



Food and Drug Administration
Detroit District
1560 East Jefferson Avenue
Detroit, MI 48207-3179
Telephone: 313-226-6260

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER
98-DT-16

September 8, 1998

Mr. Ron Ferber, President
Homedics, Inc.
2240 Greer Blvd.
Keego Harbor, MI 48220

Dear Mr. Ferber:

We are writing to you because on June 8 through June 18, 1998, an Investigator from the Food and Drug Administration (FDA) conducted an inspection at your facility which revealed a serious regulatory problem involving your firm's Sunmark Model 2000, 2025, and 2050 heating pads.

Under a United States Federal law, the Federal Food, Drug, and Cosmetic Act (the Act), this product is considered to be a medical device because it is used to treat a medical condition or to affect the structure or function of the body. The law requires that manufacturers of medical devices adhere to the Quality System Regulation. This helps protect the public health by ensuring that medical devices are safe and effective.

In legal terms, your devices are adulterated under 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 conformity with the Quality System Regulation, as specified in Title 21, Code of Federal Regulations (21 CFR), Part 820, as follows:

Failure to establish and maintain procedures for receiving, reviewing, and evaluating complaints, by a formally designated unit, which ensures that all complaints are evaluated to determine whether the complaint represents an event which is required to be reported to FDA under part 804 of this chapter, and that oral complaints are documented upon receipt, as required by 21 CFR 820.198(a). For example:

- (1) there is no documented complaint handling procedure;

- (2) complaints were not evaluated to determine whether they represent an event which must be reported to FDA under part 804; and
- (3) oral complaints are not always documented upon receipt.

Failure to establish and maintain procedures for implementing corrective and preventive action, as required by 21 CFR 820.100. For example, procedures have not been established that include requirements for analyzing complaints and other sources of quality data to identify existing and potential causes of nonconforming product, identifying the action(s) needed to correct and prevent recurrence of nonconforming product, and ensuring that information related to quality problems or nonconforming product is disseminated to those directly responsible for assuring the quality of such product.

Failure to maintain a record of all investigations, to include the date the complaint was received, the dates and results of the investigation, and any corrective action taken, as required by 21 CFR 820.198(e). For example, five of the eight complaints reviewed did not indicate the date the complaint was received, and the results of the investigations reported to have been conducted by Appliance Development Corporation were not documented.

Failure of the manufacturer to establish and maintain procedures to ensure that all purchased or otherwise received product and services conform to specified requirements, as required by 21 CFR 820.50. For example, a purchasing control program has not been established to assure that Appliance Development Corporation is in compliance with design control requirements, and that changes to the device are made in accordance with these requirements.

Failure to establish procedures for quality audits and conduct such 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, as required by 21 CFR 820.22. Homedics does not have formally established audit procedures and has not conducted an internal audit of its quality system.

The SunMark heating pad is also misbranded under section 502(t)(2) of the Act, in that information required by the Medical Device Reporting (MDR) Regulation, Title 21, Code of Federal Regulations (21 CFR), Part 804, was not provided as follows:

You failed to submit a report to FDA (and to the foreign manufacturer) on FDA form 3500A within 10 working days after you became aware of information that reasonably suggested that the SunMark heating pad had malfunctioned and would likely cause or contribute to a death or serious injury if the malfunction were to recur, as required by 21 CFR 804.25(b)(2). The FDA investigator documented that you had received 14 complaints that SunMark heating pads had scorched or burned holes in the heating pad cover and in bedding, clothing, or furniture in contact with the heating pad. In two instances, the heating pad was reported to have caught on fire, and in another instance, the user's mattress and bedding reportedly caught on fire causing a burn on the user's arm and back.

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A written MDR report for each of these 14 complaints, and any other reportable incidents received by your firm which have not been reported to FDA, are to be submitted within 15 working days of receipt of this letter. The MDR reports should reference this Warning Letter and be directed to:

Victoria A. Schmid
Reporting Systems Monitoring Branch (HFZ-533)
Office of Surveillance and Biometrics
Center for Devices and Radiological Health
1350 Piccard Drive
Rockville, Maryland 20850

You have not established and implemented written MDR procedures that address the following, as required by 21 CFR 804.34:

- (1) training programs (to inform employees of MDR obligations and how to identify and report MDR reportable events);
- (2) internal systems that provide for the timely and effective identification, communication, and evaluation of events that may be subject to MDR requirements (e.g., a standardized review process/procedure for determining when an event meets the criteria for reporting and for the timely transmission of complete MDR's to FDA and/or the manufacturer); and
- (3) documentation and recordkeeping requirements for information that may be the subject of an MDR, for the MDRs that are submitted to FDA and manufacturers, and for systems that ensure access to information and facilitate timely follow-up and inspection by FDA.

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 FDA 483 issued at the closeout 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 cause of the violations identified by the FDA. If the causes are determined to be system problems you must promptly initiate permanent corrective actions.

We acknowledge that at the conclusion of the inspection, you promised to correct the Investigator's observations noted on the form FDA 483. We acknowledge that you have submitted to this office a response concerning the observations which was submitted by your attorney, Mr. Mark Cantor, in a letter dated July 15, 1998. We have reviewed your response and note that you do not have a specific timetable for completion of the corrections, but will provide periodic status reports starting in August, 1998. The response indicates that corrections will be made, but does not make any specific

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commitments for correction of the individual violations. The letter does state that no additional heating pad will be imported until the necessary corrections are made.

Additional information from the Appliance Development Corporation has been submitted in a letter dated July 21, 1998 from your attorney. The letter lists a number of design changes to the heating pads and the design of a new fixture to manufacture the heating pads. The letter did not provide any information if the design changes will be made in conformance with Title 21 C.F.R. Part 820.30, Design Controls.

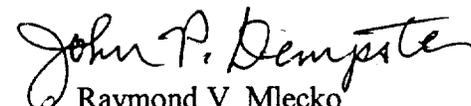
You should know that this serious violation of the law may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, seizing your product inventory, obtaining a court injunction against further marketing of the products, or assessing civil money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

It is necessary for you to take action on this matter now. Please let this office know in writing within fifteen (15) working days from the date you received this letter what steps you are taking to correct the problems. 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. We also suggest that a meeting at the Detroit District Office with you and your consultants would be beneficial to discuss the corrections. Please direct your response to Mr. David M. Kaszubski, Compliance Officer, U.S. Food and Drug Administration, 1560 East Jefferson Ave., Detroit, MI 48207.

Finally, you should understand that there are many FDA requirements pertaining to the manufacture and marketing of medical devices. This letter only pertains to the issue of Quality System and Medical Device Reporting regulations, 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 the content of this letter, please feel free to contact Mr. Kaszubski at 313-226-6260 Ext 185.

Sincerely yours,


Raymond V. Mlecko
Acting District Director
Detroit District

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cc: EF (Homedics, Inc., Keego Harbor, MI)
HFA-224 (CFN:18-32894)
HFI-35 (purged)
HFZ-300
HFZ-340
HFZ-342 (Stutsman)
HFC-210
HFC-240
HFC-120
W/L Jacket (98-DT-16)
W/L Book

EEJ

DMK
DMK 9/8/98