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VIA FEDERAL EXPRESSFood and Drug Administration
555 Winderley Pl., Ste. 200
Maitland, FL 32751WARNING LETTER

FLA-99-89

September 9, 1999

Russell Mantz, President
Zefon International, Inc.
5350 S.W. First Lane
Ocala, Florida 34474

Dear Mr. Mantz:

We are writing to you because on July 26-31 & August 3, 1999 FDA Investigator R. Kevin Vogel collected information that revealed serious regulatory problems involving anesthesiology devices (breathing circuits, gas sampling lines and anesthesia circuits), which are manufactured and distributed by your firm.

Under the Federal Food, Drug, and Cosmetic Act (the Act), these products are considered to be medical devices that are used to diagnose or treat medical conditions or to affect the structure or function of the body. The law requires that manufacturers of medical devices conform to the Quality System (QS) regulation for medical devices, as specified in Title 21, Code of Federal Regulations (CFR), Part 820.

The inspection revealed that 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 the manufacture, packing, storage, or installation are not in conformance with the QS regulation. These violations include, but are not limited to the following:

;

QS Regulation/GMPs

1. Failure to validate or to establish, implement and maintain procedures for monitoring and controlling process parameters for validated processes to ensure specific requirements are met as required by 21 CFR 820.75(a) and (b)(1) & (2). For example, assessments of all process validations, personal qualifications, and the radio frequency (RF) welding process are not validated and are not documented [FDA 483, Item #1].
2. Failure to establish and maintain procedures to control nonconforming product including evaluation, review and disposition as required by 21 CFR 820.90(a) & (b). For example, there is no analysis, review or documentation of in-process rejects [FDA 483, Item #6].
3. Failure to establish and maintain procedures to ensure that all vendor supplied products conform to specified requirements through documented evaluation of both the vendor and component(s) supplied as required by 21 CFR 820.50. For example, tubing used to manufacture pediatric anesthetic circuits exhibited holes and/or splits that resulted in device failures and anesthetic filters are not adequately inspected upon arrival [FDA 483, Item #38].

DESIGN CONTROL REGULATIONS [21 CFR 820.30(i)]

4. Failure to establish and maintain a record of 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 failed to document design changes for the inner diameter of the tube in your blood pressure cuffs.

The specific violations noted in this letter and in the List of Observations (FDA 483) issued to you at the closeout 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 the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions. We have received and reviewed your firm's responses to the Inspectional Observations (Form FDA 483) dated August 12 & 31, 1999 signed by Scott Ryan, Vice President. The responses were found to be inadequate because they fail to address design control issues which are required when device failures, nonconformities, and complaints are identified resulting in corrective and preventive action or change control. Your responses have been made part of the Florida District file.

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 awards of contracts. Additionally, no premarket submissions for devices to which QS regulation deficiencies are reasonably related will be cleared until the violations have been corrected. Also, no requests for Certificates for Products for Export will be approved until the violations related to the subject devices have been corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations 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 notify this office in writing within fifteen (15) working days of receipt of this letter, of any steps you may have taken to correct the noted violations, including (1) the time frames within which the corrections will be completed if different from those annotated on the FDA 483, (2) any documentation indicating the corrections have been achieved, and (3) an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur.

Your response should be sent to Timothy J. Couzins,
Compliance Officer, Food and Drug Administration, 555
Winderley Place, Suite 200, Maitland, Florida 32751,
407) 475-4728.

Sincerely,

A handwritten signature in black ink that reads "Douglas D. Tolen". The signature is written in a cursive style with a large, looping initial "D".

Douglas D. Tolen
Director, Florida District