



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

M2393N
Food and Drug Administration
555 Winderley Place Ste 200
Maitland, Florida 32751

**CERTIFIED MAIL
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WARNING LETTER

FLA-99-31

February 5, 1999

Aubrey Hampton, President & CEO
Aubrey Organics, Inc.
4419 N. Manhattan Ave.
Tampa, Florida 33614

Dear Dr. Hampton:

During an inspection of your facility located in Tampa, Florida on October 13-15, 1998, FDA investigator Karen G. Hirshfield determined that your firm manufactures various OTC human drug products. These products bear claims in the labeling, including a catalog, that cause them to be "drugs" as described in section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act) and "new drugs" (section 201(p) of the Act). Examples of the products and claims include the following:

Acne Drug Products:

"Aminoderm Gel" and "Maintenance for Young Skin Moisturizer"

The "Maintenance for Young Skin Moisturizer," a topical preparation, bears claims that it will "...ward off acne..." and "...helps prevent blackheads." The "Aminoderm Gel" bears claims that it will "...help clear up acne breakouts..." and "Fights acne and blemishes." Based on these claims, the products are subject to the final rule for topical acne drug products found in Title 21, Code of Federal Regulations (21 CFR), Part 333.301. The ingredients and labeling for these products do not comply with the final regulations.

Dandruff, Eczema, and/or Psoriasis Products:

"Egyptian Henna Shampoo," "Egyptian Henna Hair Rinse," "Selenium Natural Blue Shampoo," "Calaguala Fern & Pine Tar Skin Treatment Cream," "Calaguala Fern & Pine Tar Bath Emulsion Treatment," "Calaguala Fern & Cade Tar Scalp Treatment Shampoo," "Saponin A.A.C. Herbal Root Shampoo," and "Primrose & Lavender Herbal Shampoo"

These products for topical application on the scalp or body bear claims that they will cure, control or relieve the symptoms of dandruff, eczema and/or psoriasis. Based on their labeling, the products are subject to the final rule for OTC dandruff, seborrheic dermatitis, and psoriasis drug products found in 21 CFR 358.701-750. The ingredients and labeling for these products fail to comply with these regulations.

Hair Growth Products:

"Green Tea Herbal Cream Rinse," "Polynatural 60/80 Hair Rejuvenating Shampoo and Conditioner," "Swimmers Conditioner," "Biotin Hair Repair," and "Ginseng Shampoo"

You label these products to help promote hair growth and they are subject to the final rules covering OTC hair growth and hair loss prevention drug products found in 21 CFR 310.527. Under this regulation, no ingredient is generally recognized as safe and effective for that use and an OTC hair growth product may be legally marketed only if it has an approved New Drug Application (NDA).

Tanning Accelerator Products:

"Tan Up Natural Tan Accelerator" and "After Sun Natural Tanning Maintenance and Moisturizer"

Both products list tyrosine as an ingredient. "Tan Up Natural Tan Accelerator" also bears the claim "...tyrosine (sun accelerators)..." The product "After Sun Natural Tanning Maintenance and Moisturizer" bears the claim "to help increase the melanin cells in your skin and keep your tan from fading."

The May 12, 1993, Tentative Final Monograph for Sunscreen Drug Products states, on page 28293, that any product purporting to "accelerate the tanning process" or "stimulate the production of melanin" is claiming to affect the structure and function of the body and is, therefore, a drug. We are not aware of any data demonstrating that tyrosine or its derivatives are generally recognized as safe and effective in stimulating the production of melanin. Thus, any product containing tyrosine or its derivative and claiming to accelerate the tanning process is an unapproved "new drug."

Based on the information cited above, we consider the products to be "new drugs" (section 201(p) of the Act) that may not be legally marketed in this country unless they have approved New Drug Applications (NDA) (section 505 of the Act). The products are also misbranded under section 502(f) of the Act because the labeling fails to bear adequate directions for use and required warnings for the conditions for which the products are offered.

All of the drug products are misbranded as described in section 502(o) because they are manufactured in a facility that has not listed their products with the Food and Drug Administration [section 510(j)].

The inspection further revealed that all of the drugs you manufacture are also adulterated within the meaning of section 501(a)(2)(B) of the Act in that they are drug products and the methods used in, or the facilities or controls used for, their manufacture, processing, packing or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice (GMP) regulations for drugs specified in 21 CFR 211 as follows:

Failure to perform in-process or finished product testing on each batch of product manufactured prior to release for distribution, to include the identity and strength of each active ingredient or content uniformity of finished products;

Failure to maintain documentation of lot acceptance or release for distribution;

Failure to perform validation studies on the manufacturing and filling procedures for any drug products;

Failure to establish written finished product specifications for all products manufactured;

Failure to establish a written stability testing program for any drug products or maintain a record of stability test data for each product;

Failure to maintain adequate batch records;

Failure to establish specifications or a control system for the receipt, testing and acceptance/rejection of components;

Failure to maintain documentation of the calibration of any manufacturing or test equipment;

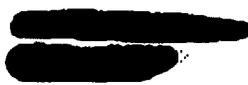
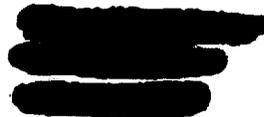
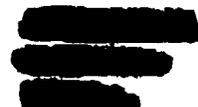
Failure to establish a written procedure for the operation and maintenance of the deionized water system, to include testing the system for microbiological or chemical contamination;

Failure to maintain documentation of label examination, acceptance or rejection.

It is your responsibility as a drug manufacturer to assure that all requirements of the GMP Regulations are met. You are also responsible for ensuring that all of the drug products you manufacture are safe and effective for all of their labeled claims.

We acknowledge receipt of your letter dated October 21, 1998, promising to correct the 19 GMP deficiencies noted during the October 13-15, 1998 inspection. However, we note that you have made similar commitments following inspections in 1987 and 1993, which were not carried out. We also note that your response made no commitment to remove any of the violative label claims discussed with you during the inspection and described above.

For your information, during our investigation, we compared the declaration of ingredients on three of your product labels to the ingredients listed in their formula. This examination found all three of the products contain inactive ingredients that are listed on the product label, but not found in the product formula, and ingredients listed in their formula, that are not declared on the product label, as shown below. The FDA Modernization Act has changed the legal requirements for listing of inactive ingredients. Regulations to implement this requirement are expected to be published soon. If you are making other changes to your product labels, you may wish to compare the label declaration of ingredients to the formula on all of your products and make the necessary changes, in order to be in compliance with the new regulation.

Product	Listed on Label but not in Formula	Listed in Formula but not on Label
Tan Up Natural Tan Accelerator	Jojoba Butter	
Sun Shade 15 Sunblock (SPF 15)	Panthenol Allantoin Carrot Oil	
Green Tea Sunblock For Children SPF 25	Rosa Mosqueta Lemon Peel Oil	

Other Federal agencies are routinely advised of Warning Letters issued so that they may take this information into account when considering the award of contracts. Additionally, pending applications for Agency approval (NDA, ANDA, SNDA, etc.) or export approval requests may not be approved.

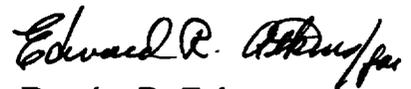
In order to facilitate the Food and Drug Administration (FDA) in making the determination that such corrections have been made and thereby enabling FDA to withdraw its advisory to other Federal agencies concerning the award of government contracts, and to resume review of any pending applications, we request that you notify this office when corrective actions are completed and you believe your facility is in compliance with the GMP regulations so that a verification inspection can be scheduled.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It remains your responsibility to ensure adherence to all requirements of the Act and regulations. You should take prompt action to correct these violations. Failure to correct these violations may result in regulatory action, including seizure and/or injunction, without further notice.

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

Your reply should be directed to Ken Hester, Compliance Officer, U.S. Food and Drug Administration, 555 Winderley Place, Suite 200, Maitland, Florida 32751, telephone (407) 475-4730.

Sincerely,



Douglas D. Tolen
Director
Florida District