



DEPARTMENT OF HEALTH AND HUMAN SERVICES

94522d

Food and Drug Administration  
Los Angeles District  
Pacific Region  
19701 Fairchild  
Irvine, CA 92612-2445

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**WARNING LETTER**

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

February 2, 2004

W/L 24-04

Jerry R. Alcorn, President/Owner  
Almil Nutritional Products, Inc.  
570 West Lambert Road G  
Brea, CA 92821

Dear Mr. Alcorn:

During our inspection of your Brea, California drug manufacturing firm on August 27, 28 and September 4, 2003 our investigators documented serious deviations from the Current Good Manufacturing Practice Regulations (CGMPs) found in Title 21 of the Code of Federal Regulations, parts 210 & 211 (21 CFR 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 (the Act). In addition, some of your products (see below) are misbranded within the meaning of Sections 502(a) and 502(c) of the Act.

There were deficiencies in your quality control unit:

1. Your firm has not established an adequate quality control unit [ref. 21 CFR 211.22(a)]. For example, your firm's quality control unit fails to review and approve all drug component test records.

There were deficiencies in your production and process controls:

2. Your firm has failed to establish adequate 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 [ref. 21 CFR 211. 100(a)]. Specifically,

Your process validations of Cheralene Child Cough Syrup, Benzalkonium Chloride Solution, 0.13%, and Rhumagesic Rub, Methyl Salicylate 3% products were incomplete and lacked conclusions and final acceptance. [REDACTED]

Changes were made to the Cheralene Child Cough Syrup master formula without stating the reasons for the change or assessing the need for revalidation.

3. Deviations from written procedures for production and process control were made without any documented justification [ref. 21 CFR 211.100(b)]. For example, deviations from your manufacturing procedure for Cheralene Child Cough Syrup lot # 6563 were made without documented justification when you changed deionized water quantities and temperatures in steps #2 and #15 of the weighing/compounding procedure.
4. There were no written procedures established that describe the in-process controls, tests, and examinations to be conducted on appropriate samples of in-process materials of each batch [ref. 21 CFR 211.110(a)]. [REDACTED] Specifically, your firm lacked written procedures to describe in-process testing requirements for the following OTC drug products:

Cheralene Child Cough  
Syrup  
Robelene DM Cough Syrup  
Robelene (Guaifenessin) Cough Syrup  
Hydrocortisone Acetate 1% Cream  
Foot Fungus, Undecylenic Acid 10% and Clotrimazole 1%  
Athlete's Foot Solution, Undecylenic Acid 10%  
Rhumagesic Rub, methyl salicylate 3%  
Benzalkonium Chloride Solution, 0.13%

There were deficiencies in your laboratory controls:

5. Your firm has failed to establish and follow an adequate written testing program to assess the stability of your drug products [ ref. 21 CFR 211.166(a) ]. Specifically,

Stability testing was not performed at all scheduled times. [REDACTED]

[REDACTED] For example,

Cheralene-Child Cough Syrup (Guaifenessin/Dextromethorphan) - [REDACTED] months test/lot # 5933; [REDACTED] months test/lot # 5848

Robelene Cough Syrup (Guaifenessin) - [REDACTED] and [REDACTED] months test/lot # 5642

Robelene DM Cough Syrup (Guaifenessin/Dextromethorphan) - [REDACTED] months test/lot # 5512; 24 months test/lot # 5650

Rhumagesic Rub, Methyl Salicylate 3% - [REDACTED] months test/lot # 5292 and 5390; [REDACTED] and [REDACTED] months tests/lot # 5473

Preservatives used in your products had not been shown to be effective. Specifically, preservative effectiveness testing (PET) had not been performed on some products and preservative analysis was not performed during stability testing. For example,

Cheralene Child Cough Syrup – PET not conducted  
Robelene DM Cough Syrup and Robelene Cough (Guaifenesin) Syrup - no preservative testing performed during stability testing

6. Annual visual examinations of reserve samples of your manufactured drug products were not performed [ref. 21 CFR 211.170(b)].

There were deficiencies in the control of components and drug product containers and closures:

7. The identity of each component of a drug product is not verified by conducting at least one test to verify the identity, using specific identity tests if they exist [ref. 21 CFR 211.84(d)].

Specifically, your firm did not conduct identity testing on all inactive ingredients of your manufactured drug products.

8. Reports of analysis from component suppliers are accepted, in lieu of testing each component for conformity with all appropriate written specifications, without establishing the reliability of the supplier's analyses through appropriate validation of the supplier's test results at appropriate intervals [21 CFR 211.84(d)].

There were deficiencies in establishing the appropriateness of equipment used in the manufacture, processing, packing, or holding of drug products:

9. Equipment used to manufacture, process, pack, or hold drugs had not been validated [21 CFR 211.63]. Specifically, the water system; Tanks #1,2,3,4; filling machines for tablets and capsules; filling machines for liquids and creams; and labeling machines have not been validated. Furthermore, your firm lacks a water system validation protocol.

10. There was no cleaning validation for tanks #2, 3, 4. Furthermore, written procedures lacked sufficient detail for the cleaning and cleaning validation of tanks #1, 2, 3, 4 [ref. 21 CFR 211.67(a) & (b)].

There were deficiencies in your records and reports:

11. Written procedures were not established and followed for evaluations done at least annually including provisions for a review of complaints, recalls, returned or salvaged drug products, and investigations conducted for each drug product. Specifically, your firm does not have a written procedure for annual product reviews. Your firm's annual review record lacked a list of products reviewed, lot numbers of products reviewed, complaints, recalls, returns, salvages, and investigations of any drug product [ref. 21 CFR 211.180(e)].

There were deficiencies in the holding and distribution of your drug products:

12. The thermometer used to monitor temperature in finished drug product storage areas was not calibrated [ref. 21 CFR 211.142(b)].

Furthermore, during the inspection, labels were collected for the following over-the-counter (OTC) drug products manufactured by your firm: Cortacilina Hydrocortisone Acetate Cream 1%, Athletes Foot Solution, Robilene Cough Formula, Robilene DM Cough Syrup, Cheralene Cough Syrup, Gastrisan Antacid Dietary Supplement, Uni-San Antifungal Lotion, Frotacion Milagrosa External Analgesic, Rhumagesic Rub, and Merthiolate First Aid Antiseptic. A review of those labels reveals several violations as described below.

The labels for Athlete's Foot Solution, Robelene Cough Formula, Robelene DM Cough Syrup, and Cheralene Cough Syrup lack the required labeling in the standard format established by regulation at 21 CFR § 201.66 (also known as Drug Facts). These products are, therefore misbranded in violation of section 502(c) of the Federal Food, Drug, and Cosmetic Act because their labeling fails to declare required information prominently and conspicuously on the outside container or wrapper of the products' packaging.

The labels for Frotacion Milagrosa and Uni-San Antifungal lotion include statements in Spanish. These products are therefore misbranded under section 502(a) of the Act because not all of the required label statements appear in this foreign language as required by 21 CFR § 201.15(c)(2).

The above-described violations are not intended to be an all-inclusive list of those existing at your firm. It is your responsibility to ensure that all requirements of the Act and promulgated regulations are being met. Adulterated or misbranded drugs may not be legally marketed in interstate commerce.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. Such action includes, but is not limited to, seizure and/or injunction. 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.

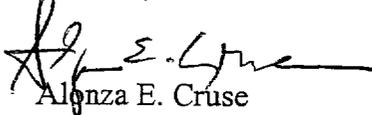
You should also notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you plan to take to assure that each of the noted violations will be corrected. Your response should also include an explanation of the specific steps that will be taken to prevent the recurrence of similar violations. Because of the repetition of similar deficiencies from previous inspections, we request that you meet with us here at the District Office to discuss your corrective actions. Please call John J. Stamp, Compliance Officer, at 949/608-4464 to arrange an appointment.

Letter to Jerry R. Alcorn, Almil Nutritional Products, Inc.  
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Your written reply should be addressed to:

Dannie Rowland, Acting Director of Compliance  
U.S. Food and Drug Administration  
19701 Fairchild  
Irvine, CA 92612

Sincerely,

  
Alonza E. Cruse  
District Director

cc: California Department of Health Services, Food & Drug Branch  
601 N. 7<sup>th</sup> Street  
Sacramento, California 94234-7320  
Attn: Jim Waddell, Chief