



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Nashville District Office
297 Plus Park Blvd.
Nashville, TN 37217

Purged

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09/08/99

September 3, 1999

CERTIFIED-RETURN RECEIPT REQUESTED

Dr. Edward A. Tyczkowski
President
Flura Corporation
610 Rock Hill Road
Newport, TN 37821

WARNING LETTER-99-NSV-22

Dear Dr. Tyczkowski:

During an inspection of your facility located in Newport, Tennessee, on August 3-5, 1999, 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). Although the Current Good Manufacturing Practice (CGMP) regulations under Title 21, Code of Federal Regulations, Parts 210 and 211, apply only to finished dosage form drugs, Section 501(a)(2)(B) of the Act requires that all drugs be manufactured, processed, packed, 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: inadequate process validation, failure to always follow manufacturing and analytical procedures, no impurity or contaminant data, no stability information, incomplete batch records, no analytical procedure validation and incomplete component specifications.

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 corrected, federal agencies will be informed that FDA recommends against the award of contracts for the affected product.

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.

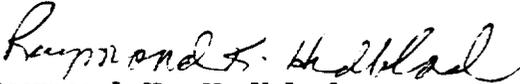
Dr. Edward A. Tyczkowski - Page 2

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,


Raymond K. Hedblad
Director, Nashville District

RKH/kl

Enclosure:

21 CFR Parts 210 and 211