



Food and Drug Administration
Denver District Office
Building 20 - Denver Federal Center
P. O. Box 25087
Denver, Colorado 80225
TELEPHONE: 303-236-3000

March 10, 1999

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Gregory J. Baldwin
President/CEO
Baxa Corporation
13760 E. Arapahoe Road
Englewood, CO 80112

PURGED

Ref # : DEN-99-05

Dear Mr. Baldwin:

During an inspection of your firm conducted between January 25 and February 8, 1999, Consumer Safety Officer Thomas B. Dowell determined your firm manufactures patient controlled analgesia infusers, total parental nutrition compounders, microfuse infusers, and other related products. These products are devices within the meaning of Section 201(h) of the Federal Food, Drug and Cosmetic Act (the Act).

The above-stated 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 the manufacturing, packing, storage, or installation are not in conformance with the Quality System Regulation (QSR), as specified in Title 21, Code of Federal Regulations, Part 820 (21 CFR 820) as follows:

1. Failure of management to assure that the firm is in compliance with the Quality System Regulation and that a Quality Policy has been established, implemented, and maintained at all levels of the organization as required by 21 CFR 820.20(a).
2. Failure to validate production processes where results cannot be fully verified by subsequent inspection and testing as required by 21 CFR 820.75(a). For example:
 - A. Review of the [x x x x x x x] Protocol and related sterilization data noted several discrepancies including, but not limited to:

- 1) [redacted] was used during validation to establish sterilization parameters for a family of products, however there was no evaluation performed to demonstrate that this product was representative of the entire family ; 2) failure to evaluate the effects of the maximum specified [redacted] on the product; and 3) failure to evaluate the packaging of the [redacted] by performing sterility tests through the expiration date.
 - B. Failure to perform initial validation of the [redacted] process using packaged product that simulates actual production runs. The initial validation was performed with empty pouches only. Further, this packaging process was not revalidated following the installation of a new sealing system.
 - C. Failure to perform validation of the [redacted] using packaged product that simulates actual production runs. The validation was performed using [redacted] [redacted] In addition, the validation of this [redacted] was conducted at a temperature range up to [redacted] however, production procedures allow for a temperature range up to [redacted]
 - D. Failure to validate the [redacted] used to seal the [redacted] or the [redacted]
3. Failure to establish and maintain procedures for implementing corrective and preventative action as required by 21 CFR 820.100(a). Specifically, corrective and preventative action procedures have not been established, including those needed to correct or prevent recurrence of nonconforming product and other quality problems.
 4. Failure to perform audits in a timely manner to assure that the quality system is in compliance with the established quality system requirements and to determine the effectiveness of the quality system, as required by 21 CFR 820.22. Specifically, a vendor audit of the [redacted] has not been conducted since January 1995.
 5. Failure to follow procedures to insure Device History Records for each batch, lot, or unit are maintained to demonstrate the device is manufactured in accordance with the Device Master Record and the Quality Systems Regulation as required by 21 CFR 820.184. Specifically, component lot numbers, signatures, and dates were missing from Device History Records for MicroFuse Dual Rate Infuser production lots.

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.

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We acknowledge your response dated February 16, 1999, to the observations noted on the FD-483. We have reviewed your response, and in general, they appear to adequately address the concerns reported.

However, I would like to point out that at the conclusion of the June 14 - 20, 1995 inspection of your firm, the Investigator noted on the FD-483: Validation: The [redacted] and the process used to [redacted] disposable products is not validated. Your firm's response (in part) to this item, dated July 13, 1995 stated: "We have purchased a [redacted] and will validate both the [redacted] and the process.....".

Additionally, at the conclusion of the February 12 through March 6, 1997 inspection of your firm, the Investigator noted on the FD-483: The [redacted] has not been validated. Your firm's response (in part) to this item, dated March 11, 1997, stated: "[redacted] will be addressed as the first priority in improving the validation of operating settings of the production machinery....".

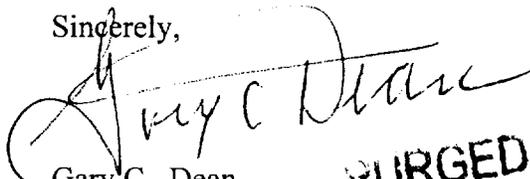
At the conclusion of the current inspection the Investigator's FD 483 noted, for the third time, validation deficiencies with the [redacted] I would like to remind you that your proposed corrections are only as effective as their implementation.

You should take prompt action to correct these and any other manufacturing or quality systems deviations identified by your internal audits. Failure to promptly correct these deviations may be identified in a follow-up inspection, and 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 days of receipt of this letter, of any additional steps you will be taking to achieve compliance which have not been previously reported to us.

Your reply should be sent to the Food and Drug Administration, Denver District Office, Attention: H. Tom Warwick, Compliance Officer, at the above address.

Sincerely,


Gary C. Dean
District Director

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