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Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Telephone: 612-334-4100

March 6, 2001

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 01 - 37

Bruce G. Paddock
President and CEO
Paddock Laboratories, Inc.
3940 Quebec Avenue North
New Hope, Minnesota 55427

Dear Mr. Paddock:

During our inspection of your pharmaceutical drug manufacturing operation located in New Hope, MN, on December 13, 14, 18-21, 2000, and January 2-5, 10, and 17, 2001, our investigator found serious violations of the Current Good Manufacturing Practices (cGMPs) for Finished Pharmaceuticals, Title 21, Code of Federal Regulations, Part 211 (21 CFR 211). Your pharmaceutical drug products are adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug and Cosmetic Act (the Act).

The violations observed during our inspection include but are not limited to the following:

1. Failure to have laboratory controls that include the establishment of scientifically sound and appropriate specifications, standards, sampling plans, and test procedures designed to assure that components, drug product containers, closures, in-process materials, labeling, and drug products conform to appropriate standards of identity, strength, quality, and purity [21 CFR 211.160(b)] in that:
 - A.) The autoclave used to sterilize media, buffers and glassware is not shown to be reaching temperatures specified in various methods. No temperature recording device is used during autoclave cycles.
 - B.) Phosphate buffer used for dilutions does not account for loss during autoclaving to assure a volume of *~*

Page Two

Bruce G. Paddock
March 6, 2001

- C.) Incubators used in the microbiology lack temperature monitoring.
 - D.) Vacuum gauges on the vacuum ovens that are used to dry various standards for assays have not been calibrated.
2. Failure to test an adequate number of batches of each drug product to determine an appropriate expiration date [21 CFR 211.166(b)] in that:
- A.) Only one lot of bulk *~~~~* was placed in a *~~~~* stability study in the *~~~~* drums to demonstrate that an extended bulk holding time is appropriate.
 - B.) None of the process re-validation lots were put into the stability program.
3. Failure of the quality control unit to approve or reject all procedures or specifications impacting the identity, strength, quality, and purity of the drug product [21 CFR 211.22(c)] in that your quality control unit is not providing the necessary oversight in the microbiology lab. This is demonstrated by the following:
- A.) The autoclave used to sterilize media, buffers and glassware is not shown to reach temperatures specified in various methods. No temperature recording device is used during autoclave cycles.
 - B.) The phosphate buffer used for dilutions does not account for loss during autoclaving to assure a volume of *~~~~*
 - C.) The incubators used in the microbiology lack temperature monitoring.
 - D.) Vacuum gauges on the vacuum ovens that are used to dry various standards for assays have not been calibrated.

The above indication of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence with each requirement of the Good Manufacturing Practice Regulations. Federal agencies are advised of the issuance of all Warning Letters about drugs so they may take this information into account when considering the award of contracts.

You should take prompt action to correct these deviations. Please be aware that failure to promptly correct these deviations may result in regulatory action without further notice. Possible actions include seizure and/or injunction. This is official notification that the Food and Drug Administration expects all your locations to be in compliance.

Page Three

Bruce G. Paddock
March 6, 2001

You should notify this office in writing, within 5 working days of receipt of this letter, of 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 5 working days, state the reason for the delay and the time within which the corrections will be completed.

Your firm has a long history of cGMP violations and we are very concerned about the apparent lack of cGMP oversight at your facility. We believe it is prudent to meet to discuss your plans for correction and we have scheduled a meeting in our District office on March 15, 2001, at 1:00 p.m. Please be prepared to discuss your corrective action plans.

Your reply should be sent to Compliance Officer Carrie A. Hoffman at the address on the letterhead.

Sincerely,



Cheryl A. Bigham
Acting Director
Minneapolis District

CAH/ccl

