



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Central Region

*m20201*

Telephone (973) 526-6002

April 4, 2000

Food and Drug Administration  
Waterview Corporate Center  
10 Waterview Blvd., 3rd Floor  
Parsippany, NJ 07054

**WARNING LETTER**

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

Paul Iacono, President  
Certified Processing Corp.  
184 Route 22 East  
Hillside, New Jersey 07205

**FILE NO.: 00-NWJ-27**

Dear Mr. Iacono:

This letter concerns FDA inspection of your active pharmaceutical ingredient manufacturing facility located at 184 Route 22 East, Hillside, N.J., from December 27 - 30, 1999. During the inspection our investigators documented significant deviations from Current Good Manufacturing Practices (CGMPs) in the manufacture of Caffeine USP, an active pharmaceutical ingredient (API).

These deviations cause the API produced to be 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 drugs be manufactured, processed, packed, and held in accordance with CGMPs. No distinction is made between active pharmaceutical ingredients and finished pharmaceuticals, and failure of either to comply with the CGMPs constitutes a failure to comply with the requirements of the Act.

The significant observations are as follows:

1. Failure to have a quality control unit.
2. Failure to validate the manufacturing process for the drug product Caffeine USP. Additionally, the firm has no validation plan in place that identifies and evaluates the processing steps, operating ranges, critical processing parameters, required equipment, sampling and testing data to be collected.



- e) The laboratory hood is not certified.
  - f) Laboratory equipment maintenance logbooks are not maintained.
  - g) The laboratory bench, sample jars, and equipment were dirty. They were covered with a white powdery material.
7. Production controls for Caffeine USP are inadequate. For example:
- a) Filter changes for the 30 inch, 24 inch, and 18 inch filter presses are not documented.
  - b) There is no calibration program for the critical production monitoring devices.
  - c) All equipment maintenance and repairs are not documented.
8. The production records for Caffeine USP are inadequate. For example:
- a) Mixing times are not documented for crude and semi-refined Caffeine mixing steps. Also, tank temperatures are not documented during semi-refined Caffeine heating operations.
  - b) Production flow rates for filtration of crude and semi-refined Caffeine are not documented.
  - c) Centrifuge speeds and times for crude and semi-refined Caffeine are not documented.
9. The firm has no written procedures for complaint handling, recall operations, change control, equipment maintenance and calibration, product failure investigations, and reprocessing of batches.
10. Failure to perform an investigation regarding two complaints for foreign particles in Caffeine USP, lot #2-452 and #2-455. The complaints reported that lot #2-452 contained "wood-like" particles and lot #2-455 contained "burnt" particles in the Caffeine product.
11. There is no established GMP training program for the firm's employees.

Certified Processing Corp.  
Warning Letter  
Page 4

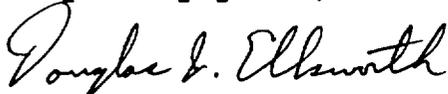
The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure adherence with the requirements of the Act. Failure to comply with CGMP constitutes a failure to comply with the requirements of the Act. We request that you take prompt action to correct any noted violations. Failure to correct these violations may result in regulatory action without further notice. This includes seizure and injunction.

Federal agencies are advised of the issuance of all Warning Letters regarding drugs and devices so that they may take this information into account when considering the award of contracts. Additionally, new drug applications (NDAs), abbreviated new drug applications (ANDAs) or export approval requests may not be approved until the aforementioned CGMP violations are corrected.

You should notify this office in writing within 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 15 working days, 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, New Jersey District Office, 10 Waterview Blvd, 3rd Floor, Parsippany, New Jersey 07054, Attention: Andrew Ciaccia, Compliance Officer.

Very truly yours,



DOUGLAS I. ELLSWORTH  
District Director  
New Jersey District Office

AC:slm