



U.S. Food and Drug Administration

New York District
850 Third Avenue, Brooklyn, New York 11232

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HE1-35 1/15/98

Telephone: [718] 340-7000 [Ext 5301]

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

JAN 7 1998

Isaac Oberndorfer, President
Norris M. Strauss Inc.
d/b/a NMS Publishing
57-11 14th Avenue
Brooklyn, New York 11219

re: 14-NYK-98

Dear Mr. Oberndorfer:

This letter is in reference to the marketing of "Super Hair Energizer™ Concentrated Shampoo", "Super Hair Energizer™ Concentrated Follicle Stimulator", "Super Hair Energizer™ Vitamins & Minerals", and "100% Pure Jojoba Oil". These products are sold individually or in "Super Hair Energizer™ Hair & Scalp Treatment" Super Trio Pak by your firm.

"Super Hair Energizer™ Concentrated Shampoo"

Its labeling includes claims of "remove sebum ... **ACTIVATES** the follicle cells", "key ingredient, Ferm-T® ..causing cellular rejuvenation", and " helps to control sebum and reduce hair loss by unclogging the hair follicles "

"Super Hair Energizer™ Concentrated Follicle Stimulator"

Its labeling includes claims of " key ingredient, Ferm-T® has a mitochondrial reaction, which produces energy cells, causing cellular rejuvenation", and "protects scalp and helps control of sebum build up," and "stimulate and activate your hair follicles."

"Super Hair Energizer™ Vitamins & Minerals"

Its labeling includes claims of "will provide essential nutrients for healthier hair while also stimulating growth", and "it will improve cell production , scalp circulation and further help to produce healthier, thicker hair."

"100% Pure Jojoba Oil"

The labeling includes claim of "soften sebum build up on the scalp."

"Super Hair Energizer™ Hair & Scalp Treatment" Super Trio Pak

The labeling includes claims of "Stop Hair Loss", " Even in advanced cases of baldness... In just one week you will be...GROWING NEW HAIR... Double or triple the amount of your hairs, fill in receding hairline, fill in sides, temples and the bald spot on the back of your head!...", "STOPS HAIR LOSS IMMEDIATELY!... It is proven, with a history of growing hair on thousands upon thousands!... It restores hairs you thought were gone forever!... activating the follicle - - follicle stimulation is the 'key' ! ", " break up hardened layers of sebum and destroy bacteria that deteriorate the follicles", and to treat "sebum-related symptoms (that) include dandruff, ... dry itchy scalp, ... acne, seborrhea, eczema, and psoriasis."

Based on these claims, the four products are drugs (Section 201(g) of the Federal Food, Drug and Cosmetic Act (the Act)) subject to the final rules covering Hair Grower and Hair Loss Prevention Drug Products for Over-the-Counter Human Use (21 Code of Federal Regulations (CFR) Part 310.527), Topical Acne Drug Products (21 CFR Part 333.301), and Drug Products for the Control of Dandruff, Seborrheic Dermatitis, and Psoriasis (21 CFR Part 358.701). These products do not meet the requirement of these final rules. Therefore, these four products are "new drugs" (section 201(p) of the Act), which may not be legally marketed in the United States since they are not the subject of an approved NDA (Section 505(b) of the Act).

These products are also misbranded because they fail to bear adequate directions for use (Section 502(f)(1) of the Act) and they were manufactured in an establishment which is not registered and further, the products have not been drug listed as required by the Act (Section 510).

The above list of violations is not intended to be an all inclusive list of deficiencies at your firm. It is your responsibility to ensure that the drug products you distribute meet all requirements of the Act and its implementing regulations. Federal agencies are advised on the issuance of all Warning Letters about drugs and devices so that they may take this information into account when considering the award of contracts.

We request that you take prompt action to correct these violations. Failure to promptly correct these violations may result in regulatory action without further notice. Such actions may include seizure and/or injunction against the manufacturer or distributor of these illegal products.

Please notify this office in writing within fifteen (15) days of receipt of this letter. Your response should describe the specific actions you will take to correct violations. Your response should also include an explanation of each step being taken to prevent recurrence of similar violations. If corrective actions cannot be completed within fifteen(15) working days, please state the reason for the delay and time within which corrections will be completed.

Your reply should be sent to the Food and Drug Administration, New York District Office, at the above address, Attention: William Friedrich, Compliance Officer.

Sincerely,

A handwritten signature in black ink, appearing to read "Brenda J. Holman". The signature is fluid and cursive, with a long horizontal stroke extending to the right.

Brenda J. Holman
District Director
New York District