U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

Bedfont Scientific, Ltd. 2/4/16

Department of Health and Human Services

Public Health Service
Food and Drug
Administration
10903 New Hampshire
Avenue
White Oak Building 66
Silver Spring, MD 20993

WARNING LETTER
FEB 4, 2016

VIA UNITED PARCEL SERVICE

Trevor Smith
Managing Director
Bedfont Scientific, Ltd.
Station Road, Harrietsham
Maid stone
ME17 1JA
United Kingdom

Dear Mr. Smith:

During an inspection of your firm located in Maidstone, United Kingdom, on September 7, 2015, through September 10, 2015, an investigator from the United States Food and Drug Administration (FDA) determined that your firm manufactures carbon monoxide monitors. Under section 201 (h) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 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 function of the body.

This inspection revealed that these 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, 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.

We received a response from Ms. Louise Bateman, Quality Assurance & Regulatory Affairs Manager, dated September 18, 2015, concerning our investigator's observations noted on the Form FDA 483 (FDA 483), List of Inspectional Observations, which was issued to your firm. We address this response below, in relation to each of the noted violations. These violations include, but are not limited to, the following:

1. Failure to establish and maintain procedures for implementing corrective and preventive action (CAPA), as required by 21 CFR 820.1 OO(a). For example:

a. Your firm's CAPA procedure, Nonconformities, Issue 2, dated April 17, 2015, does not include requirements for:

i. Verifying or validating corrective actions to ensure that such actions are effective and do not adversely affect the finished device;
ii. Implementing and recording changes in methods and procedures needed to correct and prevent identified quality problems; and
iii. Ensuring that information related to quality problems or nonconforming product is disseminated to those directly responsible for assuring the quality of such product or the prevention of such problems.

b. CAPA Ticket Nos. **(b)(4)** do not include any investigations of the cause of the non conformities and documentation of CAPA effectiveness.

We reviewed your firm's response and conclude that it is not adequate. The response indicated that your firm will determine whether additional training for staff is needed and procedures should be changed. However, the response did not indicate when these corrective actions will be completed. Additionally, your firm's corrective action plan did not include an evaluation of past CAPAs to determine if additional actions are necessary to resolve inadequacies.

2. Failure to establish and maintain procedures for receiving, reviewing, and evaluating complaints by a formally designated unit, as required by 21 CFR 820.198(a). For example, your firm's complaint handling procedures do not ensure that complaints are evaluated to determine if they represent an event which is required to be reported to FDA under 21 CFR 803, Medical Device Reporting (MDR).

We reviewed your firm's response and conclude that it is not adequate. The response indicated that the complaint handling procedures will be revised and relevant personnel will be trained on the revised procedures. However, the response did not indicate when these corrective actions will be completed. Additionally, your firm's corrective action plan did not include an evaluation of past complaints to ensure that MDR reportable events are reported to FDA.

3. Failure to establish and maintain procedures for validating the device design, as required by 21 CFR 820.30(g). For example, your firm's Design and Development procedure, Issue 3, dated August 5, 2014, does not include requirements for performing design validation under defined operating conditions on initial production units, lots, or batches, or their equivalents; testing production units under actual or simulated use conditions; and documenting the results of the design validation, including identification of the design, method(s), the date, and the individual(s) performing the validation in the Design History File (DHF). Additionally, **(b)(4)** Design Validation Testing, **(b)(4)**, do not have the date or signature of the individuals who conducted and approved the validation.

We reviewed your firm's response and conclude that it is not adequate. The response indicated that your firm will review procedures to include validation requirements and implement change control for obtaining signatures on released validation reports. However, the response did not indicate when these corrective actions will be completed. Additionally, your firm's corrective action plan did not include an evaluation of other design projects to ensure that the design validations are adequate and implement corrective actions to address any deficiencies, as appropriate.

4. Failure to establish and maintain procedures for the identification, documentation, validation or where appropriate verification, review, and approval of design changes before their implementation, as required by 21 CFR 820.30(i). For example, your firm's **(b)(4)** to V1.3, dated August 31, 2011, does not include verification or validation of all completed design changes. Additionally, your firm has not documented the approval of design changes made to the device prior to **(b)(4)**.

We reviewed your firm's response and conclude that it is not adequate. Your firm stated that all design changes will be fully documented according to procedures. However, the response did not indicate when these corrective actions will be completed. Additionally, your firm's corrective action plan did not include an evaluation of past design changes to determine if the lack of verification or validation presented any risk to the devices that were released for distribution.

5. Failure 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. Your firm's Evaluation of Suppliers procedure, Issue 1, dated December 5, 2012, requires **(b)(4)** for all critical suppliers on the approved supplier list. However, your firm has only conducted **(b)(4)** review during Management Review. Additionally, your firm has not conducted any evaluation of the supplier of the **(b)(4)** in the past three years.

b. Your firm has not defined the type and extent of control to be exercised over the suppliers. Your firm initiated two corrective action tickets **(b)(4)**. Your firm has not received any updates on these corrective actions from this supplier; however, the

ticket for the **(b)(4)** correction action is closed.

We reviewed your firm's response and conclude that it is not adequate. The response indicated that your firm will review all suppliers with new agreements. However, the response did not indicate when these corrective actions will be completed. Additionally, your firm's corrective action plan did not include an evaluation of all suppliers to ensure that incoming products and services conform to their specified requirements.

6. Failure to ensure that when computers or automated data processing systems are used as part of production or the quality system, the manufacturer shall validate computer software for its intended use according to an established protocol, as required by 21 CFR 820.70(i). For example, your firm has not validated the software, **(b)(4)**, used to manage various activities such as complaints, CAPAs, repairs, servicing, internal and external audits, and warranty service. Your firm has been utilizing this software since January 2011.

We reviewed your firm's response and conclude that it is not adequate. The response indicated that your firm will create a protocol and conduct a validation on the in-house software system. However, the response did not indicate when these corrective actions will be completed. Additionally, your firm's corrective action plan did not include an evaluation of other software systems to ensure that they are adequately validated.

7. Failure to establish and maintain procedures to ensure that sampling methods are adequate for their intended use, as required by 21 CFR 820.250(b). For example, your firm's final QA inspection of Class II medical devices, as documented in **(b)(4)**. Additionally, your firm's **(b)(4)** requires a **(b)(4)**. However, these sampling plans are not based on a valid statistical rationale.

We reviewed your firm's response and conclude that it is not adequate. The response indicated that your firm will review the sampling plan standard and implement a valid statistical rationale for the chosen sample sizes. However, the response did not indicate when these corrective actions will be completed. Additionally, your firm's corrective action plan did not include an evaluation of all sampling plans to ensure that a valid statistical rationale is consistently implemented.

Our inspection also revealed that your firm's carbon monoxide monitors are misbranded under section 502(t)(2) of the Act, 21 U.S.C. § 352(t)(2), in that your firm failed or refused to furnish material or information respecting the device that is required by or under section 519 of the Act, 21 U.S.C. § 360i, and 21 CFR Part 803 - Medical Device Reporting (MDR). Significant violations include, but are not limited to, the following:

8. Failure to develop, maintain, and implement written MDR procedures, as required by 21 CFR 803.17. For example, your firm's Vigilance procedure, Issue 1, dated May 28, 2014, and the EU MOD Vigilance Reporting procedure, **(b)(4)**, Issue 1, dated April15, 2014, do not include MDR reportability requirements.

The adequacy of your firm's response cannot be determined at this time. The response indicated that your firm will revise the procedures to include MDR reportability requirements. However, documentation of these corrective actions has not been provided for review.

Given the serious nature of the violations of the Act, carbon monoxide monitors manufactured by your firm are subject to refusal of admission under section 801 (a) of the Act, 21 U.S.C. § 381 (a), in that they appear to be adulterated. As a result, FDA is taking steps to refuse entry of these devices into the United States, known as "detention without physical examination," until these violations are corrected. In order to remove the devices from detention, your firm should provide a written response to this Warning Letter as described below and correct the violations described in this letter. We will notify you regarding the adequacy of your firm's response and the need to re-inspect your firm's facility to verify that the appropriate corrections and/or corrective actions have been made.

Also, U.S. 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 deviations are reasonably related will not be approved until the violations have been corrected.

Please notify this office in writing, within fifteen business days from the date you receive this letter, of the specific steps your firm has taken to correct the noted violations, including 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. Please provide a translation of documentation not in English to facilitate our review.

Your firm's response should be sent to: Food and Drug Administration, Center for Devices and Radiological Health, Office of Compliance, Field Inspections Support Branch, White Oak Building 66, Room 3523, 10903 New Hampshire Ave., Silver Spring, MD 20993. Refer to CMS case #486205 when replying. If you have any questions about the contents of this letter, please contact Shumaya Ali, Acting Chief, Foreign Enforcement Branch, at feb@fda.hhs.gov (email) or +1 (240) 402-4020 (telephone).

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 yours,
/S
CAPT Sean M. Boyd, MPH, USPHS
Acting Director
Office of Compliance
Center for Devices and Radiological Health

cc:
U.S. Agent
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More in 2016 (/ICECI/EnforcementActions/WarningLetters/2016/default.htm)