



Food and Drug Administration  
Kansas City District  
Southwest Region  
11630 West 80<sup>th</sup> Street  
Lenexa, Kansas 66214-3340

Telephone: (913) 752-2100

August 23, 2004

**CERTIFIED MAIL  
RETURN RECEIPT REQUESTED**

**WARNING LETTER**  
Ref. KAN 2004-16

Mr. Russell F. Bird  
Chief Executive Officer  
Medical Industries America, Inc.  
2636 289<sup>th</sup> Place  
Adel, Iowa 50003-8021

Dear Mr. Bird:

Between June 16, 2004, and July 6, 2004, an investigator from the Food and Drug Administration (FDA) inspected your establishment, which manufactures Aeroneb<sup>®</sup> Go Micropump Nebulizers. These products are intended for use by pediatric and adult patients to aerosolize physician-prescribed solutions for inhalation that are approved for use with a general-purpose nebulizer and are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 321(h).

The 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 applicable current Good Manufacturing Practice (cGMP) requirements, which are set forth in FDA's Quality Systems (QS) Regulation, codified at Title 21, Code of Federal Regulations (CFR), Part 820. Specifically:

Failure to establish and maintain procedures for implementing corrective and preventive action, as required by 21 CFR 820.100(a). The generators, manufactured by [REDACTED], and used in the manufacturing of the Aeroneb Go have at least two identified component defects. These defects can cause the nebulizer to not start or result in a low flow. You continue to use this part in the manufacture of the nebulizer, despite knowledge of the modifications necessary to correct the problems with this component.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each applicable requirement of the Act and of FDA regulations. The specific violation noted in this letter and in the Form FDA 483 provided to

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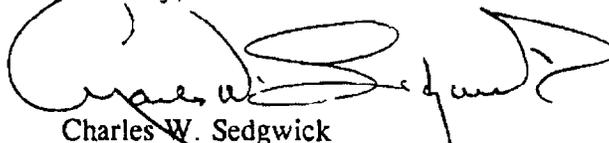
you at the close of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

You should take prompt action to correct this deviation. Failure to do so may result in FDA regulatory action without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties. Federal agencies are advised of the issuance of all Warning Letters about medical devices so that they may take this information into account when considering the award of contracts. Additionally, no premarket submissions for Class III devices to which the violation above is reasonably related will be cleared or approved until the violation has been corrected. Also, no requests for Certificates to Foreign Governments will be approved until the violation related to the subject devices has been corrected.

Our office is in receipt of your letter dated July 29, 2004, explaining the steps you are taking to correct the deviations noted on the Form FDA 483 issued to you at the close of the inspection. Please contact the District Office to schedule a meeting with us to discuss your response to this letter.

Your future correspondence should be sent to Nadine Nanko Johnson, Compliance Officer, at the above address.

Sincerely,



Charles W. Sedgwick  
District Director  
Kansas City District

cc: [REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]