



DEPARTMENT OF HEALTH AND HUMAN SERVICE

Refer to: CFN/FEI 3003075736

Public Health Service

91744d

Food and Drug Administration
Baltimore District Office
900 Madison Avenue
Baltimore, MD 21201-2199
Telephone: (410) 962-3396
FAX: (410) 962-2219

01-BLT-38

September 13, 2001

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Robert C. Miller, CEO
Strong Pharmaceutical Laboratory, LLC
2 Park Center Court
3rd Floor
Owings Mills, Maryland 21117

Dear Mr. Miller:

This letter is in reference to the marketing and distribution of "Triaxon™ 180-Day Hair Loss Treatment Kit" by your firm. During an inspection of your facility located at the above address on March 22-23, 2001, our investigator determined that you are an own-label distributor of the Kit. The labeling for "Triaxon™ 180-Day Hair Loss Treatment Kit," including the immediate container labels, the "Dear Friend" letter, the "Triaxon™ Frequently Asked Questions" list, and the "Triaxon™ Dossier of Technical Presentation," bear the following claims:

"DEAR FRIEND" LETTER

- "Through diligent, daily adherence to the morning and evening application (only 2 minutes a day), further hairloss should be significantly diminished or stopped altogether within four short months."

"TRIAXON™ FREQUENTLY ASKED QUESTIONS"

- "Triaxon™ can successfully be incorporated with hair loss prescriptions which are taken orally. However, Triaxon™ has been proven just as effective alone and without the inherent side effects of prescription drugs."

"TRIAXON™ DOSSIER OF TECHNICAL PRESENTATION"

- "Triaxon™ is a pharmaceutically bio-engineered serum technology specifically formulated for the preventive treatment of hair loss due to androgenetic alopecia, alopecia areata and alopecia resulting from chemical, environmental or medically related factors... Triaxon™ has produced consistent,

Mr. Robert C. Miller, Strong Pharmaceutical Laboratory, LLC

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statistically significant results on both male and female alopecia subjects, while eliminating potentially dangerous side effects commonly attributed to prescriptive drug therapies.”

- “Triaxon™ serum treatment substantially addresses six (6) specific physiologic ‘target’ zones providing...Effective prophylactic intervention of dominant androgenetic factors (5-Alpha Reductase / dihydrotestosterone DHT) conversion), responsible for continued hair fall and shortening the intermittent cyclic activity of the anagen active phase of hair growth...”
- “... an observed stop in hair fall in 90% of subjects after 112 days (4 months) of treatment.”
- “Triaxon™ has proved excellent as a pre and post operative adjunct to hair transplant surgery and may be further incorporated into a regime of post chemotherapy care.”

Based on the intended uses described above, “Triaxon™ 180-Day Hair Loss Treatment Kit” is a drug within the meaning of Section 201(g) of the Federal Food, Drug and Cosmetic Act (the Act). It is also subject to the final rule covering Hair Grower and Hair Loss Prevention Drug Products for Over-the-Counter Human Use in Title 21 Code of Federal Regulations (21 CFR), Part 310.527. Under that rule, no ingredients are generally recognized as safe and effective to grow hair or prevent hair loss. Any topical OTC drug product that is labeled or promoted as a hair grower or for hair loss prevention is considered as a new drug (Section 201(p) of the Act). Therefore, “Triaxon™ 180-Day Hair Loss Treatment Kit” is a new drug that may not be legally marketed in the United States without an approved New Drug Application (Section 505(a) of the Act).

The product is also misbranded within the meaning of Section 502(a) of the Act because its labeling is false and misleading in that it represents and suggests that there is substantial scientific evidence to establish that the drug is safe and effective for its intended use when, in fact, such evidence does not exist. In addition, the product is misbranded within the meaning of Section 502(f)(1) of the Act because its labeling does not bear adequate directions for use. The product is not exempt from this requirement under 21 CFR 201.115, since it is a new drug within the meaning of Section 201(p) of the Act and no approval of an application filed is effective for this drug (Section 505(b)).

This labeling review is not intended to represent an all-inclusive review of your firm’s product labeling. It is your responsibility to ensure that all products distributed by your firm are in compliance with the federal laws and regulations. You should take prompt action to correct these deviations. Failure to do so may result in regulatory action, including seizure and/or injunction, without further notice.

Please notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations and to prevent recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

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Your reply should be sent to the Food and Drug Administration, 900 Madison Avenue, Baltimore, Maryland 21201, to the attention of Nancy L. Rose, Compliance Officer. Ms. Rose can be reached at (410) 962-4017, extension 122.

Sincerely,

A handwritten signature in black ink, appearing to read 'L. Bowers', with a stylized flourish at the end.

Lee Bowers

Director, Baltimore District