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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

CFN 1110584
CFN 1120199

Baltimore District
900 Madison Avenue
Baltimore, Maryland 21201
Telephone: (410) 962-4040

October 14, 1997

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Robert Essner, President
Wyeth-Ayerst Laboratories, Inc.
Division of American Home Products Corporation
555 East Lancaster Avenue
St. Davids, Pennsylvania 19087

Dear Mr. Essner:

The Food and Drug Administration (FDA) conducted inspections of your A. H. Robins Company facilities at 1407 Cummings Drive and 2248-2300 Darbytown Road, Richmond, Virginia, on September 9 through 19, 1997, and September 17 through 19, 1997, respectively. During the inspections, our investigators documented deviations from the Current Good Manufacturing Practice Regulations (Title 21, Code of Federal Regulations, Parts 210 & 211).

The deviations at the Cummings Drive facility that cause your drug products to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act include:

1. Failure to hold the drug product, Robaxin, Lot 165, in quarantine. It was distributed prior to its release by the quality control unit.
2. Failure to establish adequate written procedures designed to assure batch uniformity and integrity, describing in sufficient detail the in-process controls and tests or examinations to be conducted on appropriate samples of in-process materials of each batch .
3. Failure of the quality control unit to review and approve laboratory control mechanisms, such as a scientifically sound and appropriate test procedure for in-process tablet and capsule weight variation, the correct specification for in-process weight checks for Ismo tablets, and in-process limits for rejected tablets and capsules.
4. Failure to calibrate various quality assurance or laboratory testing equipment used to conduct stability testing of finished dosage form drug products.

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5. Failure to establish adequate written procedures for production and process controls, designed to assure that the drug products have the identity and strength they purport or are represented to possess.
6. Failure to thoroughly investigate the failure of a batch or any of its components to meet specifications.
7. Failure of the quality control unit to follow responsibilities and procedures and to report the Out-of-Specification results for Donnatol Capsules, lot 0960419, at the [redacted] and [redacted] week test points within 24 hours to the Vice President of Quality Assurance in Radnor, Pennsylvania.
8. Failure to routinely calibrate automatic, mechanical, or electrical equipment according to a written program designed to assure proper performance.

The deviations at the Darbytown Road facility that cause your drug products to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act include:

1. Failure to identify all relevant quality control criteria to support the distribution of Dimetane DX Cough Syrup that failed to meet specifications for alcohol content.
2. Failure to establish adequate written procedures designed to assure batch uniformity and integrity, describing in sufficient detail the in-process controls and tests or examinations to be conducted on appropriate samples of in-process materials of each batch of Dimetane DX Cough Syrup.
3. Failure to establish time limits for the completion of each phase of production to assure the quality of Dimetane DX Cough Syrup.
4. Failure to calibrate at suitable intervals, in accordance with an established written program, in-process instruments, apparatus, gauges, and recording devices, such as the [redacted] scale and a pressure gauge used for burst testing on line 10.
5. Failure to have appropriate documentation that each significant step in the manufacture, processing, packing, or holding of the batch was accomplished, including: specific identification of each batch of component or in-process material used; the testing of in-process materials; the holding of in-process materials and components at specific temperatures; and weights and measures of components used in the course of processing.

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6. Failure to maintain records of the production and packaging of 63,113 tubes of Chap Stick SPF 30, Lot #41.

At the conclusion of each inspection, a written list of inspectional observations (FDA-483, enclosed) was issued to Mr. Michael L. Berg, Managing Director.

The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facilities. It is your responsibility to assure that your establishments are in compliance with all requirements of the federal regulations.

We acknowledge that Mr. Michael L. Berg, Managing Director, and Mr. Scott Blary, Director of QA/GMP, have submitted to this office a response concerning our investigators' observations noted on the Forms FDA-483. It appears that your response is adequate. Follow-up inspections will be required, however, to assure that corrections have been implemented and are adequate.

Until it has been determined that corrections are adequate, 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. Additionally, pending Antibiotic Form 6, NDA, ANDA, or export approval requests may not be approved until the aforementioned violations are corrected.

You should take prompt action to correct these deviations. Failure to do so may result in regulatory action without further notice, such as seizure and/or injunction.

You should notify this office in writing, within 15 working days of receipt of this letter, of any additional steps you have taken, since your response to the FDA-483s, to correct the noted violations and to prevent their recurrence. If corrective action cannot be completed within the time frames specified in your response, 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, Richmond Resident Post, 10710 Midlothian Turnpike, Suite 424, Richmond, Virginia 23235, to the attention of Scott J. MacIntire, Compliance Officer. Mr. MacIntire can be reached at (804) 379-1627, extension 14.

Sincerely,



Loveen M. Beck

Acting Director, Baltimore District

Enclosures

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cc: Mr. Michael L. Berg, Managing Director
Mr. Scott Blary, Director, QA/GMP
A.H. Robins Co., Inc.
1407 Cummings Drive
Richmond, Virginia 23220