



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

June 26, 1997

Ref: 97-DAL-WL-31

WARNING LETTER

FEDERAL EXPRESS

Ms. Edna M. Hennessee
Chair of the Board
Cosmetic Specialty Labs, Inc.
210 SW Texas Ave.
Lawton, Oklahoma 73502

Dear Ms. Hennessee:

During an inspection of your facility on the dates of March 4/27, May 19, and June 5, 1997, a Food and Drug Administration (FDA) investigator documented deviations from the Current Good Manufacturing Practice Regulations (Title 21, Code of Federal Regulations, Parts 210 and 211). The deviations cause your drug products to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act) as follows:

Failure to conduct laboratory determination of conformance to final specifications for any drug product, including the identity and strength of each active drug ingredient.

Failure to have documentation of laboratory determination of microbial analysis of drugs required to be free of objectionable microorganisms.

Failure to validate the microbial control procedures, equipment, and test methods utilized for drugs required to be free of microbial contamination.

Failure to have a reliable and meaningful test method for determining stability data for establishing appropriate storage conditions and expiration dating of drugs.

Failure to establish specifications for sampling, testing, approval, or rejection of components and drug product containers and closures prior to use in drug production.

Failure to establish the reliability of supplier analyses on components accepted for drug use on vendor certificates of quality.

Failure of Production Batch Sheets to include complete information, including the documentation of significant steps in manufacturing, relating to the production and control of each batch of drug product.

Failure to establish written procedures for the receipt, identification, storage, sampling, testing and approval or rejection of drug components.

Failure to establish written procedures for production and process control designed to assure that drug products have the identity, strength, quality, and purity they purport or are represented to possess.

Failure to establish written procedures designed to assure batch uniformity which describe in-process controls, tests, and examinations to be conducted on appropriate samples of each drug batch.

Failure to establish written procedures designed to prevent objectionable microorganisms in drug products required to be free of objectionable microorganisms.

Failure to establish written procedures describing the handling of drug product complaints.

The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure adherence with each requirement of the Good Manufacturing Practice Regulations. Federal agencies are advised of the issuance of all warning letters about drugs so that they may take this information into account when considering the award of contracts.

You should take prompt action to correct these deviations. I acknowledge the corrections initiated during the inspection in the development and improvement of control records for active ingredient inventory control and microbial control and testing, as well as your development of a Quality System Policy Manual. This office is appreciative of your interest in attaining full compliance. Failure to promptly correct all deviations from the regulations may result in regulatory action without further notice. Possible actions include seizure and/or injunction.

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

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corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which corrections will be completed. Please direct your response to James R. Lahar, Compliance Officer at the above address.

Sincerely,



Joseph R. Baca
Dallas District Director

JRE:JRL