367360R

DEPARTMENT OF HEALTH AND HUMAN 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 27, 2008

WARNING LETTER NO. 2008-NOL-10

FEDERAL EXPRESS
DELIVERY SIGNATURE REQUESTED

Ms. Sue Wright, CEO
Safer Sleep, LLC
3322 West End Avenue, Suite 705
Nashville, Tennessee 37203

Dear Ms. Wright:

During an inspection of your firm, located at 3322 West End Avenue, Suite 705, Nashville, Tennessee on November 13, 16 and 20, 2007, investigators from the United States Food and Drug Administration (FDA) determined your firm manufactures the SAFERsleep device. 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 are intended to affect the structure or function of the body.

This inspection revealed your 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 do not conform with the Current Good Manufacturing Practice requirements of the Quality System regulation found at Title 21, *Code of Federal Regulations*, Part 820 (21 CFR 820). These violations include, but are not limited to, the following:

1. Failure to establish and maintain procedures for validating the device design, including software validation, as required by 21 CFR 820.30(g). For example, your firm provided no documentation of validation of the embedded software in the SAFERsleep device.

2. Failure to establish and maintain procedures for implementing corrective and preventive action, as required by 21 CFR 820.100. For example, although you track issues with the [redacted] you have not established procedures for corrective and preventive actions or identified the methods used.

3. Failure to establish and maintain procedures for receiving, reviewing, and evaluating complaints, as required by 21 CFR 820.198. For example, although complaints are tracked through your support log and transcribed into [redacted] you have not

established procedures for reviewing and evaluating complaints, including procedures for determining whether complaints represent an event which must be reported to FDA under 21 CFR 803.

4. Failure to establish and maintain procedures for acceptance activities, as required by 21 CFR 820.80. For example, you have not established procedures for finished device acceptance activities, and you have not established procedures for acceptance of incoming product, including computers, keyboards, and bar code scanners. Additionally, you have not established procedures for receiving and final acceptance of hardware returned from customers after use.

5. Failure to establish and maintain installation and inspection instructions, and test procedures, as required by 21 CFR 820.170(a). For example, although you claim installation, inspection, and test procedures have been established, they were not available at the time of inspection and have not yet been provided.

6. Failure to establish and maintain procedures to ensure all purchased or otherwise received product and services conform to specified requirements, as required by 21 CFR 820.50. For example, although you claim to follow extensive procedures for evaluating potential suppliers, no documentation of this selection process has been provided.

7. Failure to establish and maintain procedures to control all documents required by 21 CFR 820, as specified by 21 CFR 820.40. For example, although you indicate your software [redacted] you have not established document control procedures for documents [redacted]

8. Failure to establish procedures for quality audits and conduct such audits to ensure 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. For example, you have not established any procedures for conducting internal quality audits.

9. Failure to establish quality system procedures and instruction, as required by 21 CFR 820.20. For example:

   a. Management with executive responsibility has not appointed a management representative;
   b. You have not conducted management reviews to review the suitability and effectiveness of the quality system;
   c. You have not established a quality plan which defines the quality practices, resources, and activities relevant to devices which are designed and manufactured; and,
   d. Management with executive responsibility has not established its policy and objectives for, and commitment to, quality, and ensured the quality policy is understood, implemented, and maintained at all levels of the organization.

   You presented the investigator with a new, written quality policy prior to the close of the inspection; however, you have not provided any documentation the policy has been implemented.

10. Failure to establish procedures for identifying training needs, and to ensure all personnel are trained to adequately perform their assigned responsibilities, as required by 21 CFR 820.25. For example, you do not have any training procedures or documentation identifying training needs.

The inspection also revealed your devices are misbranded under Section 502(t)(2) of the Act,[21 USC 352(t)(2)], because your firm failed or refused to furnish material or information with respect to the device, as required by or under Section 519 of the Act [21 USC 360i], and 21 CFR 803 - Medical Device Reporting (MDR) regulation. Significant deviations include, but are not limited to, the following:

- Failure to develop, maintain, and implement written MDR procedures, as required by 21 CFR 803.17. For example, you were unaware of the MDR regulation and do not have written MDR procedures.

On December 12, 2007, we received your response dated December 4, 2007, concerning our investigator's observations noted on the Form FDA 483, List of Inspectional Observations (483), issued to [redacted] on November 20, 2007. We reviewed your response and concluded it is inadequate because it states [redacted] to help formulate a quality system and promised establishment in early 2008, but you have not provided evidence of implementation of these corrections.

You 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 FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil money penalties. Also, Federal agencies are advised of the issuance of all warning letters about devices so 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 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 in writing within fifteen (15) working days from the date you receive this letter of the specific steps you have taken to correct the noted violations, including an explanation of how you plan to prevent these violations, or similar violation(s), from occurring again. Include documentation of the corrective action you have taken. If your planned corrections 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: Nicole F. Hardin, Compliance Officer, U.S. Food and Drug Administration at the above address. If you have any questions about the content of this letter, please contact Mrs. Hardin at (504) 219-8818, extension 102 or via fax to (504) 219-8813.

This letter is not intended to be an all-inclusive list of the violation(s) at your facility. It is your responsibility to ensure compliance with applicable laws and regulations administered by FDA. The specific violations noted in this letter and in the 483 issued at the closeout of the inspection

may be symptomatic of serious problems in your firm's manufacturing and quality assurance systems. You should investigate and determine the causes of the violation(s), and take prompt actions to correct the violations and to bring your products into compliance.

Sincerely,

H. Tyler Thornburg
District Director
New Orleans District

Enclosure: Form FDA 483