



DEPARTMENT OF HEALTH AND HUMAN SERVICE

Southwest Region

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Food and Drug Administration
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March 9, 2001

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Wayne Sanders
CEO and Chairman of the Board
Kimberly-Clark Corporation
351 Phelps Drive
Irving, Texas 75038

Ref. #: DEN-01-24

Dear Mr. Sanders:

On January 19 through the 24, 2001 Investigator Ricki A. Chase-Off of our office conducted an inspection of Ballard Medical Products in Draper, Utah. Our investigator determined that your firm manufactures various products, including the microCOUNT and microCOUNT Lite liquid scintillation counters, trach care kits, pain management kits, diagnostic test kits and oral health products. These products are devices as defined by 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 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. Management reviews of the quality system are not effective in that all quality data is not analyzed, documented and trended, as required by 21 CFR 820.20. For example, your firm does not have adequate trending procedures. Your management review procedure does not include the frequency of such reviews, only that "Each Divisional Management Review Group will conduct meetings as needed to address issues regarding the Quality System."

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2. Inadequate corrective and preventative action (CAPA) procedures, as evidenced by:
 - Not analyzing all significant sources of quality data, and using appropriate statistical methodology where necessary to detect recurring quality problems, as required by 21 CFR 820.100(a)(1). For example, your firm has failed to trend customer complaints and has not identified all potential sources of quality data. In-process rework, product returns and repairs are not captured, trended or evaluated.
 - Not investigating the cause of nonconformities relating to product, processes and the quality systems, as required by 21 CFR 820.100(a)(2). For example, your complaint procedure does not state that corrective and preventive actions are to be addressed or documented regarding complaints. Your Product Incident Reports have a section dedicated to documenting corrective actions but not preventive action.
 - Not ensuring that information related to quality problems or nonconforming product is disseminated to those directly responsible for assuring the quality of such product or the prevention of such problems, as required by 21 CFR 820.100(a)(6). For example, there is no evidence that all sources of defects/quality data are disseminated to responsible management.
3. Failure to fully evaluate and document all complaints to determine whether the complaints represent events required to be reported to FDA under the Medical Device Reporting (MDR) regulations, as required by 21 CFR 820.198. For example, several complaints were found involving trauma to patients, however no MDRs were reported. There was no justification for the decision not to report the incidents under MDR. Also, although your firm lists events such as improper cutting of endotracheal catheters, balloon failure of silicone balloon retention devices and gastric irritation from gastrostomy tubes as non-MDR events, there was no documentation of investigations or data to support this decision.
4. Failure to establish and maintain procedures for rework, to include re-testing and reevaluation of nonconforming products after rework to ensure the product meets its current approved specifications, as required by 21 CFR 820.90(b)(2). For example, rework and reevaluation activities, including a determination of any adverse effect from the rework on the product were not documented in the Device History Records (DHRs).
5. Failure to establish and maintain procedures to adequately control environmental conditions that could reasonably be expected to have an adverse effect on product quality, as required by 21 CFR 820.70(c). For example, during March, April and July 2000, the bioburden levels in the Specials Room exceeded acceptable limits. Although an investigation was conducted and possible causes identified, your firm failed to propose a

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long term plan to identify the exact cause of the deviation nor was any type of remedial action taken.

6. Statistical techniques are inadequate in that nonconformances are not analyzed to detect recurring quality problems, as required by 21 CFR 820.250. For example, your procedures do not define or identify analytical methods to be used for statistical analysis. Also, your firm has not established action or warning levels to evaluate quality data.
7. Failure to establish and maintain procedures to ensure that all purchased product and services conform to specified requirements, as required by 21 CFR 820.50. Our inspection revealed that your firm failed to establish a formal agreement with your contract firm, [XXXXXXXXXXXX] regarding quality issues, performance specifications, engineering changes, complaint handling or supplier audits.

We acknowledge receipt of your response dated February 12, 2001, signed by Mr. James E. Woods, and also acknowledge that you have contracted the services of outside consultants. With regards to your response, we have the following comments:

With regards to your use of statistical methods, we found that although you have been tracking quality data such as complaints, your firm has not used any type of statistical analysis to trend this data. Your response indicates that you are initiating/revising new SOPs to incorporate statistical techniques as well as to address the Corrective and Preventative Action procedures. However, your response did not include these new procedures and therefore, we are unable to evaluate their adequacy.

In addressing the Management Review Procedure, you did not state the interval for Management Review meetings nor did you indicate the participants in such meetings. Your response references SOP [XXXXXXXXXX] stating that it will be revised to "more clearly describe the participants, responsibilities, and documentation of monthly [XXXXXX] that are currently on-going, (but that to date have not been documented)". However, SOP [XXX] obtained by our investigator does not require a monthly meeting, only that a monthly trend analysis be performed.

In response to the observation that your Quality System failed to capture and review all sources of quality data, you state that three SOPs (SOP [XX] [XX] and [XX]) will be revised to more clearly define product returns and in-process product reworks. However, your response did not include a copy of these procedures. We therefore are unable to determine the adequacy of these revisions.

Regarding item #6 of the FD 483, although one complaint was given as an example (PIR # [XX]), our observation encompassed more than the issue of foreign vs. domestic complaint and MDR reporting. Your response is correct in that MDR reportable events received from

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foreign sources must be reported for products that are also marketed domestically. More importantly our investigator noted several other complaints which were not reported but which included patient trauma. Some of these events occurred in the U.S. There was no evidence documenting the rationale not to submit MDRs in these cases. The examples included PIR [redacted], [redacted] and [redacted]

Please be advised that our observation regarding the shipment of wrong products under item #6 on the FD 483 is a quality issue if the reason that the wrong item was shipped was due to the fact that the labeling was incorrect. It was unclear from your records if this was the case, however, under your [redacted] procedure (SOP [redacted]) your firm defines a complaint as "...dissatisfaction relative to the identity...of any product manufactured and/or sold by [redacted] .." Your firm needs to insure the language in your procedures is consistent.

Regarding item #8, quality requirements for contractors, none of the SOPs mentioned in your response were provided or discussed with our investigator during the inspection. You have included a copy of SOP [redacted], completed June 9, 2000, for [redacted] [redacted] In that [redacted] it states that [redacted] received a warning letter from the FDA. You have also attached documentation showing [redacted] as on your list of approved vendors, however, there is no evidence that you firm took any additional steps to assure products purchased from [redacted] were in accordance with your specifications subsequent to their receipt of the warning letter.

With regards to the [redacted] (SOP [redacted]) attached to your response, you state that "Although the In-Process Inspection Record is not specifically designed to report the inspection of multiple processes or operations on a single sheet, it is permissible to do so." Although you are not required to use separate sheets, it is advisable that you have separate records for each discrete operation in order to prevent inadvertent oversight, as well as to insure documentation of all processes. The headings listed on the IN-PROCESS INSPECTION RECORD form (i.e. [redacted] [redacted] and [redacted]) appear to make it designed to document specific operations.

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.

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

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Certificates to Foreign Governments will be approved until the violations related to the subject devices have been corrected.

In order to facilitate FDA in making the determination that such corrections have been made, thereby enabling FDA to withdraw its advisory to other federal agencies concerning the award of government contracts, to resume marketing clearance for Class III devices for which a 510(k) premarket notification or Premarket Approval application (PMA) have been submitted, and provide Certificates to Foreign Governments for products manufactured at your facility, we are requesting that you submit certification by an outside consultant to this office on the schedule below. Certification by an outside expert consultant should contain assurance that he/she has conducted an audit of your establishment's manufacturing and quality assurance systems relative to the requirements of the device QS/GMP regulation (21 CFR, Part 820). You should also submit a copy of the consultant's report with certification that you have reviewed the report and that your establishment has initiated or completed all corrections called for in the report.

The initial certifications of audit and corrections, and subsequent certifications of updated audits and corrections (if required) should be submitted to this office by the following dates:

- Initial certifications by consultant and establishment – April 25, 2001.
- Subsequent certifications – bi-monthly thereafter until all corrections have been made.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by us 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 any other additional 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.

Your response should be sent to Regina A. Barrell, 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 Ms. Barrell at (303) 236-3043.

Sincerely,


Thomas A. Allison
District Director

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