



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 4 1997

WARNING LETTER

VIA FEDERAL EXPRESS

Mr. Akihiko Furuya
Senior General Manager
Olympus Optical Company, Ltd.
Hinode Factory
227 Hirai Hinode-machi Nishitama-gun
Tokyo 190-01
JAPAN

Dear Mr. Furuya:

During an inspection of your firm located in Tokyo, Japan, on September 8-11, 1997, our investigator determined that your firm manufactures various endoscopes and endotherapy accessory systems. 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 manufacturing, packing, storage, or installation are not in conformance with the current good manufacturing practice (CGMP) requirements of the Quality System Regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820. The 1978 Good Manufacturing Practices (GMP) Regulation was superseded on June 1, 1997, by the Quality System Regulation. Since the records reviewed were dated prior to June 1, 1997, the deficiencies noted during the inspection are cross referenced to the 1978 GMP's. We have not received your written response to the observations noted on the FDA 483 issued by the investigator following the inspection.

1. Failure to document all activities, and their results, for corrective and prevention actions, as required by 21 CFR 820.100(b) and 820.198(e). This would also be a violation of the GMP Regulation, 21 CFR 820.162 and 820.198(c). For example, failure investigations, corrective actions, and replies to customers concerning many complaints received by your firm since [REDACTED], of wire jamming and breakage inside the FG-45U biopsy forcep, were not documented or referenced on the "Answer Sheet" (complaint form) as required: complaint #'s

2. Failure to identify the actions needed to correct and prevent recurrence of nonconforming product and quality problems as well as failure to adequately verify or validate the corrective and preventive actions to ensure that such actions are effective and do not adversely affect the finished device, as required by 21 CFR 820.100(a)(3) and 820.100(a)(4). This would also be a violation of the GMP Regulation, 21 CFR 820.20(a)(3). For example:

- a. In order to address the wire jamming and breakage inside various biopsy forceps, a quick fix was implemented in [REDACTED], by precoating the wire to increase its strength. Your firm's [REDACTED], quality meeting minutes documented continuing wire breaking problems after this change. This corrective action was neither effectively verified nor validated. As a result, a second corrective action by reducing the space clearance of the biopsy forceps was being considered.

As of now, there is no permanent solution or effective corrective action to address this continued quality problem.

- b. In order to increase the [REDACTED] air/water valve durability against the well-known Steris disinfectant solution, the material of this valve was changed from rubber to silicon in [REDACTED]. Your firm has not effectively verified or validated the use of this new material because this change has caused the valve to swell and pop off when the recommended silicon oil was applied by users during routine cleaning and disinfection. There were five complaints of air/water valve popping off (i.e., complaint #'s [REDACTED]). A second corrective action was initiated around [REDACTED] by changing parts [REDACTED] and [REDACTED] but the swollen and popped-off valve problems continued. This is evident that the second corrective action was not effectively verified or validated. A third corrective action was being proposed by making the valve thread (part [REDACTED]) wider so that it can sit in the air/water valve assembly better.

As of now, there is no permanent and effective quality assurance solution to address this continued quality problem.

3. Failure to analyze processes, work operations, concessions, quality audit reports, quality records, service records, complaints, returned product, and other sources of quality data to identify existing and potential causes of nonconforming product, or other quality problems, as required by 21 CFR 820.100(a)(1) and 820.200(b).

This would also be a violation of the GMP Regulation, 21 CFR 820.20(a)(3). For example, quality data comprising of service, repair, and complaint data for the GF-UM20 Ultrasonic Gastrofiberscope were neither kept nor analyzed for determining existing and potential causes of quality problems.

4. Failure to collect servicing data in sufficient detail to support analysis of them for identifying existing and potential causes of nonconforming product, or other quality problems, as required by 21 CFR 820.200(d). This would also be a violation of the GMP Regulation, 21 CFR 820.20(a)(3). For example, your firm's warranty repair log for the period of [REDACTED], does not contain sufficient failure data to detect and prevent recurring quality problems in that this log did not indicate which type of defective printed circuit boards causing the operation failure of the three EU-M30 Ultrasound Processors.

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.

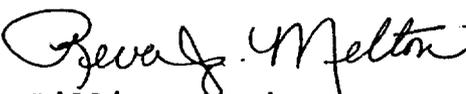
The specific violations noted in this letter and in the FDA 483 issued at the closeout of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the Food and Drug Administration. 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.

Please notify this office in writing within 15 working days of receipt of this letter, of the specific steps you have taken, or intend to take, to correct the noted violations, including 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. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed. Please include any and all documentation to show that adequate corrections have been achieved. In the case of future corrections, an estimated date of completion, and documentation showing plans for correction, should be included with your response to this letter. If the documentation is not in English, please provide a translation to facilitate our review.

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Please direct your written response to Ms. Xuan T. Vo of the Diagnostic Devices Branch, Division of Enforcement I at the above letterhead address. Should you require any assistance in understanding the contents of this letter, do not hesitate to contact her at this address, telephone 011 (301) 594-4591, or telefax 011 (301) 594-4636.

Sincerely yours,

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

cc:

Director, Regulatory Affairs
Olympus America, Inc.
Endoscope Division
Two Corporate Center Drive
Melville, New York 11747