

7/2/14
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Mid-Atlantic Region D1066B

Telephone (201) 331-2904

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

January 3, 1997

WARNING LETTER

CERTIFIED MAIL

RETURN RECEIPT REQUESTED

Bharat Patel, President & CEO
Neil Laboratories, Inc.
55 Lake Drive
East Windsor, New Jersey 08520

RELEASE

REVIEWED BY AC 1/6/97
C.O.

FILE NO.: 97-NWJ-13

Dear Mr. Patel:

This is regarding an inspection of your facility located at 55 Lake Drive, East Windsor, New Jersey by the U.S. Food and Drug Administration from December 2 through December 6, 1996. During the inspection, our investigators documented serious deviations from the current good manufacturing practices regulations (Title 21, Code of Federal Regulations, Part 210 and 211) in conjunction with your firm's manufacturing of over-the-counter drug products.

These deviations were presented to your firm's attention on an FD-483 List of Observations at the close of the inspection on December 6, 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. Neil Laboratories has no validation of manufacturing processes used to produce Acetaminophen 325 mg & 500 mg tablets and 500 mg capsules, Pseudoephedrine HCl 30 mg tablets, and Actaminophen/Diphenhydramine HCl 500/25 mg caplets.
2. No impurity profile for Acetaminophen drug substance, Pseudoephedrine HCl drug substance, or Diphenhydramine HCl drug substance. Impurity levels are not analyzed upon receipt of raw materials, at the time of release of finished product or during stability.
3. The HPLC method used for chemical testing of Acetaminophen, Pseudoephedrine HCl, or Diphenhydramine HCl drug substance and finished products on stability is not adequately validated in that there is no data to show that the method can detect all impurities.

4. No equipment qualification of manufacturing or laboratory equipment used in the production and testing of Acetaminophen 325 mg & 500 mg tablets & 500 mg capsules, Pseudoephedrine HCl 500 mg tablets, and Acetaminophen/Diphenhydramine HCl 500/25 mg capsules.
5. There are no controls in the Quality Control Laboratory to assure proper maintenance and calibration of equipment. For example:
 - a). [REDACTED] drying oven was not qualified. The firm did not have a Use Log or Calibration Log of temperature devices. Also, the interior shelves and walls were rusted.
 - b) Two Vanderkamp 600 6-spindle dissolution testers have not been validated since July 17, 1995.
 - c) No record of any calibration of the pH meter.
 - d) The [REDACTED] balance has never been calibrated manually against standards.
6. Investigations are not routinely conducted or documented when laboratory or production deviations or failures occur. Examples are:
 - a) [REDACTED] of Acetaminophen 500 mg caplets was "canceled" due to hardness and capping problems. No investigation was conducted into the cause of the problem. This raw material was then used to form batch #602007 of Acetaminophen tablets, which was released on 3/5/96.
 - b) [REDACTED] of Acetaminophen 500 mg tablets was rejected due to colored spots found on the tablets before packaging. A Certificate of Analysis releasing this batch was prepared, signed, and dated 4/26/96 prior to packaging. There was no further documentation of the decision to reject the batch. There was no production or laboratory investigation into the origin or identification of the black spots.
 - c) [REDACTED] of Acetaminophen/Diphenhydramine caplets dated 7/9/96 was placed on hold after sticking problems were observed during compression. No investigation was conducted into a

7. The stability chamber used for accelerated stability studies was not qualified in that the Relative Humidity specification of [REDACTED] was exceeded by up to [REDACTED] on several occasions. There was no documentation or investigation conducted by the firm into the cause for the deviations or the effect on the samples in the chamber at that time.
8. There was no cleaning validation completed on any piece of manufacturing equipment. Samples are not collected after cleaning of equipment or between manufacturing of different products for analysis of active drug substance residues.
9. The current standard operating procedure [REDACTED], allows for the revision ingredients, specifications, and any other changes needed to bring the product into conformance. These reprocessing procedures are not validated.

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.

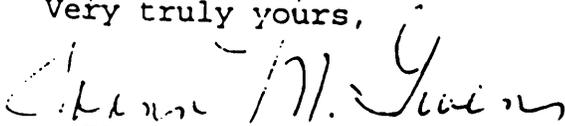
A review of your firm's history shows that you have now received a Warning Letter regarding deviations at your facility observed by our investigators during our last two FDA inspections. We request that you now come in to our office to discuss your overall plan of corrective actions and to discuss your regulatory status.

Neil Laboratories, Inc.
Warning Letter (97-NWJ-13)

January 3, 1997
Page 4

Your written 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. Please contact Mr. Ciaccia at 201-331-2904 to set up an appropriate time to come in to our office.

Very truly yours,



MATTHEW H. LEWIS.

District Director
New Jersey District Office

AC:slw