



April 29, 1999

Ref: 99-DAL-WL-14

WARNING LETTER

**VIA FACSIMILE
AND FEDERAL EXPRESS**

Mr. Gale White, General Manager
B. Braun Medical, Inc.
1601 Wallace Drive, Suite 150
Carrollton, Texas 75006

Dear Mr. White:

During an inspection of your firm located in Carrollton, Texas, on February 9-12, 1999, our investigator determined that your firm manufactures infusion pumps. These products are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The above-referenced 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 for devices set forth in the Quality Systems Regulation specified in Title 21, Code of Federal Regulations (CFR), Part 820. The 1978 Good Manufacturing Practices (GMP) Regulation was superseded on June 1, 1997, by the Quality System Regulation. Since some of the records reviewed were dated prior to June 1, 1997, the deficiencies noted during the inspection are cross referenced to the 1978 GMP's.

The following violations were provided to you on the FDA-483 and are also discussed below. Further, we are in receipt of your response to the FDA-483, dated February 26, 1999, and the results of that review are also indicated below.

1. Failure to identify action(s) needed to correct and prevent recurrence of nonconforming products as required by 21 CFR 820.100(a)(3), Corrective and Preventive Action. This would also be a violation of the 1978 Good

Manufacturing Practices Regulation 21 CFR 820.20(a)(3), Quality Assurance Program Requirements. For example:

- a. Distribution of the nonconforming devices as indicated in Item 1(a) and 1(b) on the FDA-483. Inspectional records reviewed indicated your acceptance activities, such as the functional and burn-in testing, did not assure detection of out-of-box failures related to LCD/LED display board component failures in the Horizon Nxt infusion pump devices. For example, in the Supplier Corrective Action Request and Report, No. 0590, dated 12/17/96, Braun indicated that the extensive testing should have detected an occasional weak component (IC chip and Inverter). Braun did not address how this testing failed to detect the problems and allowed distribution of the nonconforming devices in 1996, 1997 and 1998.
- b. In the February 26, 1999 response, you indicated that an additional burn-in testing was added after the final QC operation and prior to the shipment to verify the effectiveness of the final inspection. As shown in Item 1(a) and 1(b) of the FDA-483, inspectional records reviewed indicated the Horizon Nxt Infusion Pumps experienced out-of-box failures in the field with the PLCC and EPLD sockets, high infant mortality rate of the chip, and load mismatch between the Inverter and the LCD backlight. Braun's functional testing, burn-in testing, and other quality assurance procedures, failed to detect these problems until they were discovered during initial checks at the user facility. Your response does not address how this burn-in was verified or validated to detect initial and long-term quality problems and to assure conformance to specifications. Since Braun's quality assurance testing may or may not provide a complete quality assurance, Braun may need to re-evaluate its purchasing controls for evaluation of suppliers and design control process for long-term quality assurance. This response is, therefore, inadequate.
- c. Also, on page 1 of the February 26, 1999 response, you indicated the incoming inspection of all circuit board assemblies was expanded and enhanced, and the entire manufacturing process was re-evaluated to include additional critical control points. Braun has not defined what constituted "additional critical control points" or provided additional documentation on these critical control points. This response is, therefore, inadequate.

2. Failure to establish and maintain procedures for rework, to include retesting and reevaluation of the nonconforming product after rework, as required by 21 CFR 820.90(b)(2), Nonconforming Product. This would also be a violation of the 1978 Good Manufacturing Practices Regulation 21 CFR 820.115, Reprocessing of Devices or Components. For example:

Inspectional records reviewed indicated Braun was aware of a high failure rate of the [REDACTED] chips installed by the PC board supplier. All failures were attributed to date code # [REDACTED]. As a result, Braun reworked approximately [REDACTED] display boards with defective parts during the period from September of 1997 to March of 1998. During rework operations, Braun failed to assure all defective display boards in stock, including the manufacturing floor and the warehouse, had received the [REDACTED] chip upgrade removing the [REDACTED] chip. Approximately [REDACTED] infusion pumps which did not receive the chip upgrade were shipped to customers and resulted in additional customer complaints.

3. Failure to review and evaluate complaints to determine whether an investigation is necessary as required by 21 CFR 820.198(b); and
4. Failure maintain records of investigations that include any device identification, control number, and corrective action taken as required by 21 CFR 820.198(e). This would also be a violation of the 1978 Good Manufacturing Practices Regulation 21 CFR 820.198, Complaint Files. For example:
 - a. Complaint records of out-of-box failures related to the main boards and LCD/LED display boards do not contain sufficient detail to document the root cause of the nonconformities and any corrective action taken. Routine identifying and replacing a failed part (i.e., main/display board) do not represent an adequate investigation and corrective action (i.e., Investigation Reports #9705154, 9706081, 9706050). We noted that Braun had initiated Engineering Change Request, ECR 0460, dated 4/24/97, to use a new adaptor for improving solder contact in the main PC board. This information was neither documented nor referenced in the complaint records to assure these complaints were properly reviewed and evaluated. Further, records reviewed indicated the above-referenced complaints were received after ECR 0460 was initiated, and that there was no referenced information in these complaints to demonstrate if the root cause for these complaints have been determined previously and to verify effectiveness of the corrective action via ECR 0460.

On Page 2 of the February 26, 1999, response, you indicated that Braun would implement an Engineering Work Instruction (WI) to assess product problems, perform a root cause analysis, and recommend a corrective action. It does not appear the District has received the March 10, 1999 response letter as promised. Please provide this office with the new Work Instruction and documentation of training provided to appropriate employees for this new WI. This response is, therefore, inadequate.

- b. Complaint file investigation report for PIR #9611081 does not contain device control numbers for [REDACTED] Horizon Nxt 610 Infusion Pumps that were confirmed by the firm as out-of-box failures (FDA-483 Item 2).

In response to this observation, you have sent a letter to all sales representatives stating the importance of reporting complete information when relaying information back to the facility. And Braun has conducted a training session on February 16, 1999 through February 19, 1999 which again covered the essential information required. You should provide documentation of this training session (i.e., list of attendees, subject matter was covered) to this office for our review.

5. Failure to establish and maintain procedures to control all documents that are required by this part; assure that changes to documents are reviewed and approved, as required by CFR 21 820.40(b). This would also be a violation of the 1978 Good Manufacturing Practices Regulation 21 CFR 820.180, General Requirements. For example:

Sub-Assembly Burn-in Procedure, WI #430003, an obsolete document, has not been removed from the Device Master Record.

In the February 26, 1999 response, as corrective action, you indicated that Document And Data Control Procedure, No. 700098, has been revised to require [REDACTED] review of standard operating procedures and instructions for correct references to other documents and traceability to the Device Master Record. During the inspection, Braun was informed that lack of document controls was a continuing deficiency from the previous inspection in 1995. Braun should perform a current review of the DMR for removal of any other obsolete documents and discrepancies between documents. This response is, therefore, inadequate.

Page 5 - Mr. Gale White
April 29, 1999

With regard to FDA-483 Item 4, Braun was cited for not reporting two MDR reportable complaints, Mfr reports #1641965-1998-00018/24, to FDA within the 30 days time frame. Your response indicated that Braun is currently changing the complaint handling system from tracking complaint information on an [REDACTED] spreadsheet to using an off-the-shelf database system, [REDACTED] Tracker. As required by 21 CFR 820.70(i), Automated Processes, this off-the-shelf software shall be validated for its intended use if Braun has not already done so.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is Braun's 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.

Until these violations are corrected, and FDA has documentation to establish that such corrections have been made, federal agencies will be advised of the issuance of this Warning Letter so that they may take this information into account when considering the award of contracts.

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 in writing within 15 working days of receipt of this letter, of the specific steps you have taken 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, Acting Compliance Officer, at the above letterhead address.

Sincerely yours,



^{file} Joseph R. Baca
Dallas District Director