



March 17, 1997

WARNING LETTER
CHI-20-97Chicago District
300 S. Riverside Plaza, Suite 550 South
Chicago, Illinois 60606
Telephone: 312-353-5863**CERTIFIED MAIL**
RETURN RECEIPT REQUESTEDDuane L. Burnham
Chairman and Chief Executive Officer
Abbott Laboratories
101 Abbott Park Road AP6C
Abbott Park, Illinois 60064

Dear Mr. Burnham:

FDA investigators Anne E. Kelly and Thomas W. Nojek conducted an inspection of your firm's pharmaceutical manufacturing facility, Hospital Products Division (HPD), located at 1400 Sheridan Road, North Chicago, Illinois, from January 13, 1997 to February 14, 1997. During the inspection the investigators documented deviations from the Good Manufacturing Practice Regulations (Title 21, Code of Federal Regulations, Part 211) causing your drug products to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act.

The deviations include:

Inadequate investigation of the presence of small black particles in Liposyn 200 mg/ml, emulsion lots #05-476-DE, #05-492-DE, and #06-497-DE.

Leaks in the Liposyn bottle washer.

Failure to maintain a record appropriately, specifically the "Glass Inspection/Bottlesher Area" document.

Failure to maintain an accurate label count.

The general method described in the laboratory document "General Chromatographic System Procedures" fails to require or specify adequate system suitability of the chromatographic method.

Failure to include on the Vitek microbiological identification cards all the test organisms.

Failure to document the positive and negative Gram Stain controls used in the laboratory.

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Additionally, there was the failure, in the laboratory, to appropriately and correctly identify and investigate the conduct of identification of isolates from a Distilled Water sample.

The above identification of violations is not intended to be an all-inclusive listing of deficiencies at your facility. It is your responsibility to assure adherence with each requirement of the Good Manufacturing Practice Regulations. 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.

You should ensure that prompt action is taken to correct the deviations noted during the inspection. Failure to adequately correct these deviations may result in regulatory actions without further notice. Other possible regulatory actions may include seizure and injunction.

You should notify this office in writing, within 15 working days of the receipt of this letter, of the specific steps you have taken to correct the violations described in this letter, and as listed on the FORM FDA 483 (copy enclosed), 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(s) for the delay and the timeframe within which the corrections will be completed.

Your reply should be sent to the Food and Drug Administration, Chicago District Office, 300 S. Riverside Plaza, Suite 550 South, Chicago, Illinois 60606, Attn: Richard Harrison, Acting Director, Compliance Branch.

Sincerely,

RS
Raymond V. Mlecko
District Director

Enclosure: Form FDA 483 dtd 2/14/97

cc: Martin Van Trieste
Plant Quality Assurance Manager
Abbott Laboratories
1400 Sheridan Road
North Chicago, IL 60064