



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Los Angeles District

19701 Fairchild
Irvine, California 92612-2506
Telephone (949) 608-2900

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

February 2, 2007

W/L 07-07

Justin P. Callahan, President
Fisher & Paykel Healthcare, Inc.
15365 Barranca Parkway
Irvine, CA 92618

Dear Mr. Callahan:

During an inspection of your establishment located in Laguna Hills, California, on October 25 through December 6, 2006, United States Food and Drug Administration (FDA) investigators determined that your firm was assembling radiant infant warmers and neo-natal accessory products. These products are devices as defined by section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 321(h), because they are intended for use in the cure, treatment, prevention, or diagnosis of a disease or medical condition, or affect the structure or any function of the body.

The above-stated inspection revealed that these devices are adulterated under 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, their manufacture, packing, storage, or installation are not in conformance with the Current Good Manufacturing Practice (CGMP) requirements for medical devices which are set forth in the Quality System regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820. Significant deviations include, but are not limited to, the following:

1. Failure to establish, maintain and control written procedures for the handling of complaints and to conduct proper evaluations to determine whether or not the reported problems require reporting to FDA under Medical Device Reporting, 21 CFR Part 803 as required by 21 CFR § 820.198. Specifically, our investigation disclosed that your firm does not forward all necessary and relevant information regarding evaluations of complaints to the principal manufacturing site located in [REDACTED]. Our investigation disclosed five instances of malfunctions not documented as complaints. Our investigation also disclosed numerous instances of information reported from field representatives involving problems with devices not being made part of their respective complaint files. We acknowledge that your firm's written response dated December 22, 2006 indicates that you

have developed, and are in the process of implementing, a new complaint handling and MDR (Medical Device Reporting) procedure. This new procedure and your complaint handling practices will be fully evaluated on our subsequent inspection.

2. Failure to establish, implement and control adequate procedures for implementing corrective and preventive action (CAPA) as required by 21 CFR § 820.100. Specifically, our investigation disclosed that all the necessary activities needed to correct and prevent recurrences of non-conforming product and other quality problems such as repairs, upgrades and/or testing to ensure conformance to original design are not documented. Our investigation also disclosed that all the necessary information related to quality problems or nonconforming product is not disseminated to those directly responsible or assuring the quality or preventing the problems. We acknowledge that your written response dated December 22, 2006 indicates that your Quality System Plan includes a comprehensive approach to assessing and improving all of the components of your quality system, including improved and coordinated processes, procedures and documentation requirement for handling non-conformities, investigations, and CAPA activities and to prevent the recurrence. Please submit these new procedures with your response to this letter. Our next inspection will evaluate the effectiveness of these new procedures.

3. Failure to establish, implement and control procedures for performing and verifying servicing conducted and verifying that servicing meets the specified requirements as required by 21 CFR § 820.200. Specifically, our investigation disclosed service reports do not describe the work performed, procedures used, or the method and equipment used to service and repair devices.

4. Failure to ensure that all personnel are trained to adequately perform their assigned responsibilities and that the training is documented as required by 21 CFR § 820.25. Specifically, our investigation disclosed that your firm has no formal documented training program, that employees are trained on the job, and that no documented training on the requirements of the Quality System Regulation have been conducted and documented. We acknowledge that your written response dated December 22, 2006 indicates that your Quality System Plan includes a comprehensive approach to assessing and improving all of the components of your quality system, including training of employees, and that training was initiated on December 21, 2006. Please submit these new procedures and documentation of training, specifically the training regarding the Quality System Requirements with your response to this letter. Our subsequent inspection will evaluate the effectiveness of these new procedures.

5. Failure to establish, implement and control written procedures for the assembly and/or installation of devices to ensure conformance to specifications as required by 21 CFR §§ 820.70 and 820.170. Specifically, our investigation disclosed that your firm was assembling the CosyCot Radiant Infant Warmer and accessory devices in a parking lot and that there was no documentation describing the assembly, installation, measurement and test equipment used, and tests conducted to ensure that the device conforms to its specifications. We acknowledge that written responses dated December 12, 2006 and December 22, 2006 indicate that your firm ceased assembly operations on November 13, 2006. Those responses further state that assembly of these devices may resume after the Quality Improvement Plan has been fully implemented.

We acknowledge receipt of your initial December 12, 2006 response to the form FDA-483 issued to your firm on December 6, 2006. We also acknowledge receipt of your comprehensive response dated December 22, 2006. Our review has determined that these responses are partially satisfactory. We

agree that some of the observations delineated on the form FDA-483 are more the responsibility of your parent company located in [REDACTED]. We also acknowledge that your firm [REDACTED] for the CosyCot Radiant Infant Warmer and accessory devices until sufficient correction and preventive actions are completed. Additionally, your December 22 response indicates that as a result of your retrospective MDR reporting screening, you have identified a number of additional instances of problems requiring submissions of reports to the FDA. It further states that you have notified CDRH and made arrangements with them to obtain the Center's formal approval of alternative reporting. You are therefore advised that failure to comply with the requirements of 21 CFR Part 803 and Section 519(a) of the Act may further misbrand your devices within the meaning of Section 502(t)(2) of the Act.

We also acknowledge receipt of your letter dated January 4, 2007 requesting a meeting with the District. That meeting has been scheduled for Wednesday, February 7, 2007. We have received your draft agenda for that meeting.

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 violations noted in this letter and in the form FDA-483 issued at the close of the inspection 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 and preventive 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 premarket approval applications for Class III devices to which the Quality System regulation deficiencies are reasonably related will be approved until the violations have been corrected. Also, no requests for Certificates to Foreign Governments will be granted until the violations related to the subject devices have been corrected.

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

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 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 for the delay and the time within which the corrections will be completed.

If you have any questions relating to this letter please contact Senior Compliance Officer, Dannie E. Rowland at 949-608-4448. You may obtain general information about all of FDA's requirements for manufacturers of medical devices through the Internet at <http://www.fda.gov>.

Please submit your response to:

Pamela B. Schweikert
Director, Compliance Branch
Food and Drug Administration

Fisher & Paytel Healthcare, Inc. WL

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19701 Fairchild
Irvine, CA 92612-2445

Sincerely,



Alonda E. Cruse
District Director
Los Angeles District Office

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