



DEPARTMENT OF HEALTH AND HUMAN SERVICES

HFE 35 (purged)

Public Health Service

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

December 20, 2000

SENT VIA FEDERAL EXPRESS

Mr. John Scansaroli, President
Elcat Company
163 Washington Valley Road
Suite 101
Warren, New Jersey 07059

Warning Letter - 01-NSV-09

Dear Mr. Scansaroli:

During an inspection of your facility, Chattem Chemicals, Inc., located at 3801 St. Elmo Avenue, Chattanooga, Tennessee on November 14-17, 27-30 and December 1, 2000, our investigator determined that your product, Methamphetamine Hydrochloride, and other active pharmaceutical ingredients noted on the enclosed FDA 483 are 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 Current Good Manufacturing Practice (CGMP). No distinction is made between active pharmaceutical ingredients 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 concepts: inadequate validation of the manufacturing process, incomplete batch records, inadequate cleaning procedure validation, deficient master label files, incomplete standard operating procedures, inadequate calibration of laboratory equipment, incomplete annual reviews, deficient reverse osmosis water system controls, and inadequate raw material control procedures.

The above violations are not intended to be an all-inclusive list. It is your responsibility to assure compliance with Current Good Manufacturing Practice principles. Until the deficiencies are corrected and the corrections verified, federal agencies will be informed that FDA recommends against the award of contracts for the affected products.

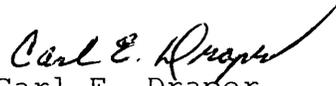
You should take prompt action to correct these deviations. Failure to make prompt correction may result in regulatory action, including seizure and/or injunction, without further notice.

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 Administer, 297 Plus Park Boulevard, Nashville, Tennessee 37217.

Sincerely,


Carl E. Draper
Director
New Orleans District

CED/kl

Enclosures:

FDA 483
21 CFR Parts 210 and 211
Guidance to Inspections of Bulk Pharmaceutical Chemicals (May 1994)

cc: James H. Kedrowski
Vice President/Site Manager
Chattem Chemicals, Inc.
3801 St. Elmo Avenue
Chattanooga, TN 37409