



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

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Chicago District
650 West Jackson Blvd., 15th Floor
Chicago, Illinois 60661
Telephone: 312-353-5883

March 25, 2004

WARNING LETTER
CHI-5-04

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Miles D. White
Chairman & CEO
Abbott Laboratories, Inc.,
One Abbott Park Road, Bldg AP6
Abbott Park, IL 60064

Dear Mr. White:

During inspections of your firm's Hospital Products Division (Abbott HPD), located at 600 N. Field Drive, Lake Forest, IL, from April 22 to May 1, 2003, and from May 28 to September 2, 2003, United States Food and Drug Administration (FDA) investigators determined that your firm manufactures intravenous administration sets. These products are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

These inspections revealed that these devices are adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packing, storage, or installation are not in conformance with the Quality System Regulation (QSR), Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

1. Your firm's management with executive responsibility failed to ensure that the quality policy was understood, implemented, and maintained at all levels of the organization as required by 21 CFR 820.22. For example, from May 2 to May 19, 2003, Abbott HPD continued to distribute the following products manufactured with [REDACTED] that Abbott HPD [REDACTED] (FDA 483 issued 09/02/2003, Item #1):

- Lifeshield Latex-Free Macrobore Ext. Set, 7 Inch with Clave and Option-Lok, List #120940402, Lot #021045H
- Lifeshield Latex-Free Secondary I.V. Set, Convertible Pin, 32 inch Piggyback with Option-Lok, List #1119530448, Lot #010804W
- Lifeshield Latex-Free Primary IV Set Convertible Pin, 100 inch, List # 119620478, Lot # 910574W
- Lifeshield Latex-Free Primary IV Set, Convertible Pin, 100 Inch, List # 119650468, Lot # 010424W
- Latex-Free Primary IV Set, Convertible Pin, 80 Inch, List # 049680478, Lot # 921204W
- Lifeshield Latex Free Primary IV Plumset, Convertible Pin, 104 Inch, List # 120300412, Lot # 941485H

- Lifeshield Latex Free Primary IV Set, Convertible Pin, 100 Inch, List #1196200478 Lot # 900584W
- Lifeshield Latex Free Secondary IV Set, Convertible Pin, 32 Inch, List #119540448, Lot # 860994W
- Lifeshield Latex Free Primary IV Set, Convertible Pin, 100 Inch, List # 119620478, Lot # 911034W
- Lifeshield Latex Free Primary IV Set, Convertible Pin, 100 Inch, List #119650468, Lot # 020984W

2. Your firm failed to revalidate the manufacturing and sterilization process where appropriate as required by 21 CFR 820.75(c). For example, on December 19, 2001, Abbott HPD began using [REDACTED] to manufacture drip chambers for [REDACTED] IV set products. Abbott HPD's specifications required [REDACTED] to be used in manufacturing IV set products [REDACTED] Abbott HPD had no documentation of validation for this new process change. (FDA 483 issued 05/01/2003, Item #1)
3. Your firm failed to maintain procedures for implementing corrective and preventive action as required by 21 CFR 820.100(a). [REDACTED]
[REDACTED] Abbott had no documentation that shows they took follow-up action in response to the [REDACTED] (FDA 483 issued 05/01/2003, Items #4-6)
4. Your firm failed to maintain procedures to ensure all purchased, or otherwise received, product conforms to specifications as required by 21 CFR 820.50. For example, Abbott's specifications require [REDACTED] to be used to manufacture [REDACTED] drip chambers. [REDACTED] entitled, [REDACTED] requires, "Verification that material meets specifications, and was produced in accordance with indicated material and process specifications." After December 19, 2001, Abbott received certificates of analysis (labeled as Certification Records) for [REDACTED] Despite receipt of the [REDACTED] certificates of analysis, Abbott used the [REDACTED] to manufacture [REDACTED] drip chambers. (FDA 483 issued 05/01/2003, Item #2)
5. Your firm failed to ensure that all personnel are adequately trained to perform their assigned responsibilities as required by 21 CFR 820.25(b). For example, the Supplier Quality Assurance Engineering Project Specialist & Supervisor (performs audits of Abbott HPD's suppliers) had not been trained on the following required procedures for Abbott supplier auditors: [REDACTED] (FDA 483 issued 05/01/2003, Item #7)

6. Your firm failed to establish adequate procedures for quality audits as required by 21 CFR 820.22. For example, the [REDACTED] did not include specific time frames for conducting internal audits. Both these procedures stated that quality audits be conducted at defined intervals and at a sufficient frequency. However, the procedures did not define the interval or frequency. (FDA 483 issued 05/01/2003, Item #8)

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. 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.

You should take prompt action to correct these deviations and to establish procedures to prevent their recurrence. Failure to promptly correct these deviations may result in regulatory action being initiated by FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties. Additionally, no premarket submissions for Class III devices to which the QS regulation deficiencies are reasonably related, will be cleared or approved until the violations have been corrected. Also, no requests for Certificates for Products for Export will be approved until the violations related to the subject devices have been corrected and verified.

We acknowledge receipt of your firm's responses to the Forms FDA-483, dated September 2 and May 1, 2003. Your firm's responses include letters dated September 18, August 4, June 10, July 28, May 29, May 23, and May 21, 2003; a teleconference dated May 12, 2003; and meetings dated July 23 and May 2, 2003. Although it appears from your responses that you are working toward correcting the deviations noted at your firm, you must adequately implement and maintain each corrective action to ensure its effectiveness. We will verify the adequacy of your corrective actions during a subsequent inspection.

Please notify this office, in writing, within fifteen (15) working days of receipt of this letter of the specific steps you have taken to correct the noted violations, including (1) the time frames within which the corrections will be completed, (2) any documentation indicating that the corrections have been achieved, and (3) an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur.

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Your response should be sent to Michael Lang, Compliance Officer, Food and Drug Administration, at 550 West Jackson Blvd., 15th Floor, Chicago, IL, 60661-5716. If you have any questions regarding this letter, please contact Mr. Lang at (312) 596-4225.

Sincerely,


Richard Harrison
Acting District Director

cc: Mr. Christopher B. Begley, President
Hospital Products Division
Abbott Laboratories, Inc.
600 N. Field Drive, Building J45
Lake Forest, IL 60045