



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration  
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Central Region  
6751 Steger Drive  
Cincinnati, OH 45237-3097  
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**WARNING LETTER**  
CIN-WL-02-14352

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

August 15, 2002

Richard J. Fisher, President  
Selective Med Components, Inc.  
6 S. Mechanic Street  
Mt. Vernon, Ohio 43050

Dear Mr. Fisher:

We are writing to you because during an inspection of your firm located at the above address by the Food and Drug Administration (FDA) on July 8-16, 2002, our Investigators collected information that revealed serious regulatory problems involving electrode products such as TENS leads/electrodes, NMES electrodes/leads and Buffered Iontophoretic Delivery Electrode System Treatment Kits which are manufactured and distributed by your firm.

Under section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act), these products are considered to be medical devices. The law requires that manufacturers of medical devices conform with the requirements of the Quality System Regulation as specified in Title 21, Code of Federal Regulations (CFR), Part 820.

The FDA inspection revealed that your firm's medical 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 the manufacture, processing, packing, storage or distribution are not in conformance with the requirements of the Quality System Regulation as follows:

Failure to ensure that finished devices meet all specifications prior to distribution (21 CFR 820.160).

- Procedures for the control and distribution of finished devices have not been established to ensure that only devices approved for release are distributed. In addition, procedures are not in place to ensure that only devices that meet current specifications are distributed. For example, design changes made to the Buffered Iontophoretic Delivery Electrode System device under Engineering Change Request (ECR #4 were transferred to production but the previous obsolete design of the device was not removed from available inventory and there is no procedure in place to ensure that only the newly approved design of the device could be distributed.

Failure to establish and maintain procedures to control product that does not conform to specified requirements and failure to document the investigation of nonconforming product (21 CFR 820.90(a)).

Nonconformances that occur during the manufacturing and assembly process of your medical devices are not evaluated. For example, a review of [REDACTED] device history records (DHRs) by the FDA Investigators revealed that all [REDACTED] DHRs contained devices that were refused due to nonconformances. None of these nonconformances were evaluated to determine if there was a need for an investigation.

Failure to establish and implement an adequate complaint handling program (21 CFR 820.198(a) (3)).

For example, complaints regarding patient burns when using the Buffered Ionophoretic Delivery Electrode System device were not adequately evaluated to determine whether the complaints represent events which are required to be reported to FDA under 21 CFR part 803, Medical Device Reporting (MDR). Decisions were based on information from the complaint summary and investigations which were incomplete, limited in scope and did not contain information sufficient to make a determination not to file the MDRs (e.g., severity of the burns or circumstances under which the burns were caused).

Failure to adequately verify or validate corrective and preventative actions to ensure that such actions are effective and do not adversely affect the finished device (21 CFR 820.100(a) (4)).

For example, several changes were made under ECR# 004 as a preventive action to eliminate the possibility of a concentration of current or a "hot spot" on the electrode which could increase the possibility of skin irritation or a burn. The changes included a change of the [REDACTED]. In addition, the top layer of [REDACTED] on the electrodes was changed to [REDACTED] and a [REDACTED] was added to the center of each [REDACTED] piece. The testing efforts that were performed were limited to testing firm employees with the electrode devices and reporting the degree of comfort and the degree of redness of the employees' skin after the electrodes were removed. No tests for example, were performed to determine if the changes made to the device have any adverse affects on the drug delivery aspects of the device. In addition the Iontophoresis electrode device used in the tests is not used in the United States or by any of your firm's customers.

Failure of management with executive responsibility to ensure that an adequate and effective quality system has been established at your firm (21 CFR 820.20).

Your firm's quality audits are not adequate to determine the effectiveness of your quality system, as required by 21 CFR 820.22. For example, internal audits are inadequate to ensure the quality system is in compliance with production and processing controls, design control, and corrective and preventive actions (CAPA). Although three quality audits which covered the above mentioned areas were performed by your firm on 9/7/01, 11/22/01, and 2/19/02, this FDA inspection revealed significant deficiencies in the same areas.

In addition, your firm does not maintain an adequate organizational structure to ensure that devices are designed and produced in accordance with the Quality System Regulation requirements, as required by 21 CFR 820.20(b). For example the same individual who participates in designing a device is the same individual who is responsible for quality assurance functions.

Procedures for identifying training needs have not been established and there is no assurance that all personnel are trained to adequately perform their assigned responsibilities, as required by 21 CFR 820.25(b). For example, of [REDACTED] employees' records (including the QA Manager's) sampled by the FDA Investigators, none of the records contained documentation that the individuals have received training in quality system requirements.

Failure to establish and implement adequate recordkeeping procedures (21 CFR 820.181 and 21 CFR 820.184)).

For example, the device master record (DMR) for the Buffered Iontophoretic Delivery Electrode System Treatment Kit does not include or refer to the location of packaging procedures and specifications. In addition, the DMR does not include or refer to the location of quality assurance procedures and specifications including acceptance criteria.

The device history records for the Buffered Iontophoretic Delivery Electrode System Treatment Kit do not include all steps performed during the manufacture, assembly and packaging of the device. Specifically, the device history records do not show that the Buffered Iontophoretic Delivery Electrode System Treatment Kit device is assembled as a kit containing an active drug delivery electrode and a return electrode, two alcohol swabs, and an insert label. In addition, the device history records do not include complete acceptance records that demonstrate the device is manufactured in accordance with the device master record. Also, label and labeling used for each finished product, lot, or batch were not adequately documented and kept in the DHRs. Also, there is no documentation in the DHRs to show that labels were issued, examined, and released for usage.

Failure to establish and maintain adequate procedures to control the design of the device in order to ensure that the specified design requirements are met (21 CFR 820.30(a)(1)).

For devices to which design changes are made, adequate procedures are not established and maintained to ensure that the design requirements relating to the device are appropriate and address the intended use of the device, including the needs of the user and patient. In addition, there is no documentation of the review and approval of the design input requirements by an authorized individual, as required by 21 CFR 820.30(c)).

Your firm's Engineering Change Request Procedure (QSM 5 dated 12/23/99), which addresses design control for design changes does not include requirements for review or approval of design inputs. The design changes made to the Buffered Iontophoretic Delivery Electrode System device under ECRs #1-#9 did not include inputs related to user needs and the intended use of the device and design input requirements were not reviewed and approved by an authorized individual.

Adequate procedures are not established and maintained for defining and documenting design output, as required by 21 CFR 820.30(d). For example, there is no documentation that design outputs were defined and documented for design changes performed under ECR #1-#9 for the Buffered Iontophoretic Delivery Electrode System device.

Adequate procedures are not established and maintained to verify and or validate the device design and to confirm that the design output meets the design input requirements for a device, as required by 21 CFR 820.30(f) and (g). Design changes made to the Buffered Iontophoretic Delivery Electrode System device under ECR #1-# 9 were not adequately validated to ensure that the device conforms to defined user/patient needs and intended uses. For example, all testing conducted for ECRs #1-#9 was conducted using only one of the drugs typically used in conjunction with the Buffered Iontophoretic Delivery Electrode System Treatment device. Also risk analysis was not performed for the design changes made to the device.

Your firm's Engineering Change Request Procedure (QSM 5 dated 12/23/99) which covers design control procedures for design changes does not include a mechanism for addressing incomplete, ambiguous, or conflicting requirements as required in 21 CFR 820.30(c).

Failure to adequately control environmental conditions in order to assure that the manufacturing site does not have an adverse effect on a device's fitness for use (21 CFR 820.70(c)).

Manufacturing and assembly of the electrodes are conducted on carpeted floors and no precautions are taken to prevent electrostatic discharge.

Failure to establish and maintain procedures to ensure that equipment is routinely calibrated, inspected, checked, and maintained (21 CFR 820.72(a)).

For example, the iontophoresis electrode device that was used by your firm for conducting verification testing of design changes made under ECR# 004 has not been calibrated or checked to determine if the device is functioning properly to deliver the correct current for a set time.

Failure to adequately ensure that incoming product is inspected, tested, or otherwise verified as conforming to specified requirements (21 CFR 820.80(b)).

For example, the FDA Investigators observed that an employee performing incoming component testing of the [REDACTED] coating (Part number [REDACTED]), which is a component of the Buffered Iontophoretic Delivery Electrode System did not perform the test according to your firm's written procedure (QP12, REV. A dated

02/01/02) for testing the component. For example, the employee was observed using a sample material test size of about [REDACTED] in length instead of the [REDACTED] sample of material specified in the procedure.

Failure to base sampling plans on a valid statistical rationale (21 CFR 820.250(b)).

For example, the sampling plans used for incoming component testing do not include a rationale for the acceptable quality level (AQL) used. Also, there are no procedures in place covering the review of sampling plans for incoming components.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and on the Form FDA 483 issued at the closeout of the FDA 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.

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 pre-market submissions for Class III devices to which the Quality System/GMP deficiencies are reasonably related will be cleared or approved until the violations have been corrected. Also, no requests for Certificates to Foreign Governments will be approved until the violations related to the subject devices have been corrected.

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. Possible actions include, but are not limited to, seizure, injunction, and/or civil penalties.

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 the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which the corrections will be completed.

Your response to this Warning Letter should be sent to Evelyn D. Forney, Compliance Officer, Food and Drug Administration, 6751 Steger Drive, Cincinnati, Ohio 45237.

Sincerely,



Dawn L. Todd-Murrell  
Acting District Director  
Cincinnati District