



WARNING LETTER
VIA EXPRESS

JAN 19 2000

Hassan Chaouki
Kosma-Kare Canada, Inc.
2044 de la Province
Longueuil, QC Canada J4G 1R7

Dear Mr. Chaouki,

During an inspection of your firm located in Longueuil, QC Canada, on December 13-16, 1999, our investigator determined that your firm manufactures medical adhesive bandages. These bandages 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 Regulation, as specified in Title 21, Code of Federal Regulation (CFR), Part 820, as follows:

- 1) Processes, whose results cannot be fully verified by subsequent inspection and test, have not been validated and approved according to established procedures as required by 21 CFR 820.75(a). Specifically,

(a) the sterilization validation protocol [REDACTED] for the current ethylene oxide (EO) sterilization process for plastic strip and flexible bandages (both labeled as sterile) was not followed in that: (1) the number of pallets and (2) the number and placement of Biological Indicators (BIs) (used during validation runs) did not follow approved criteria established in the protocol.

For example, sterilization batch records identify that half cycle run #3 and the final full cycle run each consisted of [REDACTED] pallets versus the approved [REDACTED] pallets (used during half cycle runs #1 and #2). The approved BI placement [REDACTED] identifies placement of 34 BIs within a [REDACTED] pallet load configuration. Sterilization batch records for the final full cycle run identifies retrieval of only 17 BIs;

(b) the process for manufacturing both plastic strip and flexible bandages consists of multiple steps [REDACTED] performed (each) on a single equipment unit that is people dependent. Continuous operator intervention is required, affecting [REDACTED] placement inside the primary sterile barrier. The manufacturing process has not been validated to ensure seal integrity and strength. For example, existing manufacturing and package validations fail to identify seal strength tolerances and acceptance criteria.

- 2) Procedures are not appropriate for controlling process parameters for validated processes as required by 21 CFR 820.75(b). Specifically, placement of BIs (conducted by QA) is achieved by taping BIs to the outside of cartons or dropping BIs (with tape) in between cartons that are placed directly onto sterilization pallets (i.e. these carton exteriors are directly exposed during sterilization). The current procedure does not adhere to the validation guidelines used for validating the sterilization process (i.e. placement of BIs in product cartons to achieve most difficult-to-sterilize areas).
- 3) Incoming product is not adequately inspected or tested to verify conformance to specifications as required by 21 CFR 820.80(b). Specifically, the Biological Indicators (BI) [REDACTED] used during EO sterilization (both routine and validation runs) have not been tested to verify purported strength. For example, there was no verification of BI strength for [REDACTED] used during half cycle validation run #3 and the final full cycle validation run.
- 4) Appropriate procedures have not been established (defined and implemented) for controlling environmental conditions as required by 21 CFR 820.70(c). Specifically, procedures for testing bioburden have not been defined and there is no documentation of acceptable bioburden limits.
- 5) The evaluation and investigation of non-conforming product has not been documented and documentation of non-conforming product is incomplete as required by 21 CFR 820.90(a). Specifically, procedure [REDACTED] states that non-conformances identified (in-process) that are greater than [REDACTED] will be evaluated and/or investigated. The procedure does not specify when an evaluation/investigation of non-conforming product will be identified at final inspection. A review of twenty-three (23) Device History Records (DHRs) revealed the following:
 - five (5) lots [REDACTED] identify specific non-conformances. Of these, four (4) fail to document the quantity of non-conformances identified in-process. Based on the firm's procedures [REDACTED] cannot be implemented without documentation of the quantity of non-conformances in-process. These four (4) DHRs also identify non-conformances ranging in quantity [REDACTED] and there is no documentation of evaluation and/or the reason for not investigating. In addition, one (1) of the four (4) lots identifies in-process non-conformances in excess [REDACTED] and there is no documented investigation.
- 6) There are no established procedures for analyzing sources of quality data to identify existing and potential causes of non-conforming product or other quality problems as required by 21 CFR 820.100(a)(10). Specifically, the firm has no documentation identifying any analysis of non-conformances observed during in-process or final acceptance activities.

- 7) Sampling plans for in-process acceptance activities, conducted by Quality Assurance (QA), are not based on valid statistical rationale as required by 21 CFR 820.250(b). Specifically, QA samples [REDACTED] bandages from each production machine every half hour. Approximately [REDACTED] bandages are produced each half hour. There is no documented statistical rationale for sampling [REDACTED] of total product manufactured each half hour.
- 8) Failure to establish written procedures for the timely and effective communication and identification of Medical Device Reportable (MDR) events as required by 21 CFR 820.198 (a)(1) and (3). Specifically, there is no standard review process or reporting forms on file.

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 form FDA 483 issued at the conclusion of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance system. You are responsible for investigating and determining the causes of the violations identified by the Food and Drug Administration. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

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.

Given the serious nature of these violations of the Act, all adhesive bandages manufactured by Kosma-Kare Canada, Inc. of Longueuil, QC Canada may be detained upon entry into the United States (U.S.) until these violations are corrected and verified by a passing FDA inspection.

In order to remove the devices from possible detention, it will be necessary for you to provide a written response to the charges in this Warning Letter for our review. After we notify you that the response is adequate, it will be your responsibility to schedule an inspection of your facility. As soon as the inspection has taken place, and the implementation of your corrections have been verified, your products may resume entry into this country.

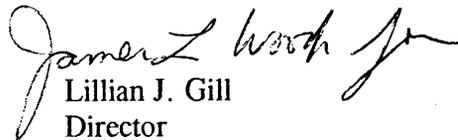
Please notify this office in writing within 15 days of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make correction to any underlying systems problems necessary to assure that similar violations will not recur. Please include any and all documentation to show that adequate correction has been achieved. In the case of future corrections, an estimated date of completion, and documentation showing plans for correction, should be included with your response to this letter. If documentation is not in English, please provide an English translation to facilitate our review.

Page 4 – Hassan Chaouki

Please address your response and any questions to the Food and Drug Administration, Center for Devices and Radiological Health, Office of Compliance, Division of Enforcement II, General Hospital Devices Branch, HFZ-333, 2098 Gaither Road, Rockville, Maryland 20850, to the attention of Ms. Carolyn Niebauer.

Should you require any assistance in understanding the contents of this letter, do not hesitate to contact Ms. Rebecca Keenan at 2098 Gaither Rd. Rockville, MD or at (301) 594-4618 or FAX (301) 594-4638.

Sincerely yours,

A handwritten signature in cursive script, appearing to read "Lillian J. Gill".

Lillian J. Gill
Director
Office of Compliance
Center for Devices and
Radiological Health