



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

g1226d

May 01, 2001

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

Ref: 2001-DAL-WL-19

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Bill Coats, CEO and President
COATS Aloe International, Inc.
2146 Merritt Drive
Garland, Texas 75041-6135

Dear Mr. Coats:

During an inspection of your drug and cosmetic manufacturing facility located in Garland, Texas, conducted on March 12-21, 2001, our investigator documented deviations from the Current Good Manufacturing Practice Regulations for Finished Pharmaceuticals (Title 21, Code of Federal Regulations, Parts 210 & 211). These 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. Examples include:

- Failure to establish a Quality Control Unit with the responsibility and authority to review, approve, and reject all activities pertaining to drug products, their manufacturing, processing, packing, holding, and release for distribution [21 CFR 211.22(a)]. For example, there is no identified individual who has ultimate or designated authority for review and approval of procedures, batch records, annual product reviews, complaint reviews and investigations, and components.
- Failure to provide adequate laboratory facilities for testing and approval or rejection of drug components, containers, closures, packaging, in-process materials, and finished products [21 CFR 211.22(b)]. For example, there is no testing equipment to perform analyses for [REDACTED] of your raw ingredient components including active ingredients such as hydrocortisone and benzoyl peroxide. Components are accepted based on their certificate of analyses and vendor audits are not conducted.
- Failure to adequately validate the manufacturing processes for your drug products [21 CFR 211.110(a)]. For example, there is no manufacturing

process validation in place for drug products and the associated equipment utilized in drug manufacturing. The same equipment is used to manufacture hydrocortisone and benzoyl peroxide drug products.

- Failure to adequately validate the cleaning processes for your drug products [21 CFR 211.67]. For example, there is no cleaning validation in place for drug products and the associated equipment utilized in drug manufacturing. The same equipment is used to manufacture hydrocortisone and benzoyl peroxide drug products.
- Failure to determine a need for an investigation and failure to conduct investigations into complaints that pertain to released drug products [21 CFR 211.198]. For example, there is no complaint evaluation to determine quality problems nor are the individuals taking these complaints trained to evaluate complaints that may indicate quality problems.
- Failure to adequately train management and operational personnel engaged in the manufacture, processing, packing, or holding of drug products [21 CFR 211.25]. For example, management personnel responsible for overseeing manufacturing and testing of drug products have not received current Good Manufacturing Practices [CGMP] training. There are no records to demonstrate that approximately [REDACTED] employees hired within the past [REDACTED] months to perform drug manufacturing activities have received CGMP training in their associated areas of responsibility.
- Failure to reject drug products not meeting established specifications [21 CFR 211.165(f)]. For example, Natural Sun Protection SPF 30+ with Lot numbers 3744, 3856, and 4183 and Hydrocortisone cream with Lot number 3010 failed established specifications for viscosity testing and were released for distribution.
- Failure to identify and control quarantined products and components [21 CFR 211.82]. For example, raw materials and finished products under quarantine are stored in a common area and are not always identified as to their status.
- Failure to protect against external factors that can cause deterioration or contamination of drug products [21 CFR 211.94(b)]. For example, in process materials are stored for undetermined periods of time in which they are loosely covered with a plastic sheet or cellophane type material.
- Failure to establish and maintain a stability testing program [21 CFR 211.166]. For example, there is no stability data to support the two (2) year expiration dates for benzoyl peroxide and hydrocortisone products.

The above deviations are 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 involving drugs, so that they may take this information into account when considering the award of contracts. Additionally, NDA, ANDA, or export approval requests may not be approved until the above deviations are corrected.

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We are aware of your firm's agreement to correct various deficiencies documented during the inspection and have reviewed your firm's written response dated April 16, 2001. We continue to find the response insufficient in that criteria are not outlined that describe the education and expertise that will be required for the Quality Control Director, nor is a projected date given for hiring an individual for this position. The revised Complaint Form does not describe investigations that would be required or the investigational procedures to be followed. The evaluation and testing of retention samples, where appropriate, is not indicated, nor is there a provision for follow-up and closure with the complainant. Additional information is needed to describe the residual testing procedures. It is not specified whether residual testing is for detergents, sanitizing agents, or product residuals. Detailed information regarding raw materials to be tested using the new laboratory equipment is not provided. Plans for vendor testing of those components that your firm is not able to test in-house are not provided. The rationale for the [REDACTED] timeframe and bioburden determinations to demonstrate the negative impact of raw materials that are subject to this [REDACTED] timeframe is not explained. An improvement to the practice of covering in-process materials with a loose plastic covering is not outlined. Details for the proposed stability program were not included.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. Possible actions include seizure and/or injunction.

Please 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 deviations and to prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed. Your reply should be sent to the Food and Drug Administration, Dallas District Office, Attention: Brenda C. Baumert, Compliance Officer, at the above letterhead address.

Sincerely,



Michael A. Chappell
Dallas District Director

MAC: bcb

Enclosure