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Food and Drug Administration  
Denver District Office  
Building 20 – Denver Federal Center  
P.O. Box 25087  
Denver, Colorado 80225-0087  
TELEPHONE: 303-236-3000

January 12, 2000

**WARNING LETTER**

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

Mr. Geno Marcovici  
Owner/Director of Clinical Research  
Advanced Restoration Technologies, Inc.  
1211 South Parker Road, Suite 100  
Denver, CO 80231

Ref #: DEN-00-04

Dear Mr. Marcovici:

This letter is in reference to the products "HAIR GENESIS Topical Activator Serum contains Minoxidil 5% ... for Men" and "HAIR GENESIS Topical Activator Serum contains Minoxidil 2% ... for Women", marketed by your firm. During inspections of your facility located at the above address in August and September 1999, our investigator determined that you are responsible for the development of product formulations, design of labeling, and preparation of promotional materials.

According to the label, "HAIR GENESIS Topical Activator Serum ...5% for Men" contains 5 % minoxidil as an active ingredient and "HAIR GENESIS Topical Activator Serum ...2% for Women" contains 2% minoxidil as an active ingredient. The label for both include statements such as "Direction: Apply 1 mL ...twice daily directly onto the scalp in hair loss", "Do Not Use If You Are: Not sure of the reason for your hair loss", and "Do Not Use If You Have: No family history of hair loss ... sudden and/or patchy hair loss ..."

Labeling for the above products, including promotional material, contains statements such as "... combines the power of minoxidil ... represents the best way to protect your hair from the effects of Male Pattern Baldness..." "HairGenesis Topical Activator Serum is believed to work by inhibiting a specific enzyme associated with a type of undesirable collagen buildup effecting vulnerable hair follicles ... Thus by using HairGenesis Topical Activator...one can combat Male Pattern Baldness ..."

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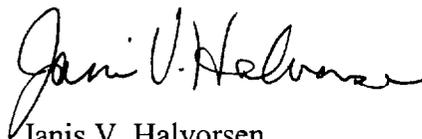
Based on the claims and intended uses described above, these products are drugs (Section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act)). Both “HAIR GENESIS Topical Activator Serum ... 5 % for Men” and “HAIR GENESIS Topical Activator Serum... 2% for Women” are subject to the final rule covering over-the-counter hair grower and hair loss prevention drugs human use (Title 21 Code of Federal Regulations (21 CFR) Part 310.527). Under that rule, no active ingredients are generally recognized as safe and effective to grow hair or prevent hair loss. Therefore, these two products are “new drugs” (Section 201(p) of the Act) that may not be marketed in the United States without an approved new drug application (NDA) (Section 505 (a) of the Act). In addition, these products are also misbranded (Section 502 (f)(1) of the Act), because they do not bear adequate directions for the indication noted above.

Further, these three products are misbranded (Section 502(o) of the Act) because they have not been drug listed as required (Section 510(j)).

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

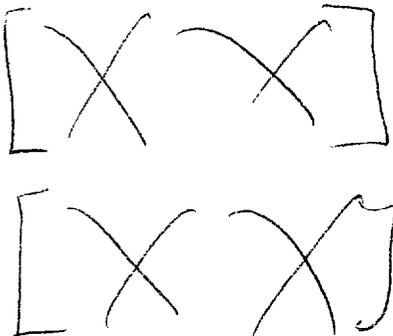
Within fifteen (15) working days of your receipt of this letter, please notify this office in writing of the specific steps you will take to correct the noted violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed. Your reply should be directed to the attention of Ms. Shelly L. Maifarth, Compliance Officer, at the above letterhead address.

Sincerely,



Janis V. Halvorsen  
Acting District Director

cc:



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