



DEPARTMENT OF HEALTH AND HUMAN SERVICE

Public Health Service

Food and Drug Administration  
New Orleans District  
Southeast Region  
4298 Elysian Fields Ave.  
New Orleans, LA 70122

Telephone: 504-589-6341  
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HF1-35

M2301.17

January 12, 1999

**WARNING LETTER NO. 99-NOL-10**

**CERTIFIED MAIL  
RETURN RECEIPT REQUESTED**

Mr. Jerry Levin, Chief Executive Officer  
Sunbeam Products, Inc.  
1615 South Congress Avenue  
Suite 200  
Delray Beach, Florida 33445

Dear Mr. Levin:

During an inspection of your firm located at 95 W.L. Runnels Industrial Drive, Hattiesburg, Mississippi, on December 7-10, 1998, our investigators determined that your firm manufactures humidifiers and vaporizers and designs, imports and repackages heating pads. These products are devices as defined by Section 201(h) of the Federal Food, Drug and Cosmetic Act (the Act).

The above-stated inspection revealed that these devices 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 manufacturing, packing, storage, or installation are not in conformance with the Good Manufacturing Practice (GMP) for Medical Devices Regulation, as specified in Title 21, *Code of Federal Regulations* (CFR), Part 820, as follows:

- Failure to establish and implement an adequate complaint handling program. For example, complaints relating to humidifiers and vaporizers are not retained or evaluated, and there are no written procedures for receiving, reviewing, and evaluating complaints in accordance with the GMP regulation;
- Failure to establish and implement an adequate failure investigation program. For example, direct customer returns of devices such as humidifiers, vaporizers, and heating pads are not evaluated to determine the cause of the product failure unless a claim is made against your firm;
- Failure to establish and maintain adequate procedures for implementing corrective and preventive action. For example, product evaluations are scheduled according to the dollar value of retailer returns. Direct consumer returns and telephone complaints are not evaluated for the existence of trends in product defects. Humidifier and vaporizer returns are not recorded or

retained and heating pad returns are not recorded in a manner to facilitate any type of trend analysis. The heating pad manufacturing facility does not receive any information regarding product failures reported by consumers;

- Failure to conduct planned and periodic audits of the quality assurance program in accordance with written procedures. For example, no audits of the quality assurance program have been performed in at least the past two years and no written procedures were available for review;
- Failure to validate the manufacturing processes with respect to humidifiers and vaporizers;
- Failure to maintain device history records for humidifiers and vaporizers to demonstrate that the devices are manufactured in accordance with a device master record;
- Failure to establish and maintain adequate purchasing controls in that the capability of device component (e.g. electric motors, cords, etc.) suppliers is not reviewed at periodic intervals to demonstrate continued conformance with specified requirements;
- Failure to establish and maintain adequate in-process controls with respect to monitoring and controlling process parameters and component characteristics during production. For example, plastic components are not evaluated for conformance with specifications periodically throughout the production cycle;
- Failure to establish and maintain adequate procedures for finished device acceptance to ensure that each production run, lot, or batch of finished devices meets acceptance criteria. For example, finished product sampling is not conducted according to a time or production volume schedule, nor are the devices to be tested selected at random from the finished lot in order to ensure that the sample is representative of the entire lot. Devices are pulled from the production line according to the availability of the auditor and palletized devices are delivered immediately to the distribution center; and,
- Failure to establish and implement procedures for management reviews in order to determine the suitability and effectiveness of the quality system.

Additionally, our investigators were unable to access records to verify your compliance with the Medical Device Reporting (MDR) Regulation as specified in 21 CFR Part 803. Failure to submit an MDR report to FDA after receiving information which reasonably suggests that one of your commercially distributed devices may have caused or contributed to a death or serious injury would cause your devices to be misbranded within the meaning of section 502(t)(2) of the Act.

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 causes of the violations identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

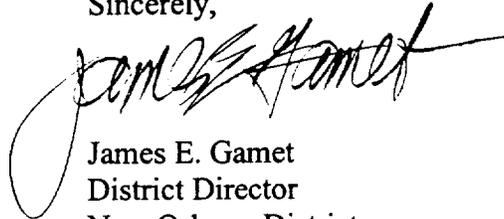
Federal agencies are advised of the issuance of all warning letters involving devices so that they may take this information into account when considering the award of contracts. Additionally, no premarket submissions for devices to which the GMP deficiencies are reasonably related will be cleared until the violations have been corrected. Also, no requests for certificates for products for export will be approved 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 Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office in writing within 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 identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur. 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. Barbara D. Wright, Compliance Officer, Food and Drug Administration, 4298 Elysian Fields Avenue, New Orleans, Louisiana 70122.

Sincerely,



James E. Gamet  
District Director  
New Orleans District

Enclosures: FDA 483  
21 CFR 820

cc: Mr. William W. Irwin, Interim Plant Manager  
Sunbeam Products, Inc.  
95 W.L. Runnels Industrial Drive  
Hattiesburg, Mississippi, 39401

Mr. Scott Myerly  
Vice-President of Research & Development, Household Products  
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