



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Central Region 9/9/01

Telephone (973) 526-6009

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

November 13, 2001

WARNING LETTER

CERTIFIED MAIL –
RETURN RECEIPT REQUESTED

James E. Foy
Owner & Chief Financial Officer
CFH Laboratories LP
114 American Road
Morris Plains, New Jersey 07950

File No.: 02-NWJ-12

Dear Mr. Foy:

During an inspection of your firm, located at 114 American Road, Morris Plains, New Jersey, from September 4 - 27, 2001, investigators from the Food and Drug Administration (FDA) determined that you are a contract manufacturer of [REDACTED] Enzymatic tablets, a contact lens care product. [REDACTED] tablets are considered to be a Class II medical device within the meaning of section 201(h) of the Federal Food, Drug and Cosmetic Act (the Act).

During this inspection our investigators also collected samples of [REDACTED] tablets from Lots U0090, U0100 and U0110, for analysis. All samples tested positive for the presence of metal fragments ranging in size from <0.1 to 2.0 mm.

Our inspection and sample analyses determined that your firm is not in compliance with the Quality System Regulations (QSR) as required by Title 21 Code of Federal Regulations (CFR) Part 820, concerning medical devices, which renders them adulterated within the meaning of section 501(h) of the Act, as follows:

820.90 Nonconforming Product

1. Your firm failed to establish and maintain procedures to control product that did not conform to specified requirements. Your firm also failed to thoroughly investigate and document the cause of the nonconformity. For example, metal contamination was suspected during the production of [REDACTED] tablets, Lots U0090, U0100 and U0110. However, your firm,
 - did not document any investigation or analytical testing intended to determine if suspect lots of [REDACTED] tablets were suitable for release and distribution;

- did not indicate in the batch records or Product Incident Reports that production personnel observed tablets with metal fragments during production or that adjustments were made to the tablet press in order to correct the problem;
- released a portion of Lot U0090 and the majority of Lot U0110 based on a visual inspection, in spite of the fact that you have no documented procedure or specifications for product release based on a visual inspection; and
- did not properly identify rejected tablets from partial Lot U0090 and all the tablets from Lot U0100 as rejected or held in quarantine, and separate from tablets considered to be acceptable.

820.70 (e) Contamination Control

2. Your firm failed to establish and maintain procedures to prevent contamination of products during manufacturing that could be reasonably expected to have an adverse effect on product quality. For example, your firm does not have a requirement or procedures to inspect [REDACTED] tablets for foreign matter.

820.70 (g) Equipment

3. Your firm failed to ensure that equipment used in the manufacturing process meets specified requirements and is appropriately designed, constructed, placed and installed to facilitate manufacturing, adjustment, cleaning and use. For example:
 - Your firm has no documentation that equipment set-up for the feed frame assembly, upper cam body and machine speed, is properly adjusted prior to each production run of [REDACTED] tablets. The inappropriate set-up of the upper cam body and increased line speed were thought to cause metal wear and fragmentation during production.
 - Your firm has no documented approval or verification by Quality Control/Quality Assurance in the Equipment Cleaning Log for August 25, 2000, October 2 and 30, 2000 and January 4, 2001, showing that equipment used during the production of [REDACTED] tablets underwent a complete cleaning. This includes production dates for Lots U0090, U0100 and U0110.

820.100 Corrective and Preventive Action

4. Your firm failed to establish and maintain procedures for implementing corrective and preventive action. Your firm documented manufacturing problems in the production of [REDACTED] tablets and proposed the following improvements however, there is no evidence that they were implemented:
 - Adopt a particle size specification for granulation.
 - Change instructions for spreading the melt granulation material.
 - Document the batch records, if operators break up the melt granulation on the trays to prevent sticking.

820.75 Process Validation

5. The process validation for [REDACTED] tablets is incomplete, in that:
- There is no documentation that processing equipment was qualified during installation, including the tableting machine, planetary blender and [REDACTED] mixer.
 - The validation protocol referred to sampling and testing only. There is no documentation to support process parameters, such as machine settings and times for blending, tableting and mixing operations.
 - Problems were encountered during the production of validation Lot U0017, in which the tablet weight target was changed from [REDACTED] and during the packing operation of validation Lot U0027. However, there is no documentation noted in these batch records that problems were encountered during production or that subsequent process adjustments were made.

820.80 Acceptance Activities

6. Your firm failed to establish and maintain acceptance procedures to ensure that specified requirements for in-process production are met. For example, your firm has no written procedures or specifications for [REDACTED] testing, which was implemented as an in-process test to monitor the uniformity of [REDACTED] tablets during production.

820.25 Training

7. Your firm failed to identify training needs to ensure that all personnel are trained to adequately perform their assigned responsibilities. For example, your firm has no documentation that operators were retrained in new procedures for calculating the average weight of [REDACTED] tablets packaged in two tablet package configurations.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and on the Form FDA483 issued at the conclusion of the inspection may be symptomatic of serious underlying problems within your establishment's quality system. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be system problems, you must promptly initiate permanent corrective and preventive actions.

Federal agencies are advised of the issuance of all Warning letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no premarket submissions for Class III devices to which the Quality System/GMP deficiencies are reasonably related will be cleared or approved until the violations have been corrected. Also, no requests for Certificates to Foreign Governments will be approved until the violations related to the subject devices have been corrected.

We have not yet received a written response regarding your plan of corrective actions as a result of the FDA483 Inspectional Observations issued to your attention on September 27, 2001. We are aware that the distributor of [REDACTED] tablets, [REDACTED], has initiated a voluntary recall of Lots U0090 and U0110, due to potential metal contamination. We note that Lot U0100 was rejected and therefore not released into commercial distribution.

You should take prompt action to correct the deviations identified above. Failure to promptly correct these deviations may result in regulatory action being initiated by the FDA without further notice. These actions include, but are not limited to, seizure, injunction and/or civil penalties.

Please 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 identify and make corrections to any underlying system problems necessary to assure that similar violations will not recur. Your response should be directed to the New Jersey District, FDA, 10 Waterview Blvd., 3rd Floor, Parsippany, New Jersey 07054, Attn: Mercedes Mota, Compliance Officer.

Sincerely,



Douglas I. Ellsworth
District Director
New Jersey District

cc:

