DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

Dallas District
4040 North Central Expressway
Dallas, Texas 75204-3145

July 24, 2002

Ref: 2002-DAL-WL- 18

WARNING LETTER

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Farouk M. Shami, President/CEO
Farouk Systems, Inc.
250 Pennbright
Houston, TX 77090

Dear Mr. Shami:

This letter is in reference to your firm's marketing of the "POWER PLUS" Hair Loss Prevention System and "BIOSILK" Dandruff Control products. A FDA investigator inspected your manufacturing and distribution facility for these products on May 29, May 30 and June 4, 2001. A follow-up inspection was conducted on May 28, 2002

"POWER PLUS" Hair Loss Prevention System:
During the inspections, the FDA investigator determined that your firm manufactures, promotes, and distributes the hair loss prevention system in kits, made up of shampoos, conditioners, and hair supplements. The ingredients of these products are declared as Stinging Nettle and other herbs, vitamins, and minerals. The products are marketed as a natural non-chemical alternative to chemical hair treatments, in kits intended for normal hair and chemically treated hair. Components of the kits are also marketed separately, and a Root Booster product is marketed separately from the kits and as a component of the "POWER PLUS" Hair Loss Prevention System.

Labeling of the "POWER PLUS" Hair Loss Prevention System includes a four-fold brochure which makes the following claims:

- **"POWER PLUS"** ... "*A NATURAL NON-CHEMICAL ALTERNATIVE * HAIR LOSS PREVENTION SYSTEM * FDA Approved * Stinging Nettle (Urtica Dioica) * the stems and leaves of the Nettle plant have been used medicinally. * Nettle also has blood purifying properties and acts as an astringent that helps speed the metabolism and blood circulation. * Power Plus system of Shampoos, Conditioners and Supplements formula contains many herbs * to help nourish the scalp and stimulate the blood circulation to promote hair growth naturally. * Active ingredient is Nettle a natural alternative to chemicals. * Can be used for both early signs and advance stages of thinning hair*".

Carton labeling for the "POWER PLUS" Hair Loss Prevention System kit intended for normal hair makes the following claims:

- **"POWER PLUS"**..."*HAIR LOSS PREVENTION SYSTEM * For Normal and Fine Hair * N-1 Priming Shampoo * NC-1 Stimulating Conditioner * N-1 Energy Nutrient Supplement * promote hair growth and reduce excessive hair loss. * stimulating the scalp to allow blood flow. * promote microcirculation of blood * grow hair stronger, faster and retain hair longer*".

Carton labeling for the **"POWER PLUS"** Hair Loss Prevention System kit intended for chemically treated hair makes the following claims:

- **"POWER PLUS"**..."*HAIR LOSS PREVENTION SYSTEM * For Chemically Treated and Dry Coarse Hair * C-1 Vitalizing Shampoo * NC-1 Stimulating Conditioner * C-1 Energy Nutrient Supplement * promote hair growth and reduce excessive hair loss. * stimulating the scalp to allow blood flow. * produce stronger healthier fuller hair. * grow hair stronger, faster and retain hair longer*".

Container Labeling of the components of the **"POWER PLUS"** Hair Loss Prevention System makes the following claims:

- **"POWER PLUS"**... "*HAIR LOSS PREVENTION SYSTEM * N-1 Priming Shampoo * to exfoliate, detoxify, and cleanse the hair * enhance the penetration and effectiveness of the supplement that will promote hair growth and reduce excessive hair loss. * INGREDIENTS: Nettle Extract *";

- **"POWER PLUS"**..."*HAIR LOSS PREVENTION SYSTEM * NC-1 Stimulating Conditioner * stimulating the scalp to allow blood flow. * energize hair follicles to produce stronger healthier fuller hair. * INGREDIENTS: Nettle Extract *";

- **"POWER PLUS"**..."*HAIR LOSS PREVENTION SYSTEM * N-1 Energy Nutrient Supplement * to improve the keratin structure, * removing free radical scavengers * contribute to thinning and hair loss. * treatment helps to promote microcirulation of blood * can contribute to grow hair stronger, faster, and retain hair longer. *";

- **"POWER PLUS"**..."*HAIR LOSS PREVENTION SYSTEM * C-1 Vitalizing Shampoo * to exfoliate, detoxify, and gently cleanse the hair * enhance the penetration and effectiveness of the supplement that will promote hair growth and reduce excessive hair loss. * INGREDIENT: Nettle Extract *";

- **"POWER PLUS"**..."*HAIR LOSS PREVENTION SYSTEM * C-1 Energy Nutrient Supplement * improve the keratin structure * while removing free radical scavengers which may contribute to thinning and hair loss. * promote microcirculation of blood to enhance the follicle that can contribute to grow hair stronger, faster and retain hair longer.*";

- **"POWER PLUS"**..."*HAIR LOSS PREVENTION SYSTEM * NC-1 Root Booster * will provide incredible volume and fullness to fine thinning hair. * nettle * INGREDIENTS: Cabbage Rose Water * Nettle Extract *".

Additionally, the **"POWER PLUS"** Hair Loss Prevention System is marketed on your Internet web site (http://www.farouk.com) which makes the same claims as those indicated in labeling of kits and components.

Based on the intended uses described above, these products are drugs under section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act). These drugs are subject to the final rule covering Hair Grower and Hair Loss Prevention Drug Products for Over-the-Counter (OTC) Human Use, Title 21, Code of Federal Regulations (21 CFR), Part 310.527. Under this rule, no ingredients are generally recognized as safe and effective to grow hair or prevent hair loss. Therefore, your "POWER PLUS" products are "new drugs" under section 201(p) of the Act. Under section 505(a) of the Act, a new drug may not be marketed in the United States without an approved new drug application (NDA). Additionally, labeling indicates these products are "FDA Approved". This statement is false and misleading in violation of section 502(a) of the Act because no such approval exists for these products.

"BIOSILK" Dandruff Control products:
In addition, the FDA investigator determined that your firm manufactures, promotes, and distributes **"BIOSILK"** Dandruff Control Shampoo and Dandruff Control Conditioner for the treatment of dandruff as evidenced by the labeling for these products, which establishes their intended use as drugs for the treatment of dandruff. These products are subject to the final rule covering Over-the-Counter Drug Products for the Control of Dandruff, Seborrheic Dermatitis, and Psoriasis, Title 21, Code of Federal Regulations (CFR), Part 358.701. Specifically, neither product bears the required indications, warning statements and directions set forth in 21 CFR 358.750(b), (c) and (d).

Additionally, the Batch Master record for Dandruff Control Conditioner indicates this product is not formulated to contain an active ingredient at a concentration specified under the final rule. Therefore, these products are also "new drugs" under section 201(p) of the Act. Under section 505(a) of the Act, a "new drug" may not be marketed in the United States without an approved NDA.

In addition, all of the drug products mentioned above are misbranded because the labeling for your drug products fails to list active ingredients as required by section 502(e)(1)(A)(ii) of the Act. Furthermore, your drug products are misbranded under section 502(o) of the Act, because they have been manufactured in an establishment that has not been duly registered under section 510 of the Act, and the products have not been listed as required by section 510(j).

The violations cited in this letter are not intended be a statement of all the violations that may exist for products marketed by your firm. It is your responsibility to assure that all your products are in compliance with federal laws and regulations. Failure to promptly correct these violations may result in enforcement action being initiated without further notice. Possible actions include seizure and/or injunction.

The FDA follow-up inspection conducted at your facility on May 28, 2002 found your marketing activities for the above products to be virtually unchanged. You should 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, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective actions cannot be completed within 15 working days, state the reason for the delay and the time frame within which corrections will be completed. Please direct your response to James R. Lahar, Compliance Officer at the above address.

Sincerely,

Michael A. Chappell
Dallas District Director

MAC:jrl