



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

g426801

August 26, 2003

Ref: 2003-DAL-WL-17

Dallas District
4040 North Central Expressway
Dallas, Texas 75204-3145

WARNING LETTER

CERTIFIED MAIL
RETURNED RECEIPT REQUESTED

Mr. Alfred C. Coats
President and Chief Executive Officer
Life-Tech, Inc.
4235 Greenbriar Dr.
Stafford, Texas 77477

Dear Mr. Coats:

Our review of information collected during an inspection of your firm located at the above-referenced address on May 22 through June 23, 2003, revealed that your firm manufactures gastroenterological and urological devices, such as Urine Collection Bags, Peripheral Nerve Stimulators and Locators, Trace II Nerve Locator for Regional Blocks, Trace III Digital Nerve Locator, Digital Uroflowmeter, and Urodynamic Systems and Catheters. These products are devices as defined in 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 their manufacturing, packing, storage, or installation are not in conformance with the Current Good Manufacturing Practice (CGMP) requirements of the Quality System Regulations for medical devices, as specified in Title 21, Code of Federal Regulation (CFR), Part 820. At the close of the inspection, you were issued a Form FDA-483 which delineated a number of significant GMP inspectional observations which include, but are not limited to, the following:

1. Failure to establish and maintain complaint handling procedures to ensure that records of investigation of MDR reportable events include all the information required by 21 CFR 820.198(d). For example, your firm received a complaint of septicemia in three patients using the Belly Bags (urine collection devices). Your investigation record does not include a

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determination of (a) whether the devices failed to meet specifications; and (b) the relationship, if any, of the devices to the reported incident or adverse event [FDA-483 Items 1, 2, 3].

2. Failure to establish and maintain complaint handling procedures to include the dates and results of the investigation [21 CFR 820.198(e)(6)]. For example, your firm received a number of complaints alleging that balloons had come off the RPC-9PU catheter body and stayed in the patients when the catheters were removed. Your firm subsequently investigated the returned catheters but failed to document the results of the investigation and possible root causes [FDA-483 Item 4(a) and (b)].
3. Failure to establish and maintain corrective and preventive action procedures to include investigating and documenting the cause of nonconformities relating to product, processes, and the quality system [21 CFR 820.100(a)(2)]. For example, in February, 2002, your firm initiated a recall of the Uropump Tube and Uropump Damping Chamber for a non-sterility problem but failed to determine or document whether the non-sterility problem was caused by packaging seal failures, contamination in the product, or defects in packaging material [FDA-483 Item 5(b)].
4. Failure to establish and maintain procedures for the identification, documentation, evaluation, segregation, and disposition of nonconforming product [21 CFR 820.90(a)]. For example, your firm did not document the investigation of the root cause of the post sterilization seal strength failures in a particular pouch [Part # ██████████] [FDA-483 Item 5(a)].
5. Failure to establish and maintain procedures for rework to include retesting and reevaluation of the nonconforming product after rework to ensure that the product meets its current approved specifications [21 CFR 820.90(b)(2)]. For example, your firm reworked the Uropump Tube and Uropump Damping Chambers as a result of Recall # Z-1091-02 to Z-1096-02 by exposing them to ██████████ full sterilization cycle. Your firm lacked validation documentation showing the products can withstand ██████████ sterilization ██████████ [FDA-483 Item 6 and 7(a)].
6. Failure to adequately validate the sterilization process with a high degree of assurance [21 CFR 820.75(a)]. For example, in order to increase the likelihood of sterility, your firm decided to subject the Uropump products to ██████████ sterilization ██████████ after the recall (Recall # Z-1091-02 to Z-1096-02) but failed to validate this process to ensure a high degree of sterility assurance

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level. Your firm also failed to determine the root cause confirming whether or not the previous [REDACTED] cycle sterilization was adequate [FDA-483 Item 6].

7. Failure to establish and maintain design plans that describe or reference the design and development activities and define responsibility for implementation [21 CFR 820.30(b)]. For example, your firm's design/project plan, consisting of [REDACTED] Charts for the Tracer III design, did not contain or reference and assign responsibility for conducting device design risk analysis and design reviews [FDA-483 Item 13].

Our inspection also documented that your firm failed to obtain and provide FDA with information that is incomplete or missing from MDR reports submitted by user facilities [21 CFR 803.50(b)(2)] [FDA-483 Items 2 and 3]. In July, 2001, your firm received a complaint of septicemia in three patients using the Belly Bags, urine collection devices, at a nursing home and initiated an investigation of the cause of this adverse event by contacting the user facility in question. Your firm could not determine a possible root cause of this adverse event, and your MDR event file remains incomplete at the time of this inspection. Your firm failed to provide documentation or document the details explaining why your firm could not obtain the necessary information from the user facility (i.e., how many phone calls you made to the facility with dates and time, who you talked to, what information or records you requested from the user facility, and what statements or records the user facility provided).

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 the regulations. The specific violations noted in this letter and in the Form FDA-483 issued at the close 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. You also must promptly initiate permanent corrective and preventative action on your quality system.

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 violations. Failure to promptly correct these violations 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.

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Please provide this office in writing within 15 working days of receipt of this letter a report of the specific steps you have taken, or will take to identify and correct 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 frame within which the corrections will be completed.

Your reply should be directed to Thao Ta, Compliance Officer, at the above letterhead address. If you have any questions concerning this matter, you may contact Mr. Ta at (214) 253-5217.

Sincerely,

A handwritten signature in black ink, appearing to read "Michael A. Chappell". The signature is written in a cursive style with a long horizontal stroke extending to the left.

Michael A. Chappell
Dallas District Director

MAC.txt