



DEC 18 1998

**WARNING LETTER**  
**VIA FEDERAL EXPRESS**

R. David Sculati  
Chief Operating Officer  
Labtician Ophthalmics  
2140 Winston Park Drive, Unit 6  
Oakville, Ontario L6H 5V5 CANADA

Dear Mr. Sculati:

During an inspection of your firm located in Ontario, Canada, on September 8-10, 1998, our investigator determined that your firm manufactures Sterile Retinal Implants (Sclera Buckles). These products 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 their manufacture, packing, storage, or installation are not in conformity with the Good Manufacturing Practice (GMP) for Medical Devices Regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

1. Failure to ensure, through design validation, that devices conform to defined user needs, as required by 21 CFR 820.30(g). For example, the Design Validation Form [REDACTED] which is used to plan and record design validation activities, does not include the criteria used to determine whether the final product meets user requirements.
2. Failure to maintain a device master record (DMR) which includes or refers to the location of, the device specifications including appropriate drawings; production process specifications; and the quality assurance procedures, as required by 21 CFR 820.181(a), (b) & (c). For example, the device master record does not detail the specific location of the drawings, process procedures, and quality assurance procedures needed in the manufacturing of the device.
3. Failure to maintain records of acceptable suppliers, as required by 21 CFR 820.50(a)(3). For example, the list of Current Approved Key Vendors includes a packaging supplier who is no longer used and does not include the current packaging supplier.

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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 FDA 483 issued 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.

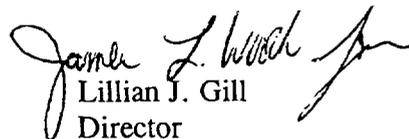
We acknowledge that you have submitted a response dated September 23, 1998, concerning our investigator's observations noted on the form FDA 483. It appears that the response is adequate to all but one observation, which was not addressed on the last FDA 483. However, a follow-up inspection will be required, to assure that corrections have been implemented. To arrange for a mutually convenient time for the inspection, please contact Mr. Ronald L. Swann, at the address above or call the telephone numbers below.

Until it has been determined that corrections are adequate, 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 pending submissions for premarket clearance for devices to which the GMP violations are reasonably related will be cleared.

You should take prompt action to correct any manufacturing or quality systems deviations identified by your internal audits. Failure to promptly correct these deviations may be identified in a follow-up inspection, and may result in the detention of your device(s) without physical examination upon entry into the United States.

If you have any questions, please contact Mr. Ronald L. Swann, at (301) 594-4613 ext. 109 or FAX (301) 594-4638 or write to the letterhead address above.

Sincerely yours,

A handwritten signature in cursive script, appearing to read "Lillian J. Gill".

Lillian J. Gill  
Director  
Office of Compliance  
Center for Devices and  
Radiological Health