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## Inspections, Compliance, Enforcement, and Criminal Investigations

### Biological Controls 2/16/10



Department of Health and Human Services

Public Health Service  
Food and Drug Administration  
Central Region  
Waterview Corporate Center  
10 Waterview Blvd., 3rd Floor  
Parsippany, NJ 07054  
Telephone (973) 331-4906

February 16, 2010

**CERTIFIED MAIL  
RETURN RECEIPT REQUESTED**

#### WARNING LETTER

Mr. Gary D. Messina  
President  
Biological Controls  
749 Hope Road, Suite A  
Eatontown, NJ 07724

10-NWJ-06

Dear Mr. Messina:

During an inspection of your firm located in Eatontown, New Jersey, on November 17, 2009 through November 30, 2009, an investigator from the United States Food and Drug Administration (FDA) determined that your firm manufactures air purification devices under the brand name MICROCON. 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 are intended to affect the structure or function of the body.

The FDA 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 (CGMP) requirements of the Quality System (QS) regulation found at Title 21, Code of Federal Regulations (CFR), Part 820.

At the close of the inspection, a FDA Investigator discussed with you the objectionable conditions observed during the inspection. On December 16, 2009, you provided a written response concerning our investigator's observations noted on the Form FDA 483, List of Inspectional Observations that was issued to you. 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). 21 CFR § 820.100(a). For example:
  - A) Your firm's written procedure for Corrective Action for Failed Components does not include requirements for analyzing all processes, work operations, concessions, quality audit reports, quality records, service records, complaints, returned product, and other sources of quality data to identify existing and potential causes of nonconforming product, or other quality problems. This is a repeat violation that was discussed with you during a previous inspection.
  - B) Your firm's Corrective and Preventive Action Practice form does not specify that you will verify or validate the corrective and preventive action to ensure that such action is effective and does not adversely affect the finished device as required by 21 CFR § 820.100(a)(4). For example, your firm needs to perform effectiveness checks in order to verify that the corrective and preventive actions were effective as to the intended purpose of the action and that new issues or concerns are not introduced.

We have reviewed your response and have concluded that it is inadequate because there is no indication that you have implemented an adequate written procedure to address the violations documented by our FDA Investigator.

2. Failure to establish and maintain procedures to control the design of the device in order to ensure that specified design requirements are met as required by 21 CFR § 820.30(a). Specifically, your firm has no design control procedures to control the design process of your device. Your firm has failed to establish a plan for the changes made to your MICRON 400 UV & 800 UV devices to determine the adequacy of the design requirements and to ensure that the design that was released to production meets the approved requirements.
3. 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). Specifically, your firm has failed to establish and maintain design control procedures for the design changes that were made to your devices during the months of May and June of 2009. For

example, your firm has made changes to the design of your MICRON 400 UV & 800UV devices by adding an (b)(4) in order to verify that the UV lamps inside the device were in working condition, and also a (b)(4) to turn off or not turn on the (b)(4) when the HEPA filter is being replaced. Your firm must establish a criterion for evaluating changes in order to ensure that the changes are appropriate for its designs.

4. Failure to establish and maintain a design history file (DHF) for each type of device as required by 21 CFR § 820.30(j). Specifically, there were no design history files for the following devices: MICROCON 400M, 400UV, 800M, 800UV, WallMAP, WallMAP PC, Ex-BB, and ExC-BB. For example, your MICROCON 800M PREPARATION LIST does not contain or reference the records necessary to demonstrate that the design was developed in accordance with the approved design plan and the requirements of this part (21 CFR § 820.30). Your firm has failed to document the complete history of the design process where such records are necessary to ensure that the final design will conform to the design specifications.

We have reviewed your response and have concluded that it is inadequate because there is no indication that you have implemented adequate written procedures to address the design control violations documented by our FDA Investigator on the FDA-483 that was issued to you.

5. Failure to maintain complaint files and 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). Specifically, your customer complaint procedure requires all customer complaints to be entered on a complaint file form. This form needs to include the customer or facility, contact person, phone number or e-mail address, product description, serial number and the date of production and the identification of the person entering the information. However, no such form was developed by your firm at the time of this inspection. For example, one complaint was handled by your firm since the last inspection conducted March 30, 2006 where the information was recorded on a Corrective and Preventive Action Practice form. The information recorded for this complaint did not have the date the complaint was received, the contact person information for the complainant, product description, date of production, and the identification of the person entering the information. This was a repeat violation that was discussed with you during a previous inspection.

We have reviewed your response and have concluded that it is inadequate because there is no evidence to show that you will establish and maintain a complaint form as required by your Customer Complaint Procedures.

6. Management with executive responsibility failed to establish its policy and objectives for, and commitment to, quality and failure to establish a quality plan which defines the quality practices, resources, and activities relevant to devices that are designed and manufactured as required by 21 CFR § 820.20 (a) and (d). Specifically, your firm failed to establish a quality policy and a quality plan at the time of this inspection. Your firm failed to take appropriate actions to ensure that your employees understand management's policies and objectives.

We have reviewed your response and have concluded that it is inadequate because there is no evidence to show that your management will ensure that your employees understand your policies and objectives through training and reinforcement on a continuous basis.

7. Failure to establish and maintain acceptance procedures to ensure that specified requirements for in-process product are met in order to ensure that in-process product is controlled until the required inspection and tests or other verification activities have been completed, or necessary approvals are received, and are documented as required by 21 CFR § 820.80 (c). Specifically, the Quality Control Checklists for your MICROCON MAP 800NIUV which documents in process inspections of components are not being filled out until the next day, and there is no system in place to verify that in-process testing activities are being completed while your devices are being assembled. Your firm has failed to identify early non conformities, before arriving at the final inspection stage, in order to avoid further processing of nonconforming product.

We have reviewed your response and have concluded that it is inadequate because there is no evidence to show that you will establish written procedures that will assure in process activities will be completed while your devices are being assembled.

8. Failure to document acceptance activities as required by 21 CFR § 820.80 (e). For example:

A. Check lists for your MICROCON devices were found to have multiple devices listed on each and contained data for only one efficiency test. Thus, there is no documentation that efficiency testing was performed for all of these devices.

B. An older version of a Check List for your WallMap device (dated May 6, 2009) was used where no efficiency testing results were recorded.

C. Results (pass or fail) for your (b)(4) tests are not being documented on your Quality Control Check Lists for each of your finished devices. This was discussed with you during the last inspection and was not adequately corrected by your firm.

We have reviewed your response and have concluded that it is inadequate because there is no evidence to show that you will adequately record all acceptance activities during production in order to control potential nonconforming product.

9. Failure to establish procedures for quality audits and conduct such 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. A report of the results of each quality audit, and reaudit(s) reports shall be reviewed by management having responsibility for the matters audited as required by 21 CFR § 820.22. Specifically, your firm does not have any written procedures relating to quality audits and management reviews, and does not conduct such audits or reviews at the time of the inspection.

We have reviewed your response and have concluded that it is inadequate because there is no indication that you will establish written procedures for conducting quality audits in order to assure that your quality system is in compliance with the established quality system regulations under 21 CFR § 820.

10. Failure to establish and maintain procedures to control all documents that are required by 21 CFR § 820.40 (a). Specifically, your firm does not document the approval date nor the signature of the approving official for your Customer Complaint Procedures, Corrective action for failed components, and Procedure for Calibrating Test equipment. Furthermore, any changes to these documents have not been recorded as required by 21 CFR § 820.40 (b).

We have reviewed your response and have concluded that it is inadequate because there is no evidence that your firm will establish and maintain a procedure to control all documents that are currently being used by your firm.

11. Failure to establish procedures for identifying training needs and ensure that all personnel are trained to adequately perform their assigned responsibilities, and training shall be documented as required by 21 CFR § 820.25 (b). Specifically, your firm has failed to establish procedures for identifying training needs and has also failed to record personnel training so that records can be updated and gaps in training can readily be identified and filed.

We have reviewed your response and have concluded that it is inadequate because your firm has failed to establish a training procedure that would ensure personnel adequately performed their assigned responsibilities, and were provided with information about the CGMP requirements and how their particular job functions relate to the overall quality system.

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 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. 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 violations, 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: Robert J. Maffei, Compliance Officer, U.S. Food and Drug Administration, 10 Waterview Boulevard, 3rd Floor, Parsippany, New Jersey, 07054. If you have any questions about the content of this letter, please contact Mr. Maffei at 973-331-4906.

Finally, you should know that 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 FDA-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 violations, and take prompt actions to correct the violations and to bring your products into compliance.

Sincerely,

/S/

Diana Amador-Toro  
District Director  
New Jersey District Office

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