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**DEPARTMENT OF HEALTH & HUMAN SERVICES**

**Public Health Service  
Food and Drug Administration**

May 23, 1997

**WARNING LETTER**  
**CHI-29-97**

Chicago District  
300 S. Riverside Plaza, Suite 650 South  
Chicago, Illinois 60606  
Telephone: 312-353-5863

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

Mr. Kenneth Maltas, President  
Orion Life Systems, Inc.  
97 Marquardt Drive  
Wheeling, IL 60090-6423

Dear Mr. Maltas:

During an inspection of your firm from March 21 to April 15, 1997, Investigator Tamara Alicea determined that your firm manufactures prefilled syringes (for flushing devices) and medical procedure kits. Prefilled syringes and medical procedure kits are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The inspection revealed that the methods used in, or the facilities or controls used for manufacturing, packing, storage, or installation are not in conformance with the Good Manufacturing Practice (GMP) Regulations for Medical Devices and Drugs, as specified in Title 21, Code of Federal Regulations (CFR), Parts 820 and 211, as follows:

1. Failure to control changes to manufacturing processes and device packaging. For example, the radiation dose range was widened for the sterilization of water, saline and acetic acid jars and syringes. The effect of the (radiation dose) change on product packaging was not evaluated before effecting this change. Also, a change was made adding two inner pouches to the chevron pouch for 60cc syringes. Product was manufactured and packaged on February 13, 1997. The change documentation was approved on February 20, 1997.
2. Failure to maintain stability data that supports the storage conditions and expiration dates for device kits containing drugs: povidone iodine and hydrogen peroxide.
3. Sterility failures in samples from dose audits (of the gamma irradiation cycles) are replaced with new units and retested. In April 1996 and June 1996, sterility test failures were found during the quarterly dose audits. After your contract laboratory determined that the vials were contaminated within the lab, replacement vials were retrieved and retested to obtain the acceptable number of vials. A complete sample retest should be made.

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We acknowledge the receipt of your response to our FDA 483, dated April 18, 1997. We have reviewed your response and find that it does not adequately address our concerns. For example, you continue to justify replacement of individual samples for a failed dose audit. We do not agree with this practice.

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.

In order to facilitate FDA in making the determination that such corrections have been made and thereby enabling FDA to withdraw its advisory to other federal agencies concerning the award of government contracts, and to resume marketing clearance, and export clearance for products manufactured at your facility, we are requesting that you submit to this office on the schedule below, certification by an outside expert consultant that it has conducted an audit of your firm's manufacturing and quality assurance systems relative to the requirements of the device and drug GMP regulations (21 CFR, Parts 820 and 211). You should also submit a copy of the consultant's report, and certification by your firm's CEO (if other than yourself) that he or she has reviewed the consultant's report and that your firm has initiated or completed all corrections called for in the report. The attached guidance may be helpful in selecting an appropriate consultant.

The initial certifications of audit and corrections and subsequent certifications of updated audits and corrections (if required) should be submitted to this office by the following dates:

- o Initial certification by consultant - 6/15/97
- o Subsequent certification - 6/15/98

Until these violations are corrected, and FDA has documentation to establish that such corrections have been made, Federal Agencies will be 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 export approval requests will be approved.

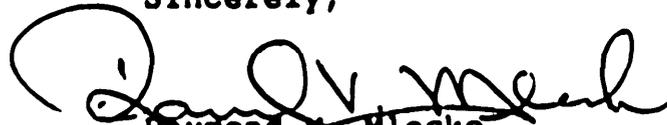
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You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions can include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office in writing within 15 working days of receipt of this letter regarding the specific steps you have taken to correct the above violations, including an explanation of each step being taken to prevent the recurrence of similar violations. 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.

Your response should be sent to Stephen D. Eich, Compliance Officer.

Sincerely,

  
Raymond V. Mlecko  
District Director

Enclosure

cc: Mr. John Laemmar  
Executive Vice President/Co-Owner  
Orion Life Systems, Inc.  
97 Marquardt Drive  
Wheeling, IL 60090-6423