



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Cincinnati District Office
Central Region
6751 Steger Drive
Cincinnati, OH 45237-3097
Telephone: (513) 679-2700
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August 18, 2003

WARNING LETTER
CIN-03-18581

VIA FEDERAL EXPRESS

Mr. Phillip E. Muccio
President
Bioflex Inc.
3055 Templeton Road
Columbus, OH 43209

Dear Mr. Muccio:

An inspection of your medical device manufacturing firm located in Columbus, OH conducted by our investigator on July 14, 17 & 21 2003, revealed that your firm manufactures electrical stimulation devices. These products are medical devices as defined in section 201(h) of the Federal Food, Drug and Cosmetic Act (the Act).

Your 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 manufacturing, packing, storage, or installation are not in conformance with the Quality System Regulation (QSR), as specified in Title 21, Code of Federal Regulations (CFR), Part 820. The deviations from the QSR include, but are not limited to, the following:

Management Controls

1. Failure to establish adequate management controls to ensure that an effective quality system has been established and maintained. [21 CFR 820.20] For example:
 - A quality policy has not been established, documented, and implemented. [21 CFR 820.20(a)]
 - A quality plan has not been established, documented, and implemented. [21 CFR 820.20(d)]
 - A management representative has not been appointed. [21 CFR 820.20(b)(3)]

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- Management with executive responsibility has not conducted reviews of the quality system. [21 CFR 820.20(c)]
 - Quality system procedures have not been established. [21 CFR 820.20(e)] For example, there are no procedures for conducting management reviews, for conducting quality audits and for controlling the design process.
2. Failure to conduct quality audits to assure that the quality system is in compliance with the established quality system requirements and to determine the effectiveness of the quality system. [21 CFR 820.22]
 3. Failure to adequately train personnel to perform their assigned responsibilities. [21 CFR 820.25(b)] Specifically, no quality or manufacturing employees have been trained on the quality system regulations.

Production and Process Controls

4. Failure to have procedures for addressing the identification, documentation, evaluation, segregation, disposition, and investigation of nonconforming products; and failure to document any nonconformances. [21 CFR 820.90(a)]
5. Failure to document rework and reevaluation activities, including a determination of any adverse effect from the rework upon the product, in the device history record. [1 CFR 820.90(b)(2)] Specifically, the FDA investigator was told that if a wire is found to be nonconforming during finished product testing, the wire is replaced, but no record of the nonconforming wire and rework is maintained.
6. Failure to perform acceptance activities, including inspections, tests, and other verification activities, for incoming components and in-process product; and failure to establish procedures for receiving, in-process and finished device acceptance. [21 CFR 820.80]
7. Failure to develop, conduct, control, and monitor production processes to ensure that the electrical stimulation garments conform to its specifications. [21 CFR 820.70(a)] Specifically, the instructions for manufacturing the stimulation garments do not list or refer to the device specifications; do not specify which components or parts are to be used; do not specify the precise placement of the electrodes; and do not describe how the wiring must be attached. Also, these instructions have not been approved and dated by a designated individual.

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8. Failure to establish procedures to ensure that equipment is routinely calibrated, checked and maintained. [21 CFR 820.72(a)] For example, the [REDACTED] meter used to test the electrodes on the BioShort electronic stimulation garments has not been calibrated and there is no calibration program for this meter.
9. Failure to establish a Device Master Record for the electronic stimulations garments. [21 CFR 820.181]
10. Failure to establish procedures to ensure that the device history records for each batch, lot or unit are maintained to demonstrate that the device is manufactured in accordance with the device master record and the Quality System Regulation. [21 CFR 820.184] Specifically, the device history records do not include the following: the dates manufactured, quantity manufactured, quantity released for distribution, acceptance records to demonstrate the device is manufactured in accordance with the device master record, and primary identification label and labeling used for each production unit.

Corrective and Preventive Actions

11. Failure to establish procedures for implementing corrective and preventive actions; and failure to document corrective and preventive activities, including analysis of quality data sources, investigations of causes of nonconformances, and implementation of corrective and preventive actions. [21 CFR 820.100]
12. Failure to establish complaint handling procedures for receiving, reviewing, and evaluating complaints and failure to document the failure investigations and corrective actions taken. [21 CFR 820.198(a)] Specifically, the complaint received on 6/29/01 concerning the Bioflex garment's Velcro pulling loose did not document any failure investigations and any corrective actions taken.
13. Failure to develop written Medical Device Reporting procedures. [21 CFR 803.17]

Design Controls

14. Failure to establish a design change control procedure for the identification, documentation, validation or where appropriate verification, review, and approval of design changes before their implementation. [21 CFR 820.30(i)]

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You should know that these are serious violations of the law. You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the FDA without further notice. Possible actions include, but are not limited to, seizure, injunction, and/or civil penalties.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. As president of Bioflex Inc., it is your responsibility to assure adherence to each requirement of the Act and regulations. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be system problems, you must promptly initiate permanent corrective actions.

Please notify this office in writing within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct these deficiencies. In addition, please submit any additional documentation to show the corrections initiated in conformance with the requirements of the Quality System Regulation. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the timeframe within which the corrections will be completed.

Federal agencies are advised of the issuance of all Warning Letters about medical devices so that they may take this information into account when considering the award of contracts. Additionally, no requests for Certifications to Foreign Governments will be approved until the violations related to the subject devices have been corrected.

Your written response to this Warning Letter should be sent to Ms. Gina Brackett, Compliance Officer, Food and Drug Administration, 6751 Steger Drive, Cincinnati, Ohio 45237. If you have any questions concerning the contents of this letter, you may contact Ms. Brackett at (513) 679-2700, extension 167, or you may forward a facsimile to her at (513) 679-2773.

Sincerely,



Carol A. Heppe
District Director
Cincinnati District