



DEPARTMENT OF HEALTH AND HUMAN SERVICE

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Southwest Region

Food and Drug Administration  
Denver District Office  
Bldg. 20-Denver Federal Center  
P.O. Box 25087  
6<sup>th</sup> Avenue & Kipling Street  
Denver, Colorado 80225-0087  
Telephone: 303-236-3000  
FAX: 303-236-3100

July 11, 2003

**WARNING LETTER**

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

Mr. Wayne K. Barlow  
President/CEO  
Wescor, Inc.  
459 South Main Street  
Logan, Utah 84321

Ref. #: DEN-03-19

Dear Mr. Barlow:

On May 23-29, 2003, investigators from the U.S. Food and Drug Administration (FDA) conducted an inspection of Wescor, Inc., in Logan, Utah. The investigators determined that your firm manufactures various products, including the Macroduct Sweat Collection System and the Nanoduct Neonatal Sweat Analysis System, which are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The 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 manufacturing, packing, storage, or installation are not in conformance with the Quality System/Good Manufacturing Practice (QS/GMP) for Medical Devices Regulation, as specified in Title 21, Code of Federal Regulations (21 CFR), Part 820. The deviations are as follows:

1. Procedures were not established, defined, documented, completed and followed for the validation or verification of design changes before implementation, as required by 21 CFR 820.30(i) and 21 CFR 820.3(k). Specifically, there is no documentation to show that validation of the change in Pilogel Disc formulation by ~~X~~ ~~X~~ ~~X~~ ~~X~~ ~~X~~ ~~X~~ was performed to insure the product continued to conform to defined user needs and intended uses. This change in formulation resulted in erroneous diagnostic test results for customers using osmometric analyses.

2. Procedures for validating the device design were not established, defined, documented, and implemented, as required by 21 CFR 820.30(g). Specifically, 1) there is no documentation to show that predetermined acceptance criteria or simulated use conditions were used in the design validation of the Nanoduct Neonatal Sweat Analysis System; and 2) there is no documentation to support the extension of the expiration dates of the active pharmaceutical ingredient, ~~XXXXXX~~: from 18 March 2003 to 18 March 2006; or the finished pharmaceutical, Pilogel Discs from 12 months to 24 months. As demonstrated by labeling requirements in 21 CFR Part 809, the basis for establishing stability should be determined by reliable, meaningful, and specific test methods such as those described in 21 CFR 211.166.
3. Process validation activities and results have not been documented, as required by 21 CFR 820.75(a). Specifically, there is no documentation to show that validation of manufacturing processes ( ~~XXXXXX~~ ) has been performed.

The above-identified deviations are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure that your establishment is in compliance with all requirements of the Federal regulations. The specific violations noted in this letter and in the Form FDA-483 issued at the conclusion of the inspection may be symptomatic of serious underlying problems in your establishment's quality system. You are responsible for investigating and determining the causes of the violations identified by the FDA. You also must promptly initiate permanent corrective and preventive action on your Quality System.

We acknowledge receipt of your June 5, 2003 and June 23, 2003 responses to the FDA-483. Your responses were inadequate because you have included no supporting documents.

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. Additionally, no premarket submissions for Class III devices to which the QS/GMP deficiencies are reasonably related will be cleared until the violations are 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 FDA initiating regulatory action without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

You should 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 and to prevent their recurrence. 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.

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Your response should be sent to H. Tom Warwick, Compliance Officer, Food and Drug Administration, Denver District, P. O. Box 25087, Denver, CO 80225-0087. If you have any further questions, please feel free to contact Mr. Warwick at (303) 236-3054.

Sincerely,

A handwritten signature in black ink, appearing to read "B. Belinda Collins". The signature is fluid and cursive, with a large initial "B" and a long, sweeping underline.

B. Belinda Collins  
District Director