U.S. Food and Drug Administration

Inspections, Compliance, Enforcement, and Criminal Investigations

HMI Industries, Inc. 2/23/10

Department of Health and Human Services

Public Health Service
Food and Drug Administration
Cincinnati District Office
Central Region
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February 23, 2010

WARNING LETTER
CIN-10-94646-05

VIA FEDERAL EXPRES

Kirk Foley
Chairman and Chief Executive Officer
HMI Industries, Inc.
13325 Darice Pkwy, Unit A
Strongsville, OH 44149-3819

Dear Mr. Foley:

During an inspection of your firm located in Strongsville, OH on December 1, 2009 through January 15, 2010, a investigator from the United States Food and Drug Administration ("FDA") determined that your firm is the manufacturer of a residential room air filtration system, called the "Defender". Under section 201 (h) of the Federal Food, Drug and Cosmetic Act (the "Act"), 21 U.S.C. § 321(h), this product is a device because it is intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, or is 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 your response dated January 27, 2010 stating that you have hired a consultant to help you address out investigator's observations noted on the Form FDA 483, List of Inspectional Observations that was issued to you. These violations include, but are not limited to, the following:

1. Failure to document corrective and preventive action activities, including investigations of causes of nonconformities, the actions needed to correct or prevent reoccurrence of nonconforming product, and the verification of the effectiveness of the corrective actions, as required by 21 C.F.R. § 820.100(b).

For example, CAPA #1224, dated 10/25/07 relating to complaints on "motor noise" and CAPA #1226, dated

4/4/08, relating to complaints on problems with the power circuit board and "carmelization" on the boards; you failed to document the immediate corrective actions taken, the root cause assessments, all permanent corrective/preventive actions taken, and the verification of the effectiveness of the corrective actions. Additionally, both of these Corrective and Preventive Action (CAPA) forms were canceled on 9/28/09 due to "no activity", even though there were several complaints received in 2009 relating to motor noise and power board problems.

2. Failure to implement your "Complaint Handling and Medical Device Reporting" and "Failure Investigation" procedure to assure complete complaint files are maintained, as required by 21 CFR § 820.198(a).

Specifically, out of the 29 complaints reviewed: 6 did not document if a Corrective and Preventive Action is required per procedures; 24 complaints did not have a documented root cause; 18 complaints did not have a documented corrective action; and all 29 did not document the evaluation to determine if the event was reportable to FDA under 21 CFR Part 803 (Medical Device Reportable).

3. Failure to develop production processes to ensure that the "Defender" air filtration system, Model #DP360 conforms to its specifications, as required by 21 CFR § 820.70(a).

4. Failure to implement your "Device History Record" procedure to ensure that the device history record for each lot demonstrate that the device is manufactured in accordance with device master record, as required by 21 CFR § 820.184. For example:

- Three of 29 device history records reviewed did not have a completed "Finished Production Conformance Checklist" form, which is required by your "Device History Record" procedure.

- Your film is not recording all the dates in which a lot is manufactured on the "Production Route Sheet". For example, lot #091001 contains 1,682 "Defender" air filtration systems and your Director of Quality stated this lot would have taken about a month to manufacture. Your "Production Route Sheet" for this lot only has one day recorded for manufacturing the entire lot.

5. Failure to document the evaluation of the suppliers of your three major components of the "Defender" air filtration system, as required by 21 CFR § 820.50(a)(1).

6. Failure to maintain a design history file for the "Defender" air filtration system, as required by 21 CFR § 820.300). Specifically, your firm could not locate the design inputs, outputs, verification and validation documents, design reviews and design changes for the "Defender".

7. Failure to establish a device master record for the "Defender" air filtration system, model #RAC-4000A, as required by 21 CFR § 820.181(a).

8. Failure to conduct an audit to assure the quality system is in compliance with the established quality system requirements, 21 CFR Part 820; and failure of your "Internal Quality Audits" procedure, #13.1 Revision D, dated 8/06/07 to address the frequency of internal audits and assure that all parts of the quality system will be covered during the audit, as required by 21 CFR § 820.22.

9. Failure to implement your management review procedure, as required by 21 CFR § 820.20(c). Specifically, your "Management Review" procedure, dated 8/6/07 states that management review meetings are held quarterly. Your firm has not documented a management review meeting since December 15, 2004.

10. Failure to establish and maintain an organizational structure to ensure that devices are designed and produced to meet the requirements of 21 CFR part 820, as required by 21 CFR § 820.20(b).

For example, complaints are left open with no further documented evaluation, assembly procedures are outdated, management reviews have not been conducted since 2005, and the Design History File for the "Defender" could not be found.

The inspection also revealed that your devices are misbranded under section 502(t)(2) of the Act, 21 U.S.C. §

352(t)(2), in that your firm failed to include a standardized review process for determining when an event meet the criteria for reporting a Medical Device Reporting event in your written "Complaint Handling and Medical Device Reporting" procedure as required by Section 519 of the Act, 21 U.S.C. § 360i, and 21 CFR 803.17(a)(2).

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 o 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 step 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 film' 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,
/S/ Teresa C. Thompson
District Director
Cincinnati District

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