



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

M 52537

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

March 12, 2001

Ref: 2001-DAL-WL-10

WARNING LETTER

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Paige Upton, President
Aromatique
Highway 25 B North
Heber Springs, Arkansas 72543

Dear Mr. Upton:

On January 25 through 31, 2001, an FDA investigator conducted an establishment inspection of your drug and cosmetic manufacturing firm, United Labs, Inc., 220 South Woods, West Memphis, Arkansas. The investigator determined that your firm manufactures prescription dental caries preventatives "SF 5000 Plus" containing sodium fluoride in gel and cream form for Cypress Pharmaceutical, Inc., Madison, Mississippi. United Labs, Inc. also manufactures an OTC diaper rash ointment and an external analgesic product.

These products meet the definition of drugs under Section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act). During the inspection, the investigator documented significant deviations from the Current Good Manufacturing Practices for Finished Pharmaceuticals -Title 21, Code of Federal Regulations, Parts 210 and 211 (CGMPs). Pursuant to Section 501(a)(2)(B) of the Act, a drug is adulterated if the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practices to assure that such drug meets the requirements of the Act as to safety and has the identity and strength, and meets the quality and purity characteristic, which it purports or is represented to possess.

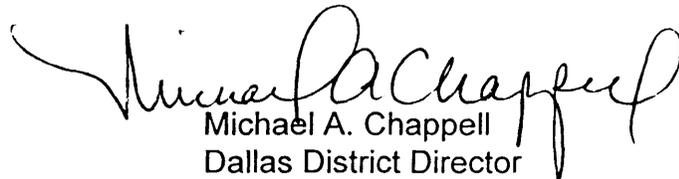
The investigator issued a List of Inspectional Observations (Form FDA 483) to Dr. John R. Spotts, Vice President and General Manager, at the conclusion of the inspection. A copy of the FDA 483 is attached for your information, and identifies many production, process, and operational control deficiencies causing the drug products manufactured by your firm to be adulterated. For example, during the review of production records, the investigator determined that the production batch size of SF 5000 Plus, lot# 1600 was 64% of the theoretical yield for the batch. No documentation exists showing any efforts by your firm to determine the reason for the product loss.

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The observations listed on the FDA 483 are not intended to be an all-inclusive list of the violations and deficiencies that may exist at your firm. Any person responsible for the failure to comply with the regulations, and for the adulteration of a drug, may be subject to regulatory action. It is your responsibility to ensure all requirements of the Act and regulations promulgated thereunder, are being met. 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 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 corrective actions cannot be completed within 15 working days, state the reason for the delay and the time within which corrections will be completed. Failure to promptly correct these deviations may result in enforcement action being initiated without further notice. Possible actions include seizure and/or injunction. Please direct your response to James R. Lahar, Compliance Officer at the above address.

Sincerely,



Michael A. Chappell
Dallas District Director

MAC:jrl

Enclosure: FDA-483

cc: Mr. Max Draughn, President & CEO
Cypress Pharmaceuticals, Inc.
135 Industrial Blvd.
Madison, Mississippi 39110