

**WARNING LETTER**
VIA EXPRESS MAILFood and Drug Administration
Center for Devices and
Radiological Health
2098 Gaither Road
Rockville, MD 20850

FEB 9 2001

Mr. David J. Walsh
Owner
Walsh Manufacturing Ltd.P.
(dba Walsh Medical Devices, Inc.)
1200 South Service Road W., Unit 3
Oakville, Ontario, CANADA L6L5T7

Dear Mr. Walsh:

We are writing to you because on November 27 through 30, 2000, an investigator from the U.S. Food and Drug Administration (FDA) inspected your facility and determined that your firm continues to manufacture Crawford Lacrimal Intubation sets.

Under a United States Federal law, the Federal Food, Drug and Cosmetic Act (the Act), this product is considered to be a medical device because it is used to treat a medical condition or to affect the structure or function of the body. The above-stated inspection revealed that this device continues to be adulterated within the meaning of section 501(h) of the Act, in that the methods used in, or the facilities or controls used for the manufacturing, packing, storage, or installation are not in conformance with the Good Manufacturing Practice (GMP) requirements set forth in the Quality System (QS) regulation found in Title 21, Part 820 of the U.S. Code of Federal Regulations. The following deviations were identified:

21 CFR 820.75

Failure to validate and document production processes that could not be fully verified by subsequent inspection and test. Your firm washes the intubation sets with tap water and soap prior to packaging. This process has not been validated to ensure that any particulate matter has been removed or that no soap residue exists. Your December 13, 2000, response indicated that your firm was [REDACTED] and that you hoped to provide FDA with a validation protocol and initial results by February 1, 2001. At the time of our review, no further response had been received from your firm.

Also in June 2000, your firm decided to use a dry heat oven to control the adhesive drying process, but did not conduct any validation to ensure that the device was not adversely affected and still met your specifications. Your December 2000, response indicated that you planned to evaluate the dry heat oven and drying cycle utilizing IQ, OQ and PQ according to documented protocols. You indicated that you hoped to complete this evaluation by February 15, 2001.

21 CFR 820.70 (c)

Failure to establish and maintain, document and review procedures to adequately control environmental conditions that could reasonably be expected to have an adverse effect of product quality. (This observation was also noted on the previous Warning Letter sent to you in March 2000 concerning your previous location.) The controlled environment area at your new location has not been validated and your firm has not established specifications for particulate, humidity or temperature. You also have no specification for the tap water used in the controlled environment and no testing is conducted to verify the water quality.

Your December 2000, response indicated that you had ordered a calibrated particle counter that you planned to use to monitor the air quality in the controlled environment room. You also planned to develop a protocol for establishing room norms for particle counts, Rodac plate counts, temperature and humidity. You also expected to install a new water treatment system. However, FDA has received no documentation regarding any of these plans at the time of our review.

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 its implementing 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 systems. You are responsible for investigating and determining the causes of the violations identified by FDA. When the violations involve systems problems, you must promptly initiate permanent corrective actions.

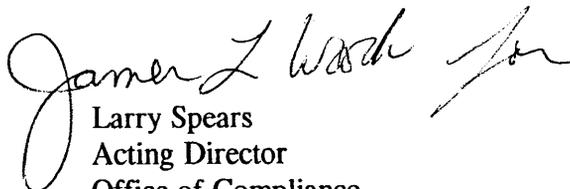
We acknowledge that Walsh Manufacturing Ltd. P. submitted to this office a response to our investigator's observations noted on the FDA-483. We have reviewed your response and have concluded that it is inadequate in that it is necessary for FDA to receive documentation showing that you have implemented the new procedures developed to address the identified deficiencies. When you submit this documentation, you should indicate when these procedures will be implemented and when your facility will be ready for re-inspection by FDA to verify your corrections.

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. Given the serious nature of the violations that have been identified, all devices manufactured at Walsh Manufacturing Ltd. P. may continue to be detained upon entry into the United States until these violations are corrected.

Page 3 - Mr. David J. Walsh

Your response should be sent to Mary-Lou Davis, 2094 Gaither Road (HFZ-331), Rockville, Maryland 20850.

Sincerely yours,

A handwritten signature in black ink that reads "Larry Spears". The signature is written in a cursive style with a large initial "L" and a long horizontal stroke at the end.

Larry Spears
Acting Director
Office of Compliance
Center for Devices and Radiological Health