



May 12, 2004

Chicago District
550 West Jackson Blvd., 15th Floor
Chicago, Illinois 60661
Telephone: 312-353-5863

WARNING LETTER
CHI-9-04

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. David S. Grosky
Chairman and CEO
Efoora, Inc., dba Virotek, LLC.
900 Asbury Drive
Buffalo Grove, IL 60089-4551

Dear Mr. Grosky:

During inspection of your firm from December 12 to December 19, 2003, United States Food and Drug Administration (FDA) investigators determined that your firm manufactures lancets and inoculating loops. These products are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

This inspection revealed that these 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 manufacturing, packing, storage, or installation are not in conformance with the Quality System Regulation (QSR), Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

1. Management with executive responsibility failed to ensure that the quality policy was understood, implemented, and maintained at all levels of the organization as required by 21 CFR 820.20.
2. Your firm failed to establish adequate procedures for quality audits as required by 21 CFR 820.22. For example, audits performed of your firm's quality system failed to determine that the [REDACTED] electronic data management system lacked validation. Additionally, quality audits failed to detect that your firm was not consistently following procedures.
3. Your firm failed to establish and maintain requirements, including quality requirements, that must be met by contractors and consultants as required by 21 CFR 820.50(a). For example, your firm's Vendor Qualification Procedure, SOP-Q-401, does not include provisions for qualification of contractors and consultants.
4. Your firm failed to validate computer software used as part of the quality system as required by 21 CFR 820.70(i). For example, your firm has no documented validation activities and results for the [REDACTED] electronic data management system.

Page 2

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 regulations. The specific violations noted in this letter and in the Form FDA-483, Inspectional Observations, issued at the conclusion of the inspection may be symptomatic of serious underlying problems in your establishment's quality system. You are responsible for investigating and determining the causes of the violations identified by the FDA. You should promptly initiate permanent corrective and preventive action on your Quality System.

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. No premarket submissions for Class III devices, to which the QSR deficiencies are reasonably related, will be cleared or approved until the violations have been corrected. Also, no requests for Certificates to Foreign Governments will be approved until the violations related to the subject devices have been corrected and verified.

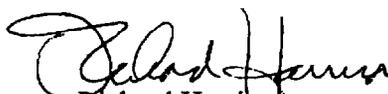
You should take prompt action to correct these deviations and to establish procedures to prevent their recurrence. Failure to promptly correct these deviations may result in regulatory action being initiated by FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

We acknowledge receipt of your responses to the Form FDA-483, dated December 19, 2003. Your responses include letters dated January 20, 22, 30, and February 17, 2004. Although it appears from your responses that you are working toward correcting the deviations noted at your firm, you must adequately implement and maintain each corrective action to ensure its effectiveness. We will verify the adequacy of your corrective actions during a subsequent inspection.

Please notify this office, in writing, within 15 working days of receipt of this letter of the specific steps you have taken to correct the noted violations, including (1) the time frames within which the corrections will be completed, (2) any documentation indicating that 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 Michael Lang, Compliance Officer, Food and Drug Administration, at 550 West Jackson Blvd., 15th Floor, Chicago, IL, 60661-5716. If you have any questions regarding this letter, please contact Mr. Lang at (312) 596-4225.

Sincerely,


Richard Harrison
Acting District Director