



DEPARTMENT OF HEALTH & HUMAN SERVICES

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New York District

Food & Drug Administration
158-15 Liberty Avenue
Jamaica, NY 11433

CERTIFIED RECEIPT REQUESTED

September 21, 2000

Giora Carni, President and CEO
Clay-Park Laboratories, Inc.
1700 Bathgate Ave.
Bronx, New York 10457

Ref: NYK 2000-98

Dear Mr. Carni:

An inspection of your drug manufacturing facilities located in Bronx, New York conducted by Food and Drug Administration investigators between July 6 and August 10, 2000 found significant deviations from current Good Manufacturing Practice (cGMP) regulations for Finished Pharmaceuticals (Title 21, Code of Federal Regulations, Part 211). Such deviations cause finished pharmaceuticals to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug and Cosmetic Act (the Act).

Our investigators found the following deviations:

- 1) Failure to conduct appropriate laboratory determination of satisfactory conformance to final specifications in that finished product testing was not performed on 164 batches of Prep Hem Suppositories manufactured between April 14, 1999 and July 17, 2000. [211.165].
- 2) Failure to validate the manufacturing process for the majority of over-the-counter (OTC) drug products made by your firm. [211.110(b)].
- 3) Failure to establish scientifically sound and appropriate specifications designed to assure that drug products conform to appropriate standards of identity, strength, quality, and purity in that preservative effectiveness studies, to determine the minimum effective concentration of preservatives, were not conducted on various OTC drug products [211.160(b)].
- 4) Procedures do not assure that correct labeling will be used and product mix-ups will be prevented in that there have been several recent instances of mislabeled products. For example, Muscle Rub lot AN032 was mistakenly used to fill containers labeled for Polar Heat, lot AN435; inserts for Gentamycin were used in the packaging of Triamcinolone Acetonide Cream 0.1%, lot AM 457; and jars of Analgesic Balm lot AM387 were labeled with the wrong lot number. These incidents were subsequent to your firm's November, 1999 recall of Acetaminophen Suppositories where 650 mg. suppositories were packaged into

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cartons labeled as 120 mg. [211.130].

The above is not intended to be an all-inclusive list of violations. As a manufacturer of finished pharmaceuticals, you are responsible for assuring that your overall operation and the products you manufacture and distribute are in compliance with the law.

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 violations and to establish procedures to prevent their recurrence. Failure to promptly correct these violations may result in regulatory action without further notice, such as seizure and/or injunction.

We are in receipt of your firm's August 30, 2000 written response to the observations noted on the Inspectional Observations Form FDA-483. We have the following comments:

The response to FDA-483 point 1 indicates that retain samples are being tested for each of the previously untested and released batches of Prep Hem Suppositories. We remain concerned about the Prep Hem Suppositories product in the marketplace since normal finished product testing is conducted on a larger, statistically valid sample based on batch size. What are your intentions concerning the batches still in distribution?

The response to FDA-483 point 2b includes copies of Preservative Effectiveness Tests (PET) found after the inspection and submitted as attachment five. Some of these tests were completed soon after manufacture; they provide no data to support that these levels of preservatives will be effective throughout the expiry period. For example, the PET data sheets for Preparation H Ointments batches 0695-08 (50%) and AB434 (100%) were each tested within one to two months of manufacture. There is no data indicating these preservatives are still effective at the end of the product expiration dates.

The response to FDA-483 point 3 refers to page 74, attachment 7 as a process revalidation schedule dated July, 1996. The schedule indicates that products compounded beginning January 1997 are to be revalidated based upon established criteria; these were not submitted with the response. The schedule also indicates that one batch would be revalidated every ten days; the investigators found that only 12 of the OTC products were validated since then. We agree that your firm should keep the District Office informed, through quarterly reports, as to the progress of your firm's validation efforts.

The remaining corrective actions relating to the cGMP observations, FDA-483 points 4 through 12, appear adequate and will be confirmed during a future inspection.

We request that you reply in writing within 15 working days of the steps you are taking to correct

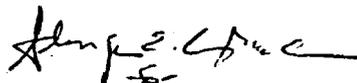
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the violations. Upon receipt of your reply, if you still desire a meeting as indicated in your correspondence of August 30, 2000, we will make arrangements as to a convenient date and time.

Correspondence concerning this matter should be directed to the attention of Richard T. Trainor, Compliance Officer, US Food and Drug Administration, 300 Hamilton Ave., White Plains, New York 10601.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Robert L. Hart". The signature is written in a cursive style with a long horizontal stroke at the end.

Robert L. Hart
Acting District Director