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Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Telephone: 612-334-4100

June 25, 1998

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 98-38

C. Ray Holman
Chairman and CEO
Mallinckrodt, Inc.
675 McDonnell Boulevard
Hazelwood, Missouri 63042

Dear Mr. Holman:

On June 9-15, 1998, an investigator from the Food and Drug Administration (FDA) collected information that revealed a serious regulatory problem involving the apnea/heart rate monitors that are manufactured at your Nellcor Puritan Bennett, Minneapolis, MN, facility.

Under United States Federal law, the Federal Food, Drug and Cosmetic Act (Act), these products are considered to be medical devices because they are used to diagnose or treat a medical condition or to affect the structure or function of the body. Apnea/heart rate monitors are medical devices as defined by Section 201(h) of the Act.

The law requires that manufacturers of medical devices adhere to Quality System Regulations for Medical Devices (QSRs) as specified in Title 21, Code of Federal Regulations (CFR), Part 820 in the methods used in, facilities or controls used for manufacturing, packing, storage or installation of medical devices.

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Our inspection found your products violate the law because of:

1. Failure to establish and maintain procedures for implementing corrective and preventive action (21 CFR 820.100) in that, for the Model 9700:
 - A. The validation test plan had not been approved although the validation testing was nearly complete (FDA-483 item 1);
 - B. The validation test plan contains errors such as specifying the wrong revision levels for the circuit boards being tested and the applicable device specification, and the list of changes incorrectly denotes that a resistor was added to the on/off FET (FDA-483 item 2); and
 - C. The corrective and preventive action was not verified to ensure that it was effective and did not adversely affect the product because field testing was performed that was not included in the written design validation plan (FDA-483 item 3).
2. Failure to review and evaluate all complaints to determine whether an investigation is necessary [21 CFR 820.109(b), FDA-483 item 4] in that complaints were found that have not been identified, documented and entered into the complaint system per your firm's own standard operating procedure (SOP). Although the information referenced as "complaints" was received through a customer survey, it constitutes a complaint as defined by 21 CFR 820.3(b): "Complaint means any written, electronic or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness or performance of a device after it is released for distribution."
3. Failure to establish and maintain procedures for receiving, reviewing and evaluating complaints to ensure that all complaints are processed in a uniform and timely manner, and that oral complaints are documented upon receipt. For example, complaints received regarding the Ami Monitor since as long ago as January, 1998, were not entered into the complaint system until June 4, 1998 [21 CFR 820.198, FDA-483 item 5].

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In legal terms, the products are adulterated under Section 501(h) of the Act.

I emphasize that the deficiencies stated herein may not be limited to the specific product that was reviewed by the investigator. The deviations from QSR are symptomatic of breakdowns in the validation and complaint handling systems in place at your firm.

You should know that this serious violation of the law may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, seizing your product inventory, obtaining a court injunction against further marketing of the product or assessing civil money penalties. Also, other Federal agencies are informed about the Warning Letters we issue, such as this one, so that they may consider this information when awarding government contracts.

The specific violations noted in this letter and in the FDA-483 issued at the close-out of the inspection on June 15, 1998, 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 the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

We have received Gene Redig's written response to the FDA-483 dated June 19, 1998. Although the responses adequately address the concerns referenced in the FDA-483, no time frames are given for the completion of your actions. After we receive notification from you that the corrections are complete, we will schedule your firm for a re-inspection to evaluate your responses to the specific items.

It is necessary for you to take action on this matter now. Please let this office know in writing within 15 working days from the date you received this letter what steps you are taking to correct the problem. We also ask that you explain how you plan to prevent this from happening again. If you need more time, let us know why and when you expect to complete your correction. Please direct your response to Compliance Officer Howard E. Manresa at the address indicated on the letterhead.

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Finally, you should understand that there are many FDA requirements pertaining to the manufacture and marketing of medical devices. This letter pertains only to the issue of Quality System Requirements for your devices and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for manufacturers of medical devices by contacting our Division of Small Manufacturers Assistance at 1-800-638-2041 or through the Internet at <http://www.fda.gov>.

If you have more specific questions about how FDA marketing requirements affect your particular device or about the content of this letter please feel free to contact Mr. Manresa at (612) 334-4100 ext. 156.

Sincerely,



James A. Rahto
Director
Minneapolis District

HEM/ccl

Enclosure: FDA-483, 6/15/98

xc: Mack G. Nichols
President and COO
Mallinckrodt, Inc.
675 McDonnell Boulevard
Hazelwood, MO 63042

Gerald R. Mattys
Vice President and General Manager
Nellcor Puritan Bennett, Inc.
2800 Northwest Boulevard
Minneapolis, MN 55441