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Food and Drug Administration
Rockville MD 20857

WARNING LETTER
VIA FEDERAL EXPRESS

MAR 15 2000

Mr. David J. Walsh
Owner
Walsh Manufacturing Ltd. P. dba Walsh Medical Devices
1209 North Services Road East
Oakville, Ontario, CANADA L6H1A7

Dear Mr. Walsh:

During an inspection of your facility located in Oakville, Ontario, Canada on December 20/21, 1999, our investigator determined that your firm manufactures and distributes Crawford Lacrimal Intubation Sets. These are devices as defined by Section 201(h) of the Federal Food, Drug and Cosmetic Act (the Act) and are subject to the Good Manufacturing Practice and Quality System Regulations set forth in the Quality System Regulation found in Title 21 of the Code of Federal Regulations (CFR) Part 820.

This current inspection disclosed that your firm may be distributing adulterated devices to the United States. Your devices are considered adulterated under section 501(h) of the Food, Drug and Cosmetic Act because the methods used in, or the facilities or controls used for manufacturing, packing, storage or installation were not in conformance with the Good Manufacturing Practice and Quality System Regulations.

The Crawford Lacrimal Intubation Sets are considered adulterated because they may have a design defect that causes the silicone tubing to separate from the metal probe. Your firm has failed to adequately investigate this failure of the device to meet its design specification as required by 21 CFR 820.90.

The current inspection revealed that your firm was not adequately investigating device failures specific to tubing and joint glue breakage of the intubation sets. However, your response indicates that your firm considers this the most frequently occurring problem with this device and you indicated that you are considering a design change because of this problem. You provided a memo to file dated January 3, 2000 that discusses this problem. However, you did not provide adequate evidence of starting a formal design change process. You need to determine a solution to this problem, document your design change process to correct his problem and demonstrate that you can manufacture this product without this defect.

Our investigator found that 15 of 17 complaints that she reviewed (a significant trend) were for this problem and indicated that one of the complaints was an MDR reportable event that had not been reported to FDA within the required 30-day time frame.

You provided an MDR report number (1926681-1999-00001) and claimed that this report was submitted on November 19, 1999, a date that was within the 30-day requirement. Our Office of Surveillance and Biometrics confirmed that this report was entered into the FDA MDR tracking system within the required time frame.

The inspection also found that your firm did not have adequate procedures for management review as required by 21 CFR 820.20 (3)(c). You had draft procedures that covered the general requirements but did not have procedures to specify defined intervals for reviews to ensure that your quality system met established quality policy and objectives. You provided a new procedure that indicates that the Management Review Committee shall meet every three (3) months or more frequently if deemed necessary. You also indicated that you had one meeting of this committee. This correction will need to be verified during a re-inspection of your firm.

The inspection also disclosed that you did not have adequate procedures for implementing corrective and preventive actions as required by 21 CFR 820.100. Your response to the FD 483 indicated that you have modified your customer complaint and problem reporting procedure following recommendations from your Management Review Committee meeting. You indicated that you will be requiring trend analysis of customer complaints to highlight problems that may be associated with specific time periods of production or specific issues. You also indicated that a formal process of reporting and analyzing quality data from the production area will be reviewed by a responsible individual for further analysis and corrective action where indicated. However, you did not provide any documentation of this new procedure. You will need to provide this documentation so that it may be evaluated prior to re-inspection of your firm to determine whether this policy is adequate, then a re-inspection will be needed to show the policy is being appropriately implemented.

The inspection also determined that your firm had not established adequate procedures for monitoring and testing bioburden or documenting acceptable bioburden limits as required by 21 CFR 820.70 (c). An adequate procedure to correct this deviation was provided prior to the closeout of the inspection.

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 on the form 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 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.

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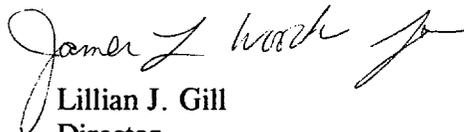
Given the serious nature of these violations of the Act, all Crawford Lacrimal Intubation Sets manufactured by Walsh Manufacturing Ltd. P. may be detained upon entry into the United States until these violations are corrected. You need to provide FDA with documentation showing adequate corrections as soon as possible.

In order to remove these devices from this detention, it will be necessary for you to provide a written response to the charges in this Warning Letter for our review. After we notify you that your response is adequate, it will be your responsibility to schedule an inspection of your facility. As soon as the inspection has taken place, and the implementation of your corrections has been verified, your products may resume entry into this country.

Please notify this office in writing within 15 days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step taken to identify and make corrections to any underlying system problems necessary to assure that similar violations will not recur. Any and all documentation showing plans for correction should be included with your response to this letter.

Your response should be sent to the attention of Ms. Mary-Lou Davis, Dental, ENT and Ophthalmic Devices Branch, at 2094 Gaither Road, HFZ-331, Rockville, Maryland 20850.

Sincerely yours,



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