



August 7, 2000

Chicago District
300 S. Riverside Plaza, Suite 550 South
Chicago, Illinois 60606
Telephone: 312-353-5863WARNING LETTERCHI-28-00CERTIFIED MAIL
RETURN RECEIPT REQUESTEDMr. Miles D. White
Chief Executive Officer
Abbott Laboratories
100 Abbott Park Road
Abbott Park, IL 60064-6020

Dear Mr. White:

During the inspection of Abbott Laboratories' Hospital Products Division (Abbott HPD) from March 20 to April 10, 2000, Investigator Chad E. Schmeier determined that your firm manufactures infusion pumps. Infusion pumps are medical devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The Corrections and Removals regulation requires manufacturers, importers, and distributors to report promptly to FDA corrections or removals of devices undertaken to reduce a risk to health within 10 working days. The inspection revealed that your firm's Plum XL infusion pumps are misbranded within the meaning of Section 502(t)(2) of the Act in that your firm failed to submit a Report of Correction or Removal to the FDA as required by Title 21, Code of Federal Regulations (21 CFR), Part 806, Medical Device Corrections and Removals, promulgated under Section 519(f) of the Act.

During the inspection, our investigator confirmed that your firm had received increased complaints concerning alarms with the Plum XL infusion pumps. The alarms caused nursing staffs to increase the changing of central line tubing, thereby increasing the infection rate. The investigator was provided a Technical Service Bulletin dated February 2000, that your firm released to institute a field corrective action to replace a stiffer valve spring in approximately [REDACTED] infusion pumps in distribution. Another Technical Service Bulletin was also issued in February on the correct procedures for cleaning and maintenance of the [REDACTED] [REDACTED] and Plum XL series infusion systems. These actions meet the definition of a correction as defined in 21 CFR Part 806.10(a)(1), which requires manufacturers, importers, and distributors to submit a written report to FDA of any correction or removal of a device if the correction or removal was initiated to reduce a risk to health. Since improperly functioning infusion pumps can, and have caused serious adverse health consequences, the corrections described in the February 2000 Technical Service Bulletins should have been reported to FDA within 10 working days after the corrections were initiated.

We acknowledge the May 26, 2000, Important Field Correction letters your firm sent to its end user accounts informing them of the on-going replacement of the internal valve springs and stressing the importance of proper priming of the administration set.

You are required to submit a report of all unreported corrections and removals to the FDA within 15 working days of the receipt of this letter. Please send your report to our office and address it to Ms. Kathleen E. Haas, Recall & Customer Complaint Coordinator.

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 violation noted in this letter may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If you determine that your systems caused the problems, you must promptly initiate permanent corrective actions.

If you have any questions regarding this letter, please contact Mr. Michael Lang, Compliance Officer, at (312) 353-5863, Ext. 171.

Sincerely,

\s\
Raymond V. Mlecko
District Director

cc: Ms. Yvonne Richardson
Director, Quality Assurance Device Operations
Abbott Laboratories
Hospital Products Division
200 Abbott Park Road
Abbott Park, IL 60064-3500