



Food and Drug Administration
Cincinnati District Office
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April 6, 1999

**WARNING LETTER
CIN-WL-99-191**

**CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

Mr. Claus H. Wiegel, President
Beiersdorf-Jobst Inc.
5825 Carnegie Blvd.
P.O. Box 471048
Charlotte, NC 28247-1048

Dear Mr. Wiegel:

On February 22-26 and March 1-3, 1999, the Food and Drug Administration (FDA) conducted an inspection of your Toledo, Ohio facility which manufactures compression garments for burn and vascular patients. The compression garments are devices as defined by Section 201(h) of the Food, Drug and Cosmetic Act (the Act).

The investigators found deviations from the Quality System Regulations (QSR) for Medical Devices as listed in Part 820 of Title 21, Code of Federal Regulations (CFR). This causes the compression garments to be adulterated within the meaning of Section 501(h) of the Act in that the methods used in the facilities or controls used for the manufacturing, packing and storage are not in conformance with QSR's, Part 820.

The following deviations from the Device QSRs were documented.

- 1) Failure to manufacture compression garment devices in accordance with Device Master Record Specifications or Patient Measurements in all cases.
- 2) Failure to establish procedures for implementing corrective and preventative action:
For example, fifty-five garments were documented as being re-cut due to in-process non-conformities such as dots, cut short, laser cuts/slits, dirt from lasers, off-core, shape and burns.

- 3) Failure to review, evaluate or investigate returned compression garments in association with customer's complaints.
For example, between December 1996 and November 1998, 31 garments were returned to the firm as part of a customer complaint. These returned devices were not evaluated.
- 4) Use of an incoming inspection grading scale that contains overlapping specifications. The patient measurement and prescribed compression are translated and adjusted in design engineering. As such the pattern is drawn in accordance with the gram weight of fabric to be used in production.
- 5) Failure to validate the cleaning system for the [REDACTED] Cutting Edge Laser fabric holding bed for use with a scrubber and cleaning reagent to rid the bed of laser cut residues.
- 6) Failure to follow the [REDACTED] Cutting Edge Laser manufacturers prescribed laser exhaust daily head cleaning.
- 7) Failure to address the use of wrinkled fabric in the laser equipment during the cutting operation in validation studies.

We acknowledge the March 16, 1999 letter from Charles M. DeVore, Director, Custom Products which was sent in response to the FDA-483, Inspectional Observations, issued at the close of the inspection. The letter covered corrections that Beiersdorf-Jobst has made since the inspection. We have the following comments – questions.

Observation #2

One of the procedures that is addressed in the response is the "Quality Review Board, SOP 025, revised 5/24/98". Section 3.2 of this procedure addresses that, "...the review board shall review trend reports from data generated by the inspection and/or testing of rework of assemblies, reprocessed goods and error reports from in-process manufacturing operations..." Another procedure that is addressed is the "Failure Investigation, SOP 026" revised 9/27/96. Section 2.1 of this procedure addresses that, "...(a) failure investigation is considered to be a 3 step process...identification of the specific assembly or component that failed..." Neither of these procedures were implemented in association with re-cuts of fabric due to in-process nonconformities.

The response also indicates that your firm will "...add more definition..." and will "...create a more detailed procedure, Corrective and Preventative Action, SOP 043..." When is this to be drafted and/or implemented? Will this procedure address in-process nonconformities? Will it include "...triggers...for internal failures related to the laser cutting system?" The Quality Review Board has initiated a project to perform an in depth investigation of the internal failures coming from the laser cutting operation. What is the projected time frame for implementation?

Observation #4

Your response indicates that the inspection followed the procedures as instructed. This was not observed during the inspection in that the inspectors were instructed to assign a gram weight of fabric (when the fabric fell within the ambiguous specifications) that represented the central

tendency of that lot of fabric being tested. Your letter indicates that the incoming inspection grading scale for fabric has been revised. What scientific or engineering rationale supports the manufacturing operational change?

Observation #5

Your response indicates that the cleaning procedure will be validated. How? Will you use a standard? When are you planning to conduct this validation study?

Observation #6

Your letter indicates that you have revised the laser exhaust head cleaning procedure to an "as needed" basis. This suggests that the cleaning will not be conducted until in-process failures appear (i.e. "dots" appearing on the compression garment fabric during cutting from the laser exhaust being pulled through the fabric and the holes in the cutting bed). At this time (when "dots" appear on the fabric), the laser exhaust head will be cleaned. Is this correct?

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. The GMP deviations are similar to those noted before. Your firm received a Warning Letter on GMPs dated August 4, 1992. GMP deviations were also found during an inspection that concluded on May 26, 1993. Your firm promised and made corrections but apparently has not continued to maintain your production and quality control systems in a state of control.

In order to facilitate FDA in making the determination that permanent corrections have been made and thereby enabling FDA to withdraw its advisory to other federal agencies and to provide 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. The consultant should conduct an audit of your firm's manufacturing and quality assurance systems relative to the requirements of the device QSR regulations (21 CFR, Part 820). You should 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.

In our opinion, the initial certifications of audit and corrections and subsequent certifications of updated audits and corrections (if required) should be submitted to this office by September 1999.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this into account when considering the award of contracts. Additionally, no premarket submissions for devices to which the GMP deficiencies are reasonably related will be cleared until the violations have been corrected. Also, no requests for Certificates For Products for Exports 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. These actions include, but are not limited to, seizure injunction and/or civil penalties.

Please notify this office within 15 days of receipt of this letter of the specific steps you will be taking to comply with our request. Please update on any additional corrections to the 3/16/99 letter made and information on the consultant.

Your response should be sent to Lawrence E. Boyd, Compliance Officer, Food and Drug Administration, 6751 Steger Drive, Cincinnati, Ohio 45237.

Sincerely,



Henry L. Fielden
District Director
Cincinnati District

Attachment: CP 7382.830, attachment G

cc: Mr. Charles M. DeVore
Director, Custom Production
Beiersdorf-Jobst Inc.
653 Miami Street
Toledo, OH 43605-2277