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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Cincinnati District Office
Central Region
6751 Steger Drive
Cincinnati, OH 45237-3097
Telephone: (513) 679-2700
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May 28, 2008

WARNING LETTER
CIN-08-8546-17

VIA FEDERAL EXPRESS

John Rademacher
President
Cardinal Health 414 LLC
7000 Cardinal Place
Dublin, OH 43017

Dear Mr. Rademacher:

During an inspection of your firm located in Dublin, OH, on April 10 through 15, 2008, an investigator from the United States Food and Drug Administration (FDA) determined that your firm is the specification developer and own label distributor of a point-of-use sharps container, called the Secure Safety Insert System. Under section 201(h) of the Federal Food, Drug and Cosmetic Act (the Act), 21 U.S.C. § 321(h), these products are devices because they are intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, or are intended to affect the structure or function of the body.

This inspection revealed that the medical devices are adulterated within the meaning of section 501(h) of the Act, 21 U.S.C. § 351(h), in that the methods used in, or the facilities or controls used for manufacturing, packing, storage, or installation are not in conformity with the Current Good Manufacturing Practice (CGMP) requirements of the Quality System (QS) regulation found at Title 21, Code of Federal Regulations (CFR), Part 820. We received a response from William J. Northam, Director, Manufacturing Quality, dated April 22, 2008 concerning our investigator's Form FDA 483 Observations (Form 483) that was issued to you at the close of the inspection. However, at this time we cannot evaluate the adequacy of your response because you are still in the process of developing procedures for the numerous proposed corrective actions that you estimated, in your response letter, would be completed by May 15, 2008. These violations include, but are not limited to, the following:

1. Failure to establish adequate management controls to ensure that an effective quality system has been established and maintained. [21 CFR § 820.20] Specifically:

   - Quality system procedures have not been established. [21 CFR § 820.20(e)] For example, there are no written corrective and preventive action procedures, design change control procedures, complaint procedures, and medical device reporting procedures.

- A management representative has not been appointed to ensure that the quality system requirements are met, and to report to management on the performance of the quality system. [21 CFR § 820.20(b)(3)]

- Management reviews do not ensure that the quality system satisfies the requirements of part 820 and your quality policy and objectives. [21 CFR § 820.20(c)]

2. Failure to conduct quality audits to assure that the quality system is in compliance with the established quality system requirements and to determine the effectiveness of the quality system. [21 CFR § 820.22]

3. Failure to establish procedures for implementing corrective and preventive actions; and failure to document corrective and preventive activities, including analysis of quality data sources, investigations of causes of nonconformances, and implementation of corrective and preventive actions. [21 CFR§ 820.100]

   Specifically, your firm has not developed corrective and preventive action procedures. Additionally, your Director of Manufacturing Quality stated that the design of the sharp container cap was changed to allow the cap to secure tightly. This corrective and preventive action was not documented.

4. Failure to establish complaint handling procedure for the receiving, reviewing, and evaluating complaints; and failure to evaluate complaints. [21 CFR § 820.198(a)]

   Specifically, your firm has not developed a complaint handling procedure to assure all complaints are documented, evaluated, and if necessary investigated. For example, the four complaints that you received concerning needle sticks have not been evaluated and/or investigated to determine if the device caused or contributed to the needle stick.

5. Failure to establish procedures for acceptance and rejection of incoming product; and failure to perform acceptance activities, including inspections, tests, and other verification activities, for incoming products. [21 CFR § 820.80(b)]

   Specifically, your firm has not established procedures for the acceptance activities related to receipt of the Secure Safety Insert Systems, which you have contract manufactured Additionally, you do not perform any testing on these devices when they are received from the contract manufacturer. You do not have a written quality agreement nor do you receive a certificate of conformance from them.

6. Failure to establish design change control procedures for the identification, documentation, validation and/or verification, review, and approval of design changes before implementation. [21 CFR § 820.30(i)]

   Specifically, between 2003 and 2006, design changes were made to the Secure Safety Insert System. The molding operation was changed to improve the visibility of the biohazard symbol on the cap; the interlock of the cap into the tube was changed to improve the pull strength testing; and short caps were added to accommodate different size syringes. Verifications and/or

validations, design reviews, design releases, and design approvals were not performed for any of these changes.

The inspection also revealed that your devices are misbranded under section 502(t)(2) of the Act, in that your firm failed to develop written Medical Device Reporting procedures as required by 21 CFR 803.17.

You should take prompt action to correct the violations addressed in this letter. Failure to promptly correct these violations may result in the initiation of regulatory action without further notice. This may include, but is not limited to, seizure, injunction, and/or civil money penalties. Also, 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, premarket applications for Class III devices to which the Quality System regulation deviations are reasonably related will not be approved until the violations have been corrected. Requests for Certificates to Foreign Governments will not be granted until the violations related to the subject devices have been corrected.

Please notify this office within fifteen (15) working days from the date you receive this letter of the specific steps you have taken to correct the noted violations, including an explanation of how you plan to prevent these violations, or similar violations, from occurring again. Include documentation of the corrective actions you have taken. If your planned corrective actions will occur over time, please include a timetable for implementation of those corrections. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be sent to Ms. Gina Brackett, Compliance Officer, Food and Drug Administration 6751 Steger Drive, Cincinnati, Ohio 45237. If you have any questions about this letter, you may contact Ms. Brackett at (513) 679-2700, ext. 167, or you may forward a facsimile to her at (513) 679-2773.

Finally, you should know that this letter is not intended to be an all-inclusive list of violations at your facility. It is your responsibility to ensure compliance with applicable laws and regulations administered by the FDA. The specific violations noted in this letter and in the FDA 483s may be symptomatic of serious problems in your firm's manufacturing and quality assurance systems. You should investigate and determine the causes of the violations, and take prompt action to correct the violations and to bring your products into compliance.

Sincerely,

Carol A. Heppe
District Director
Cincinnati District

cc: R. Kelly Clark
Cardinal Health Inc.
President and CEO
7000 Cardinal Place
Dublin, OH 43017