



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

m4190 n
Food and Drug Administration
New Orleans District Office
6600 Plaza Drive, Suite 400
New Orleans, LA 70127

September 14, 2000

CERTIFIED-RETURN RECEIPT REQUESTED

*Received
9/14/00
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Mr. Earnie W. Davenport, Jr.
Chairman and Chief Executive Officer
Eastman Chemical Company
Eastman Road
Kingsport, TN 37762

WARNING LETTER - 00-NSV-25

Dear Mr. Davenport:

During an inspection of your facility located in Kingsport, Tennessee on August 9-11 and 17, 2000, our investigator determined that your product, ~~XXXXXXXXXX~~, a bulk pharmaceutical chemical, is adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug and Cosmetic Act (the Act). Section 501(a)(2)(B) of the Act requires that all drugs be manufactured, processed, packaged, and held in accordance with CGMP. No distinction is made between bulk pharmaceutical chemicals (your ~~XXXXXXXXXX~~) and finished pharmaceuticals and failure of either to comply with CGMP constitutes a failure to comply with the requirements of the Act.

Our inspection revealed the following deviations from CGMP: failure to coordinate change control programs for different departments, incomplete batch production records, inadequate analytical method validation and procedures, no validation summary of the lots manufactured during February 2000 as required by the protocol, your quality assurance department does not have the authority to reject a lot of product, inadequate stability testing program and incomplete process validation protocols.

The above identification of violations is not intended to be an all-inclusive list of deficiencies. It is your responsibility to ensure adherence to each requirement of the Good Manufacturing Practice regulations. Until the violations are completed, federal agencies will be informed that FDA recommends against the award of contracts for the affected products.

Eastman Chemical Company

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

Please notify this office in writing within fifteen (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 action cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be addressed to the attention of Joseph E. Hayes, Compliance Officer, Food and Drug Administration, 297 Plus Park Boulevard, Nashville, Tennessee 37217.

Sincerely,


Carl E. Draper, Director
New Orleans District

CED/k1

Enclosure: 21 CFR Parts 210 and 211