



DEPARTMENT OF HEALTH & HUMAN SERVICES

94914d
Food and Drug Administration

July 30, 2004

Dallas District
4040 North Central Expressway
Dallas, Texas 75204-3145

Ref: 2004-DAL-WL-28

WARNING LETTER

CERTIFIED MAIL
RETURNED RECEIPT REQUESTED

Mr. Charlie Mills, Chief Executive Officer
Medline Industries, Inc.
One Mundelein Place
Mundelein, Illinois 60060-4486

Dear Mr. Mills:

On May 24 through 28, 2004, an investigator from the Food and Drug Administration (FDA) conducted an inspection of your facility located at 9303 Stoneview Drive, Dallas, Texas 75237. Our inspection determined that your Dallas establishment manufactures a variety of medical device kits, such as the Maternity Kit, Open Heart Set Up ICU Kit, and Employee Protection Kit. These products are medical devices under section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 321(h).

The inspection revealed that these products 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, their manufacture, packing, storage, or installation are not in conformity with the current Good Manufacturing Practice (cGMP) requirements set forth in FDA's Quality System (QS) Regulation, codified in Title 21, Code of Federal Regulation (CFR), Part 820.

The investigator noted the following QS Regulation violations, which are also listed in the FDA Form 483 (copy enclosed) provided to your Dallas facility at the end of the inspection:

1. Failure to establish and maintain procedures for management reviews of the quality system, as required by 21 CFR 820.20(c). Specifically,
 - a) Management meetings are held [REDACTED] to discuss issues, including quality issues, in each department of the Dallas facility. Your Dallas facility manager

- kept informal notes of each meeting for his own records. His notes were not dated, and there is no procedure established to indicate what types of notes are considered informal or formal records for record keeping; and
- b) There is a [REDACTED] conference call with all the facility managers and the corporate vice presidents to discuss general issues, including quality issues. The issues and information were discussed and provided to all facilities. However, the meetings or records discussing the Dallas facility's quality issues were not documented or kept, respectively; and
 - c) Kit department meetings are held as needed to discuss quality issues, but these meetings were not documented.
2. Failure to provide adequate resources, including the assignment of trained personnel, for management, performance of work, and assessment activities, including internal quality audits, as required by 21 CFR 820.20(b)(2). See FDA-483 Item 2. Specifically, your firm reassigned a quality inspector to another position within the Dallas facility. Since February 1, 2004 no in-process/finished device kit inspections have been performed after the reassignment of this quality inspector.
3. Failure to establish and maintain procedures for internal quality audits and failure to conduct and document such audits to assure that your firm's quality system is in compliance with the established quality system requirements, as required by 21 CFR 820.22. See FDA-483 Item 1. Specifically,
- a) Although your firm has a specific procedure to audit manufacturing operations of the maternity kit, no internal quality audits of the maternity kit manufacturing operations have been performed; and
 - b) Your firm has no documentation to demonstrate that internal quality audits of manufacturing operations for all device kits have been performed; and
 - c) Your firm has no written procedure or plan for conducting internal quality audits nor have access to your corporate office's audit procedures.
4. Failure to maintain complaint files and to establish and maintain procedures for receiving, reviewing, and evaluating complaints as required by 21 CFR 820.198. See FDA-483 Item 6. Specifically,
- a) Your firm has not established or implemented procedures for documenting and investigating oral complaints that are received directly by your firm from customers or sales representatives; and

- b) Your firm has no procedure to determine whether or not device returns or customer credits are considered product complaints; and
 - c) Your firm does not have access to the complaint handling procedures maintained by your firm's corporate office; and
 - d) Your firm did not document detailed descriptions of product complaints. For example, return good authorization [REDACTED] documented that a customer refused and subsequently returned 103 cases of maternity kits. The reason for this product return was not documented. A customer was credited for one case of the Open Heart Set Up Kits due to "damage." A full description of "damage" was not documented; and
 - e) Your corporate office provides [REDACTED] summary reports of device kit complaints to your Dallas facility for their review. However, your Dallas facility did not maintain copies of the product complaints and investigation results.
5. Failure to establish and maintain procedures for in-process acceptance activities to ensure that specified requirements for in-process product are met and documented, as required by 21 CFR 820.80(c). See FDA-483 Item 3. Specifically, your Dallas facility management stated that prior to February 1, 2004, quality inspections of the device kits have been performed but they were unable to locate documentation of the inspection results, and that no quality inspections have been performed after February 1, 2004.
6. Failure to establish and maintain production and process control procedures to ensure a device conforms to its specifications, as required by 21 CFR 820.70. See FDA-483 Item 4. Specifically, your firm failed to document the expiration dates for eight cases of the Open Heart Set Up Kits in their device history records or on their carton labels, as required by your firm's MP 105 Kit Assembly Procedure, effective 8/19/03, for traceability of expiration dated products. Some of the kit components include sterile connecting tubing, sterile gauze sponges, sterile syringes, and sterile cannula with expiration dates.
7. Failure to establish and maintain procedures to ensure that device history records for each batch, lot, or unit are maintained to demonstrate that the device is manufactured in accordance with the device master record, as required by 21 CFR 820.184. See FDA-483 Item 3, 4, and 5. Specifically, your firm did not document (a) the expiration dates for eight cases of the Open Heart Set Up Kits; and (b) quantity manufactured, quantity released for distribution, and in-process and final acceptance results.
8. Failure to establish and maintain procedures for implementing corrective and preventive actions, as required by 21 CFR 820.100, and to include documentation

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of their activities and results, as required by 21 CFR 820.100(b). See Warning Letter Item 1 above, FDA-483 Item 7 and 8. In addition, our inspection documented that:

- a) Your corporate office has established corrective and preventive action procedures for the corporate site but has not implemented them for the Dallas site; and
- b) Your Dallas facility manager was not aware that these CAPA procedures existed or applied to the Dallas facility;
- c) Your Dallas facility manager received [REDACTED] summary reports of product complaints from your corporate office for his review. These reports did not document details of the product complaints because they merely summarized the number of complaints for all manufacturing facilities, including the Dallas facility. After his review of these reports and discussions of quality issues with his production team leaders, these reports were discarded.

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 applicable requirement of the Act and FDA regulations. The specific violations noted in this letter and in the Form FDA-483 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. You also must promptly initiate permanent corrective action and preventative action on your quality system.

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 applications for premarket approval of Class III devices to which the QS Regulation deficiencies are reasonably related will be approved until the violations have been corrected. Also, no requests for Certificates for Foreign Government will be granted until the violations related to the subject devices have been corrected.

You should take prompt action to correct these violations. Failure to promptly correct these violations may result in the initiation of FDA regulatory action without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please provide to this office in writing within 15 working days of receipt of this letter a report of the specific steps you have taken, or will take to identify and correct those problems and to assure that they and similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time

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frame within which the corrections will be completed. Your reply should be directed to
Thao Ta, Compliance Officer, at the letterhead address.

Sincerely,



Michael A. Chappell
Dallas District Director

MAC:txt

cc:
Mr. John T. Gray, Branch Manager
Medline Industries, Inc.
9303 Stoneview Drive
Dallas, Texas 75237

Mr. Wes Swearingen, Vice President of Operations
Medline Industries, Inc.
One Mundelein Place
Mundelein, Illinois 60060-4486