Somnowell, Inc. 5/12/16

Department of Health and Human Services

Public Health Service
Food and Drug Administration
New Orleans District
404 BNA Drive
Building 200 – Suite 500
Nashville, TN 37217
Telephone: (615) 366-7801
FAX: (615) 366-7802

May 12, 2016

WARNING LETTER NO. 2016-NOL-05

UNITED PARCEL SERVICE
Delivery Signature Requested

David M. Thoni, CEO
Somnowell, Inc.
8533 McCrory Lane
Bellevue, Tennessee 37221

Dear Mr. Thoni:

During an inspection of your firm located in Bellevue, Tennessee on February 11 through March 10, 2016, an Investigator from the United States Food and Drug Administration (FDA) determined your firm is a specification developer for an anti-snoring/sleep apnea device which is manufactured by your contract manufacturer, **(b)**

(4). Under Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 *United States Code* (USC) 321(h)], these products are devices because they are intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body.

This inspection revealed these devices are adulterated within the meaning of Section 501(h) of the Act [21 USC 351(h)], because the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation are not in conformity with the current good manufacturing practice requirements of the Quality System regulation found at Title 21, *Code of Federal Regulations* (CFR), Part 820. These regulations can be found at www.fda.gov. These violations include, but are not limited to, the following:

1. Failure to establish and maintain procedures for conducting quality audits, and the failure to conduct quality 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.

Specifically, procedures for quality audits have not been established, and your firm has not conducted any quality audits.

2. Failure to establish and maintain procedures for conducting management reviews, and the failure to conduct management reviews, as required by 21 CFR 820.20(c).

Specifically, procedures for conducting management reviews were not established, and your firm has not conducted any management reviews.

3. Failure to establish and maintain procedures to ensure that all purchased or otherwise received products and services conform to specified requirements, as required by 21 CFR 820.50.

Specifically, your firm has not established procedures for the evaluation of suppliers, contractors, consultants, and purchasing data. Such procedures should include, but not be limited to, the responsibilities and requirements of your contract manufacturer(s) for your “Somnowell” anti-snoring/sleep apnea device.

4. Failure to establish and maintain a design history file to demonstrate that the design of your “Somnowell” anti-snoring/sleep apnea device was developed in accordance with its approved design plan as well as the design control requirements found in 21 CFR 820.30, as required by 21 CFR 820.30(j).

Specifically, your firm has not established a design history file for your “Somnowell”

device, which is a Class II medical device used for treating snoring and sleep apnea.

5. Failure to establish and maintain procedures for the identification, documentation, validation or when appropriate verification, review, and approval of design changes before their implementation, as required by 21 CFR 820.30(i).

Specifically, your firm has not established and maintained procedures for design changes.

6. Failure to establish and maintain procedures for implementing corrective and preventive actions, as required by 21 CFR 820.100(a).

Specifically, your firm has not established and maintained procedures for implementing corrective and preventive actions.

7. Failure to maintain complaint files, and the failure to establish and maintain procedures for receiving, reviewing, and evaluating complaints, to include, but not be limited to, the evaluation of whether the complaint represents an event which is required to be reported to FDA under the Medical Device Reporting (MDR) requirements, by a formally designated unit, as required by 21 CFR 820.198(a).

Specifically, your firm was not maintaining a complaint file, and has not established and maintained complaint handling procedures. Your firm also does not have procedures for determining whether any of the complaints received represent an event which is required to be reported to FDA under the MDR requirements.

8. Failure to establish and maintain procedures to control all documents that would include the procedures for the approval and distribution of all necessary documents, as well as the procedure for the approval and distribution of any changes needed for these documents, as required by 21 CFR 820.40.

Specifically, your firm has not established procedures for the control of documents.

Your firm should take prompt action to correct the violations addressed in this letter. Failure to promptly correct these violations may result in regulatory action being initiated by the FDA without further notice. These actions include, but are not limited to, seizure, injunction, and civil money penalties. Also, federal agencies may be advised of the issuance of warning letters about devices so that they may take this information into account when considering the award of contracts.

Additionally, premarket approval applications for Class III devices to which the Quality System regulation violations 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 in writing within 15 business days from the date you receive this letter of the specific steps your firm has taken to correct the noted violations, as well as an explanation of how your firm plans to prevent these violations, or similar violations, from occurring again. Include documentation of the corrections and/or corrective actions (which must address systemic problems) that your firm has taken. If your firm's planned corrections and/or corrective actions will occur over time, please include a timetable for implementation of those activities. If corrections and/or corrective actions cannot be completed within fifteen business days, state the reason for the delay and the time within which these activities will be completed. Your firm's response should be comprehensive and address all violations included in this warning letter.

Your firm's response should be addressed to: David Van Houten, Compliance Officer at the above address. If you have any questions about the contents of this letter, please contact: David Van Houten, Compliance Officer at615-366-7813.

Finally, you should know that this letter is not intended to be an all-inclusive list of the violations at your firm's facility. It is your firm's responsibility to ensure compliance with applicable laws and regulations administered by FDA. The specific violations noted in this letter and in the Inspectional Observations, FDA 483, issued at the close of the inspection may be symptomatic of serious problems in your firm's manufacturing and quality management systems. Your firm should investigate and determine the causes of the violations, and take prompt actions to correct the violations and bring the products into compliance.

Sincerely,
/S/
Ruth P. Dixon
District Director
New Orleans District

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Silver Spring, MD 20993
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