



DEPARTMENT OF HEALTH & HUMAN SERVICES

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Public Health Service
Food and Drug Administration

Dallas District
3310 Live Oak Street
Dallas, Texas 75204-6191

March 12, 1998

Ref: 98-DAL-WL-26

WARNING LETTER

**VIA FACSIMILE AND
FEDERAL EXPRESS**

Mr. Andre H. Pradzynski
Vice President
Halinco Skin Care Products, Inc.
Division of Halina Andre, Ltd.
5355 Burnet Road
Austin, TX 78767

Dear Mr. Pradzynski:

This letter is in reference to "Azelaic Acne Lotion" which is manufactured and distributed by your firm. This product is labeled for acne treatment and, according to the label, contains "Purified Water, SD-Alcohol 40A, Polysorbate-20, Allantoin, Azelaic Acid, Salicylic Acid, Chloroxylenol, Lavender Oil, Chlorophyllin" as ingredients. This product is labeled for over-the-counter (OTC) sale.

The labeling (label and promotional brochures) for this product bears claims for the treatment of acne. The label claims that this product ". . . helps control acne symptoms by peeling, reducing oiliness and inhibiting proliferation of *propionibacterium acnes*" and "Azelaic Acid has been shown to inhibit follicular keratinization which prevents formation of acne lesions." These claims make this product a drug [Section 201(g) of the Federal Food, Drug and Cosmetic Act (the Act)].

Over-the-counter (OTC) acne drug products are subject to final regulations (Title 21 Code of Federal Regulations (21 CFR), Part 333.301) which became effective on August 16, 1992. As labeled and formulated, this product fails to meet all the requirements of the final OTC monograph.

Although the active ingredients in this product are not specifically identified on the product label, labeling distributed with this product promotes azelaic acid for acne treatment. Azelaic acid is not permitted under the regulations in an OTC acne product. Coupled with the use of the trade name "Azelaic Acne Lotion," these labeling claims

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make the product a "new drug" (as described in Section 201(p) of the Act) which may not be legally marketed in the United States without an approved New Drug Application (Section 505).

In addition to the violations noted above, the product is misbranded (Section 502 of the Act) for failure to fully comply with the final regulations covering topical acne products under 21 CFR § 333.301. The labeling fails to bear a statement of identity, indications, adequate directions for use, and warning statements required by the monograph (21 CFR § 333.350 et seq.) and fails to distinguish active ingredients as required by 21 CFR §201.10 (c) (4).

During an inspection of your manufacturing facility conducted on January 14 through 20, 1998, our investigators documented deviations from the Current Good Manufacturing Practice Regulations (21 CFR, Parts 210 and 211). These deviations cause your "Azelaic Acne Lotion" to be adulterated within the meaning of Section 501(a)(2)(B) of the Act. For example:

- (1) Failure to conduct finished drug product testing on each batch of "Azelaic Acne Lotion" to assure conformance with final specifications [Part 211.165(a)]. For example, tests including the identity and strength of each active ingredient are not performed.
- (2) Failure to sample and test or examine each lot of components, drug product containers and closures prior to release for use [Part 211.84].
- (3) Failure to maintain a written stability testing program and conduct stability studies of drug products [Part 211.166].
- (4) "Azelaic Acne Lotion" fails to bear an expiration date [Part 211.137].
- (5) Failure to maintain reserve samples of drug products [Part 211.170].
- (6) Failure to maintain batch records for "Azelaic Acne Lotion" batch numbers 380, 387 and 401 [Part 211.180].
- (7) Failure to include all required information in batch records [Part 211.188]. For example, records for "Azelaic Acne Lotion" batch numbers 345, 390, 419, 450 and 745 failed to include:
 - (a) the identity of major equipment used [Part 211.188(b)(2)];
 - (b) records of inspection in the packaging and labeling area [Part 211.188(b)(6)];

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- (c) a statement of percentage of theoretical yield [Part 211.188(b)(7)];
 - (d) labeling control records [Part 211.188(b)(8)]; and
 - (e) a description of the drug product containers and closures [Part 211.188(b)(9)].
- (8) Failure to reconcile labels used in the manufacture of drug products [Part 211.125(c)].
- (9) Failure to maintain written procedures for the manufacture and distribution of drug products including:
- (a) procedures for the control of components, drug product containers and closures prior to release for use [Part 211.80];
 - (b) procedures to control labeling [Part 211.125(f)];
 - (c) for complaint handling [Part 211.198(a)];
 - (d) for distribution [Part 211.142];
 - (e) for warehousing [Part 211.150]; and
 - (f) for reprocessing [Part 211.115(a)].

The above list of violations is not meant to be an all-inclusive list of deficiencies by your firm. It is your responsibility to ensure that all drug products manufactured and distributed by your firm are in compliance with the Act. Federal agencies are advised of 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 action immediately to correct these violations. Failure to do so may result in regulatory action without further notice. This action may include seizure and/or injunction.

Please respond to this office in writing within 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 prevent recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which corrections will be completed.

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Your reply should be addressed to the Food and Drug Administration, Dallas District,
3310 Live Oak Street, Dallas, Texas 75204, Attn: James Austin Templer, Compliance
Officer, telephone number (214) 655-5317 extension 337.

Sincerely yours,

A handwritten signature in cursive script that reads "Joseph R. Baca".

Joseph R. Baca
Dallas District Director