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Food and Drug Administration
Florida District
555 Winderley Place
Suite 200
Maitland, Florida 32751

Telephone: 407-475-4700
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VIA FEDERAL EXPRESS

WARNING LETTER

FLA-01-71

July 20, 2001-

John Postlewaite
President, CEO
VF Works, Inc.
4159 Corporate Court
Palm Harbor, Florida 34583

Dear Mr. Postlewaite:

During an inspection of your establishment located in Palm Harbor, Florida on May 29-31, 2001, FDA Investigator Ronald T. Weber determined that your establishment manufactures videoflourosopes, which are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The above-stated 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 for medical devices, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

1. Failure to establish and maintain procedures for implementing corrective and preventive actions as required by 21 CFR 820.100. For example, there are no procedures that include requirements for analyzing sources of quality data, investigating the cause of nonconformities, identifying actions needed to correct and prevent the recurrence of nonconforming product, and verifying or validating the corrective and preventive actions (FDA 483, Item #1).

Your response dated June 15, 2001 is inadequate because the new Corrective and Preventive Action procedures were not provided and no evidence of implementation or training of personnel responsible for these activities was provided. Further, there are seven items under CAPA that need to be addressed when responding to this observation and the attached procedures have not been approved as the new, implemented revisions.

2. Failure of management with executive responsibility to ensure that an adequate and effective quality system has been established as required by 21 CFR 820.20(a)(2), (a)(3)(i). For example, there are continuing CAPA violations that were listed during previous inspections, management review is inadequate and written procedures are ambiguous, and no internal QA audits have been conducted for 20 months (FDA 483, Item #2).

Your response dated June 15, 2001 appears to be adequate.

3. Failure to conduct planned and periodic audits of your quality assurance program pursuant to your own written procedures as required by 21 CFR 820.22. For example, your firm's procedures required that audits be conducted on an annual basis and, no audits have been conducted for a minimum of 20 months (FDA 483, Item #3).

Your response dated June 15, 2001 is inadequate because a complete audit has not been completed and there was no documentation provided showing those audits that have been completed.

4. Failure to establish and maintain procedures to validate the design of a device or a change in the design of a device as required by 21 CFR 820.30(g). For example, written design validation procedures covering new device designs or device changes are ambiguous and are not understood by operating personnel (FDA 483, Item #4).

Your response dated June 15, 2001 appears to be adequate.

5. Failure to establish and implement adequate record keeping procedures as required by 21 CFR 820.181. For example, device master records including device drawings (DMRs) are not signed/dated as approved by a designated individual (This observation was not listed on the FDA 483, but was discussed with you during the inspection).

Your firm's written response dated June 15, 2001 to the Inspection Observations (FDA 483) issued to you on May 31, 2001 have been reviewed and will be made part of the Florida District files.

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.

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, no pre-market submissions for Class III 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.

In order to facilitate FDA in making the determination that such corrections have been made and thereby enabling FDA to withdraw its advisory to other federal agencies concerning the award of government contracts, and to resume marketing clearance, and export clearance for products manufactured at your facility, we are requesting that you submit to this office on the schedule below, certification by an outside expert consultant that they have conducted an audit of your firm's manufacturing and quality assurance systems relative to the requirements of the device QS regulation/GMPs (21 CFR Part 820). You should also submit a copy of the consultant's report, and your certification that you have reviewed the consultant's report and that your firm has initiated or completed all corrections called for in the report.

The initial certifications of audit and corrections and subsequent certifications of updated audits and corrections (if required) should be submitted to this office by the following dates:

- Initial certifications by consultant and establishment - September 15, 2001
- Monthly reports and timeline of progress to achieve compliance to be submitted by the last day of each month until all corrective actions have been completed not to exceed 6 months.
- Final certification of accomplished corrective and preventive actions related to this Warning Letter to be submitted no later than January 15, 2002.
- An annual certification and a report of an annual audit by an outside consultant for each of the next two years covering your firm's current status with regard to the Quality Systems regulation.

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.

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,



Emma R. Singleton
Director, Florida District

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