



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Detroit District Office
Central Region
1560 East Jefferson Avenue
Detroit, MI 48207-3179
Telephone: (313) 226-6260
FAX: (313) 226-3076

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER
2001-DT-21

June 14, 2001

Mark Thom, President
Tyco Healthcare Imaging
675 McDonnell Boulevard
St. Louis, MO 63134

Dear Mr. Thom:

During a May 16 - 24, 2001 inspection of the drug manufacturing operations of Lafayette Pharmaceuticals, Inc. Lafayette, Indiana, Investigator Jeffrey Sommers documented serious deviations from the Current Good Manufacturing Practice Regulations (CGMP - Title 21, Code of Federal Regulations, Parts 210 and 211). A copy of the FD 483, List of Observations issued at the conclusion of the inspection is enclosed. These deviations cause your drug products to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act.

1. Failure to have a document, which delineates the responsibilities and procedures applicable to the Quality Control Unit. [21CFR 211.22(d)]
2. Failure to adequately investigate batches, which did not meet specifications. [21CFR 211.192]
3. Failure to always include complete and accurate information in the Batch Record relating to the production of drug product. [21CFR 211.188]
4. Failure to test the preservative level or preservative effectiveness at the time of release for manufactured lots of Barium Sulfate that are formulated to contain preservatives. [21CFR 211.160]
5. Failure to have an Out of Specification procedure, which addresses the disposition of data not found to be in error from testing or inconclusive from the laboratory investigation. [21CFR 211.165]

The above list of deviations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure adherence to each requirement of the Good

The above list of deviations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure adherence to each requirement of the Good Manufacturing Practice Regulations. Other Federal agencies are advised of the issuance of all Warning Letters about drugs so that they may take this information into account when considering the award of contracts. Additionally, pending NDA, ANDA, or export approval requests may not be approved until the above violations are corrected.

We request that you take prompt action to correct these deviations and to ensure that your drug manufacturing systems are in full compliance with the Act and regulations promulgated thereunder. Failure to make prompt corrections may result in regulatory action without further notice, such as seizure and/or injunction.

We did receive a June 1, 2001 letter from Mr. [REDACTED] which states that a detailed written response to the FD 483 will be forthcoming no later than June 13, 2001. The response has just been received, however, not yet reviewed. Mr. [REDACTED] has also verbally requested to meet in Detroit District. As soon as the response is reviewed, we will make arrangements to meet with him at a mutually agreeable time.

Please notify this office in writing, within 15 working days of receipt of this letter, of any additional 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 additional corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which corrections will be completed.

Any additional correspondence should be directed to the Food and Drug Administration, attention Mrs. Judith A. Putz, Compliance Officer at the above address.

Sincerely,


David M. Kaszubski
Acting District Director
Detroit District

Enclosure: FD 483, May 24, 2001 Lafayette Pharmaceuticals, Inc. Lafayette, IN

CC: James E. Kudla, Plant Manager
Lafayette Pharmaceuticals, Inc.
526 N. Earl Avenue
Lafayette, IN 47904