



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

Telephone (201) 331-2904

November 15, 1996

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Douglas G. Watson, CEO
Ciba-Geigy Corporation
520 White Plains Road
Tarrytown, New York 10591

FILE NO.: 97-NWJ-05

Dear Mr. Watson:

This is regarding an inspection of your facility located at 556 Morris Avenue, Summit, New Jersey by the U.S. Food and Drug Administration between the dates of September 24 and October 23, 1996. During the inspection our investigators documented serious deviations from the current good manufacturing practice regulations (Title 21, Code of Federal Regulations, Part 210 and 211) in conjunction with your firm's manufacture of prescription drugs.

These deviations were presented to your firm's attention on an FD-483 List of Observations at the close of the inspection on October 23, 1996. The CGMP deficiencies cause your products to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act.

The significant observations are as follows:

1. The validation for the Transdermal Nitroglycerin 0.2 mg/hr and 0.4 mg/hr is inadequate in that a high percentage of rejected batches experienced in the 0-6 hour Nitroglycerin release rate. For example, in 1995 six (6) batches of Transdermal Nitroglycerin 0.2 mg/hr out of [redacted] batches produced [redacted] and seven (7) batches of the 0.4 mg/hr out of [redacted] batches [redacted] were rejected for high release rate at the 0-6 hours; and January 1996 through October 1996 a total of three (3) batches of 0.4 mg/hr out of [redacted] batches produced [redacted] has been rejected for high rate release at the 0-6 hours.
2. The product development data for Transderm-Nitro 0.2 mg/hr and 0.4 mg/hr was not available during the inspection to show that the number of samples taken and tests performed on incoming EVA film batches are representative of critical component parameters required in the manufacturing process.

3. The validation of the Purified Water System used for the manufacture of Ritalin HCl bulk drug substance had not been initiated and the Validation Protocol had not been approved as of October 3, 1996.
4. [REDACTED] did not include an acceptance criteria for samples taken to assure that analysts performing sterility testing do not contribute microbial contamination to the test.
5. There were no alert or action limits for environmental monitoring samples taken before and/or after sterility testing.
6. There was no documentation of any action or follow up conducted by the firm as a result of their monthly environmental monitoring of the sterile test and gowning areas. The results of the March 1996 monitoring data revealed [REDACTED] CFU observed on a sedimentation plate in the gowning area. This exceeded the action limit of [REDACTED] CFU.

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 each requirement of the good manufacturing practices regulations.

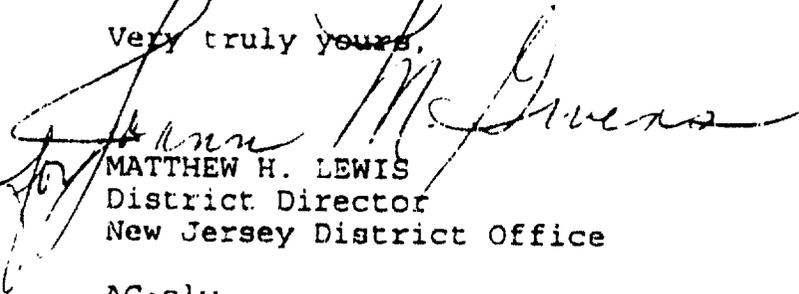
Federal agencies are advised of the issuance of all warning letters about drugs and devices so that they may take this information into account when considering the award of contracts.

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

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,



MATTHEW H. LEWIS
District Director
New Jersey District Office

AC:slw

cc: Charles Lay, President
Pharmaceutical Division
Ciba-Geigy Corporation
556 Morris Avenue
Summit, New Jersey 07901