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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

Mr. Anthony Imbriolo
President
Global Vision Products, Inc.
227 E. 56th Street, 3rd FL.
New York, New York 10022

April 3, 2003

Ref: NYK-2003-19

Dear Mr. Imbriolo:

This letter is in reference to your firm's marketing of AVACOR™ Hair Care System (AVACOR™) which consists of: Scalp Detoxifying Shampoo, Step 1; Physicians Topical Formula, Step 2; and Nutricap®, DHT Blocker capsules, Step 3. Each component product of this hair care system is marketed together as one system and is not available separately.

AVACOR™ accompanying promotional material, the brochure booklet, Hair & Skin Treatment Center, New York, NY AVACOR includes claims that AVACOR™ is for the treatment and prevention of hair loss and also for promotion of hair growth. Examples include: "This therapeutic approach represents the latest and most advanced treatment in the management of androgentic alopecia (hair loss) in both men and women"..."The decreased amount of receptor binding and production of DHT achieved by our special herbal formulations allows for prevention of further hair loss and promotes hair regrowth in thinning and bald areas"..."The overall outcome of this therapeutic modality has proved to be an extremely beneficial treatment approach in the management of androgenetic alopecia (hair loss)"..."Avacor, the most advanced hair re-growth program"..."Physicians Topical Formulation not only helps regrow the hair you have lost but also strengthens and nourishes the existing hair from future hair loss"..."This product is responsible for blocking the D.H.T. from reaching your hair follicle (root). As you already know, it stops your hair from falling out enabling our other two steps to work efficiently in stopping your hair loss and re-growing new hair..."

Statements on your Internet website, www.avacorusa.com, from which consumers can buy this hair care system, indicate that the AVACOR™ system of three component products is useful in treatment and prevention of hair loss and also in the promotion of hair "regrowth."

AVACOR™ Scalp Detoxifying Shampoo, Step 1:

According to the product label, this product "is to cleanse the scalp of many types of pollutants, and improve the absorbency of the Physician's Topical Formulation." You claim that the shampoo acts as a synergistic agent for the Physician's Topical Formula, Step 2, enhancing the hair growth and hair loss prevention drug aspects of the Physicians Formula, Step 2. In addition, you claim that the shampoo is one of three components that must be used to regrow hair. Because of these claims, the shampoo is a drug under section 201(g) of the Federal Food, Drug and Cosmetic Act (the Act).

AVACOR™ Physicians Topical Formula, Step 2:

According to the ingredient declaration on the product label, and confirmed by our analysis of a sample, the product contains minoxidil (2,4-diamino-6-piperidinopyrimidine 3- oxide). All topical drug products that contain minoxidil and are intended for use as baldness remedies are drugs under section 201(g) of the Act. Drug products that are available over-the-counter (OTC) for external use as hair growers or for hair loss prevention are subject to the final rule covering Hair Grower and Hair Loss Prevention Drugs for OTC Human Use, Title 21, Code of Federal Regulations (21 CFR) Part 310.527. According to this final rule, no OTC drug products for external use offered as a hair grower or for hair loss prevention can be considered to be generally recognized as safe and effective for its intended use.

AVACOR™ Nutricap® DHT Blocker Capsules, Step 3:

The bottle label for Nutricap® capsules states: "...necessary to combat the bad chemicals in our body that causes thinning and balding." and "...very important step in the process of regrowing new hair." Based on these claims as well as the claims described above printed in the AVACOR™ accompanying promotional brochure, this product is a drug under 201(g) of the Act because it affects the structure or any function of the body of man.

As discussed above, based on the claims made for the AVACOR™ Hair Care System and the three individual products of which it is composed, the kit and its components are drugs under section 201(g) of the Act. Each product is a required component of your AVACOR™ Hair Care System for the intended use. Further, this system and its three component products are new drugs under section 201(p) of the Act. They are not generally recognized as safe and effective for their labeled uses. 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). We are unaware of any approved NDA or abbreviated new drug application (ANDA) for your AVACOR™ Hair Care

System and its three individual component products. In addition, the three individual component products of the AVACOR™ Hair Care System are misbranded in violation of the Act because their labeling fails to list the active ingredients as required by section 502(e)(1)(A)(ii) of the Act.

We acknowledge receipt of the August 16, 2002 letter from Sheldon S. Lustigman of The Lustigman Firm, P.C., which includes proposed labeling changes for your products. However, the proposed labeling changes are not adequate to bring these products into compliance with the requirements of the Act. As stated above, the AVACOR™ products are new drugs and require an approved drug application for marketing.

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

We request that you take prompt action to correct these violations. Failure to do so 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.

Please respond to this office in writing within fifteen (15) working days of receipt of this letter. Your response should describe the specific actions you will take, or have taken, to correct the 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.

You should send your reply to the Food and Drug Administration, 158-15 Liberty Avenue, Jamaica, NY 11433, Attention: Laurence D. Daurio, Compliance Officer. If you have any questions regarding the content of this letter, Mr. Daurio can be reached at (718) 340-7000, ext. 5585.

Sincerely,

Jerome G. Woyshner
District Director