



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
93185d

Dallas District
4040 North Central Expressway
Dallas, Texas 75204-3145

April 18, 2002

Ref: 2002-DAL-WL-13

WARNING LETTER

CERTIFIED MAIL
RETURNED RECEIPT REQUESTED

Mr. Albert P. Shepherd, President
A-VOX Systems, Inc.
28267 Ruffian Drive
Fair Oaks Ranch, Texas 78015-4809

Dear Mr. Shepherd:

On March 12 through 14, 2002, our FDA investigator conducted an inspection of your device manufacturing facility located at 12001 Network Blvd., Building F, Suite 210, San Antonio, Texas. Our investigator determined that your firm manufactures several models of oximeters, which are used for whole blood measurement of total hemoglobin, oxyhemoglobin, carboxyhemoglobin, methemoglobin, and oxygen content, and disposable cuvettes. These products are medical devices as defined in Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

At the conclusion of the inspection, our investigator issued a list of Inspectional Observations (Form FDA-483) to you listing significant deviations from Current Good Manufacturing Practices (CGMP). Your devices are adulterated within the meaning of Section 501(h) of the Act in that the methods used in, or the facilities or controls used for their manufacturing, packing, storage, or installation are not in conformance with the CGMP requirements of the Quality System Regulation, as specified in Title 21, Code of Federal Regulation (CFR), Part 820. Significant CGMP deviations include, but are not limited to, the following:

1. Failure to maintain device history records to demonstrate the devices are manufactured in accordance with the device master record [21 CFR 820.184]. For example, your firm did not keep test records [Individual Device Records] as required by your procedures for the six oximeter devices cited in FDA-483 Item 1.

Page 2 – Mr. Albert P. Shepherd, President
A-VOX Systems, Inc.
April 18, 2002

2. Failure to establish and maintain procedures to control product that does not conform to specified requirements [21 CFR 820.90]. For example, your firm failed to maintain the non-conforming reports (NCR) as required by your procedures for the four oximeter devices cited in FDA-483 Item 5.
3. Failure to establish and maintain procedures for implementing corrective and preventive action [21 CFR 820.100]. For example, your firm had not investigated and documented the device failure causes or completed the corrective action reports (CAR) for the non-conforming oximeter devices listed in FDA-483 Items 1, 2, and 5 in order to identify the actions needed to prevent recurrence of the device failures.
4. Failure to maintain procedures to ensure all purchased or otherwise received products and services conform to specified requirements [21 CFR 820.50; see also 820.80]. For example, your firm failed to ensure that the supplier of the main computer board (i.e., [REDACTED] Main Board) documented all of the required test results to indicate the supplier's quality acceptance of the [REDACTED] computer boards manufactured and delivered to your firm.
5. Failure to establish and maintain schedules and maintenance activities for the adjustment, cleaning, and other maintenance of manufacturing equipment [21 CFR 820.70(g)(1)]. For example, your firm does not have a maintenance procedure/schedule or keep documentation of maintenance activities for the two [REDACTED] and the [REDACTED] [FDA-483 Items 3 and 4].

Your firm orally promised our investigator that it would correct FDA-483 Items 1, 2, 5, and 6 and placed FDA-483 Items 3 and 4 under consideration. You have not provided a written response confirming your promise and outlining specific steps your firm has taken or will take to correct the above GMP deficiencies (although your firm stated its intention to respond in writing to the FDA-483 within one month of the inspection, to date we have not received such a response).

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 requirement of the Act and the regulations. The specific violations noted in this letter and in the FDA-483 issued at the close of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems.

Page 3 – Mr. Albert P. Shepherd, President
A-VOX Systems, Inc.
April 18, 2002

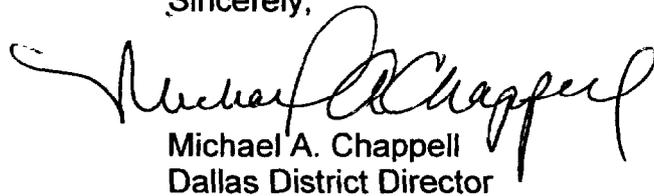
You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

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.

You should take prompt action to correct these violations. Failure to promptly correct these violations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please provide this office in writing within 15 working days of receipt of this letter a report of the specific steps you have taken, or will take to identify and correct any underlying systems problems necessary to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed. Your reply should be directed to Thao Ta, Compliance Officer, at the above letterhead address.

Sincerely,



Michael A. Chappell
Dallas District Director

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