline (a.k.a. Lipostabil) is injected into fatty areas, like the butt and thighs, where it is said to break down and dissolve fat, slimming and smoothing the skin. It claims to break down fat deposits with 5-6 injections over 2-3 weeks. Although not a replacement for liposuction because it only minimizes small amounts of fat, it is perfect for the person who wants to lose those last 5-10 pounds."

The above claims demonstrate that this product is being marketed as an injectable product. As such, it does not qualify as a dietary supplement since it is not intended for ingestion as set forth in section 210(ff)(2)(A)(i) of the Federal Food, Drug, and Cosmetic Act (the Act).

Based on the route of administration (i.e., injectable) of this product and the claims made for the product to affect the structure or function of the body, it is a "drug" within the meaning of section 201(g) of the Act. Moreover, the product is a "new drug" [section 201(p) of the Act] because there is no substantial evidence that the product is generally recognized as safe and effective for its intended use. Since the product is a "new drug" it may not be marketed in the United States without an approved new drug application [section 505(a) of the Act]. In addition, in accordance with section 503(b)(1) of the Act, injectables other than insulin may not be sold directly to consumers.

Furthermore, false promotional statements are being made by you on the website www.geocities.com/lipodissolve such as:

“Though it is widely used in Europe and South America, Lipostabil injections are now being performed in the US. Lipostabil does not have approval from the FDA. It is made of a nutritional supplement lecithin, which does not fall under the FDA’s jurisdiction, that’s why it’s legal to inject and sell Lipostabil... You’re probably asking yourself is that legal? Yes it is. Since Lipostabil is made up of a nutritional supplement lecithin, which doesn’t fall under the FDA’s jurisdiction it is legal to inject and sell Lipostabil... Lipostabil is developed by the industry leader Aventis.”

The above statement incorrectly states that this product does not require FDA approval for marketing and that this product is legal to be sold and shipped to US consumers. These false and misleading statements on your Internet website cause this drug to be misbranded under section 502(a) of the Act.

This letter is not intended be an all-inclusive review of all labeling and products your firm may market. It is your responsibility to ensure that all products marketed by your firm are in compliance with the Act and implementing regulations.

You are instructed to immediately cease marketing and distributing this product and to take prompt action to correct these violations. Failure to promptly correct violations may result in enforcement action being initiated by the Food and Drug Administration without further notice. The Federal Food, Drug, and Cosmetic Act provides for the seizure of illegal products and for injunction against the manufacturer and/or distributor of illegal products.

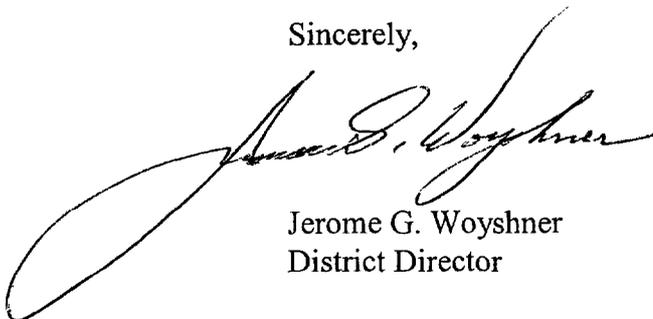
By copies of this letter, we are advising the New York State Department of Health, the State of New York Board of Pharmacy, and the New York Office of Professional Discipline regulatory officials of these violations.

Please notify this office in writing within fifteen (15) working days of receipt of this letter as to the specific steps you have taken to correct the stated violations. Your response should also include an explanation of each step being taken to identify and make corrections to assure that similar violations will not recur. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which corrections will be completed.

Ayoula Dublin
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You should send your reply to the Food and Drug Administration, 158-15 Liberty Avenue, Jamaica, NY 11433, Attention: Laurence D. Daurio, Compliance Officer.

Sincerely,

A handwritten signature in black ink, appearing to read "Jerome G. Woysner". The signature is fluid and cursive, with a large loop at the end.

Jerome G. Woysner
District Director

cc: Terry Simel, Chairman, CEO, and Director
Yahoo!, Inc.
701 First Avenue
Sunnyvale, CA 94089

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