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VIA CERTIFIED MAILFood and Drug Administration
555 Winderley Pl., Ste. 200
Maitland, FL 32751**WARNING LETTER**

FLA-03-38

July 17, 2003

Jonathan J. Vitello, President
International Medical Industries, Inc.
2881 West McNab Road
Pompano Beach, Florida 33069

Dear Mr. Vitello:

During an inspection of your establishment located in Pompano Beach, Florida on May 12-14, 2003, United States Food and Drug Administration (FDA) Investigator R. Kevin Vogel determined that your establishment is a manufacturer of sterile micro tubing extension sets and mini-spike sets, sterile radioisotope bolus injection units, sterile tamper evident caps, and various types of sterile needles (Class II). These products are used by medical practitioners to deliver drugs and IV fluids to patients for medical therapy and they are devices under section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The investigator documented violations of the Act causing the device(s) to be adulterated within the meaning of section 501(h) and misbranded within the meaning of section 502(t)(2) of the Act. The Act requires that manufacturers conform to the Quality System (QS) Regulation for medical devices, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, and Medical Device Reporting, as specified in Title 21, Code of Federal Regulations (CFR), Part 803.

Quality System Regulation

The investigator noted the following violations of the QS regulation, which render your devices adulterated within the meaning of section 501(h) of the Act:

1. Your firm's procedures for conducting quality audits are not complete as required by 21 CFR 820.22. Your firm failed to identify and document Quality System regulation sections including: Corrective and Preventive Action, Process Validation, Purchasing Control, and Design Control for coverage during internal audits. Your firm also failed to document internal audits required to be completed twice a year as declared in your own audit schedule (FDA 483, Item #5).

Your response dated June 3, 2003 is inadequate because the observation is not addressed except to state that correction is promised in the future. Your response fails to state when you expect to make correction and when internal audits will be conducted pursuant to your own audit schedule.

2. Your firm failed to validate processes whose results cannot be fully verified by subsequent inspection and test according to established procedures as required by 21 CFR 820.75(a). Your firm lacks process validation of the injection molding process; the validation for the package seal process including post-sterilization of the product is incomplete; there is no validation of the drying process for Cyrolite plastic, and there is no heat distribution study for the gas exposure time during the EO sterilization cycle (FDA 483, Item #1).

Your response dated June 3, 2003 is inadequate because it only promises future corrective action. Your response also addressed a heat distribution study, which is inadequate because it fails to provide a protocol used to conduct the heat study and to identify the placement of probes in the empty chamber.

3. Your firm's corrective and preventive action (CAPA) procedures are not complete as required by 21 CFR 820.100. For example, there is no written procedure addressing the requirement to complete quality analysis and verification/validation to assure actions taken are effective and not detrimental to the finished device; there was no validation of changes to the molding process in response to a 2002 complaint, which identified a tamper-resistant cap coming off without breaking the sleeve; and there was no validation of changes to the molding process to ensure compatibility between tamper-resistant caps and Monoject syringes. Furthermore, none of these changes were adequately documented (FDA 483, Item #6).

Your response dated June 3, 2003 is inadequate because it fails to address design changes to ensure that documentation, validation, or where appropriate verification, review, and approval of design changes before implementation. Your responses referencing the 2002 complaint with respect to validation of changes to the molding process and validation of compatibility of tamper-resistant caps to monoject syringes are not addressed. A QC test of retained samples does not replace an adequate investigation and evaluation of a complaint including the resulting corrective and preventive action taken. Testing of retained samples is only one aspect of a complaint investigation that must be undertaken to determine the root cause of the problem.

4. Your firm failed to establish and maintain requirements to verify each supplier's Certificates of Analysis assuring that they are accurate as required by 21 CFR 820.50(a)(1). You fail to verify that supplied components including various plastics and EO gas meets your specifications for processing by periodic audit of the supplier or test of the product (FDA 483, Item #4).

Your response dated June 3, 2003 is inadequate because medical test data does not address the acceptability of the supplied product for processing and you failed to provide copies of independent lab tests of the EO for our review.

5. Your firm failed to establish procedures to calibrate and maintain inspection, test and measuring equipment as required by 21 CFR 820.72(a). Your firm failed to perform calibration of pressure gauges and timers used to monitor the injection molding machines; to perform calibration of scales used to weigh cylinders of EO gas; to document calibration of temperature sensors used during empty chamber heat penetration studies, which was last accomplished in 1996; to complete the leak check of the EO sterilizer vacuum pump or to clean the vaporizer used with the EO sterilizer; and to complete mold maintenance to ensure the molds are clean and in good repair (FDA 483, Item #2).

Your response dated June 3, 2003 fails to provide adequate documentation showing that the calibration of scales and temperature sensors was conducted. Further, ISO requirements do not always coincide with AAMI and FDA requirements. You should check the current AAMI requirements to ensure that the number and placement of probes is adequate. Your response did not provide copies of documentation of the vacuum pump leak check and maintenance of the vaporizer. Your response addressing mold maintenance appears to be adequate.

6. Your firm's records of complaint investigations do not include the nature and details of the complaint as required by 21 CFR 820.198(e)(5). A complaint reported a bolus injection unit that burst, resulting in the radiopharmaceutical contents spraying onto a patient's head. There was not enough information obtained to determine the reportability of the incident under MDR (FDA 483, Item #8).

Your response dated June 3, 2003 is inadequate because the only individuals that can assess the hazard presented to a patient are licensed medical practitioners including nurses, medical technologists and physicians. The author of the letter does not appear to have the knowledge and/or experience to make this determination. It is your firm's responsibility to fully review and investigate all complaints. The letter from Tuen Mun Hospital also requests that your firm, "investigate and provide an investigation report on the incident." There is no evidence reported that this was accomplished.

7. Your firm's procedures to control the design process are incomplete. [See 21 CFR 820.30(a)]. Your design control procedures fail to address requirements for design validation, change, risk analysis, and the need to submit a new 510(k) premarket notification (FDA 483, Item #7).

Your response dated June 3, 2003 states that your design control procedures are under review. Please provide documentation covering any actions taken to address this observation.

8. Your firm failed to assure that devices provided to an own-label distributor meet stability requirements. [See 21 CFR 820.150 and 820.120]. Devices provided to the distributor declare a 3 year expiration when data only supports a 2 year expiration (FDA 483, Item #9).

Your response dated June 3, 2003 is inadequate because it fails to relate reported test results to corresponding dates, it does not identify the tests conducted, the analyst, or the individual verifying that test results are accurate and supportable.

9. Your firm failed to identify training needs as required by 21 CFR 820.25(b). Personnel qualification to conduct manual processes such as bonding and rubber valve application was not completed to ensure that individuals could successfully conduct each process consistently meeting specifications (FDA 483, Item #3).

Your response dated June 3, 2003 is inadequate because it fails to address the observation, i.e., to identify training needs of individuals, scheduling periodic review of personnel capabilities to ensure that designated tasks are conducted successfully and consistently, and to document each personnel training folder as appropriate.

Medical Device Reporting (MDR)

Your devices are misbranded within the meaning of section 502(t)(2) in that there was a failure to comply with a requirement prescribed under section 519 of the Act respecting the device as follows:

10. Your firm failed to establish and maintain adequate written MDR procedures as required by 21 CFR 803.17. The MDR procedure fails to address malfunction in its definition of a MDR event, lacks requirement for baseline form, and fails to address which MDR events should be sent (FDA 483, Item #10).

Your response dated June 3, 2003 is inadequate because it states that your MDR procedures are under review and promises to modify the procedure to achieve compliance in the future. Please provide a copy of any corrective actions for our review documenting the modifications taken.

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. 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.

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. Additionally, no premarket 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.

Please notify this office in writing, within fifteen (15) working days of receipt of this letter, of the steps you have taken to correct the noted violations, including (1) the time frames within which the corrections will be completed, (2) any documentation indicating the corrections have been achieved, and (3) 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. 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,

A handwritten signature in black ink, appearing to read 'Emma Singleton', with a long horizontal flourish extending to the right.

Emma Singleton
Director, Florida District