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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
2098 Gaither Road
Rockville, MD 20850

JAN 24 2002

VIA FEDERAL EXPRESS

WARNING LETTER

Mr. William M. Goodwin
President
Dumex Medical
104 Shorting Road
Toronto, Ontario M1S 3S4
Canada

Dear Mr. Goodwin:

During an inspection of your firm located in Toronto, Ontario, Canada on July 23, through July 26, 2001, our investigator determined that your firm manufactures Dupaque sponges (class II medical device), operating room sponges, wound dressings, specialty wound care products, and gauze, cotton, and synthetic bandages. These 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, the manufacture, packing, storage, or installation are not in conformance with the Current Good Manufacturing Practice (CGMP) requirements of the Quality System regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as listed below.

1. Failure to establish and maintain adequate procedures for finished device acceptance to ensure that each production run, lot, or batch of finished devices meets acceptance criteria and are held in quarantine or otherwise adequately controlled until released, and not to release the devices for distribution until the release is authorized by the signature of a designated individual(s), as required by 21 CFR 820.80(d)(3). For example, a Quality Assurance (QA) technician without documented training and proper authorization was releasing finished goods into finished goods inventory.

2. Failure to establish and maintain adequate procedures for receiving, review, and evaluation of complaints by a formally designated unit ensuring all complaints are processed in a uniform and timely manner, as required by 21 CFR 820.198(a)(1), (3) and (b). For example:

   a. Returned Goods Authorization (RGA) submittals are not routinely evaluated, investigated or processed as complaints to determine the cause of the defect in accordance with the Dumex Standard Operating Procedures

(SOP). SOP #GMP021001-01, Complaint Processing, effective February 25, 2000, states "...any written, oral or expression of dissatisfaction relative to the identity, quality, durability, reliability, safety, effectiveness, or performance of any device manufactured by this firm would be considered a complaint", and SOP #GMP021-00, Complaint Files, effective February 22, 2000, requires "any complaint involving the possible failure of a device to meet any of its performance specifications shall be reviewed, evaluated and investigated". These procedures were not followed for the three RGAs below that were not investigated as complaints:

RGA #1488 dated January 15, 2001, reported the return of one roll of DUP2906X for "x-ray line separating from product". The roll was labeled as "Defective" and returned to Quality Control (QC). The QA action form indicated the product was returned in an unsellable condition and would be used as raw material in the production of DUP 4868.

RGA #1232 dated December 2, 1999, reported the return of two cases of DUP 9469S because "this lot # produces too much lint for the operating room". The returned product was returned to QC. The Reject Non-Conforming Material Report (NMR) related to RGA #1232 dated January 10, 2000, reported the same complaint.

RGA #1326 dated May 11, 2000, reported one case of DUP 43199 was returned due to "x-ray line missing". The returned product was determined to be "defective" and returned to QC. The Reject NMR related to RGA #1326 dated May 23, 2000, reported the same complaint.

b. A review of the complaint files by the firm determined that complaints not investigated have no documented reason for the lack of an investigation.

c. Complaints are not reviewed and evaluated to determine whether it represents an event reportable to the FDA under part 803 of Medical Device Reporting.

3. Failure to establish and maintain adequate procedures for implementing corrective and preventive action including requirements for analyzing processes, work operations, concessions, quality audit reports, quality records, service records, complaints, returned product, and other sources of

nonconforming product, or other quality problems, as required by 21 CFR 820.100(a)(1). For example, not all sources of quality data are utilized to identify potential or existing causes of nonconforming products and other quality problems. Data obtained from NMRs and returned goods reports are not analyzed and trended to detect potential recurring quality problems or needed corrective and preventive actions. Dumex confirmed information obtained from RGA and NMR reports are not utilized to detect trends or take corrective and preventive actions.

4. Failure to ensure that all personnel are trained to adequately perform their assigned responsibilities and to document the training, as required by 21 CFR 820.25(b). For example:

   a. The QA Technician was releasing finished goods into finished goods inventory without documented training or authorization. The only personnel authorized to release finished devices into finished goods inventory are the Directors of QA and Regulatory Affairs (RA), and the Supervisors of QA and RA. A review of the Device History Records (DHRs) determined several inappropriate finished device release activities.

      (1) Product code #25-496 from lot number 38000 failed random sampling for seal integrity during post Sterile Finished Product and Packaging Inspection. The product code was placed on hold for [redacted] inspection on November 8, 2000, by the QA Supervisor. On November 28, 2000, the QA Technician released product code #25-496 from lot number 38000.

      (2) [redacted] cases of product code #8012 from lot number 42500 and [redacted] cases of #18001 from lot number 38000 were placed on hold due to no receipt of post sterile samples following the Post Sterile Finished Product and Packaging inspection. All other product codes were released by the QA Supervisor to finished product inventory on December 27, 2000. The QA Technician released the [redacted] cases of product code #8012 from lot number 42500 and [redacted] cases of product code #18001 from lot number 38000 on January 8, 2001.

      (3) The purchase order for lot #42500 indicates that 66 of cases of lot #18001 were released into finished goods inventory. However, the Rework Instructions on Rework Number 01001 indicates that [redacted] cases of lot number #18001 were reworked. The bottom of the form used for indicating the number

of devices passing inspection indicates [redacted] pieces. Both forms were completed and initialed by the QA Technician. Neither the QA Technician nor the QA Supervisor was able to determine whether [redacted] cases or [redacted] pieces were reworked, and whether [redacted] cases or [redacted] pieces passed inspection. This same problem is exhibited on Rework Number 01009 for lot #525W12 which states one roll of product can be used as raw material in the production of lot #4868. The bottom of the form indicates one roll is complete, has been reworked and is in quarantine.

b. The QA Inspector responsible for testing and acceptance activities does not have any documented training prior to July 16, 2001 although the inspector has been employed since 1997. SOP #GMP003001.00, Employee Training, requires, "All personnel shall have the necessary training to perform their assigned responsibilities adequately". The procedure also requires that employees be trained in their tasks, and provided or instructed on how to procure all material necessary to perform their tasks.

5. Failure to have quality audits conducted by individuals who do not have direct responsibility for the matters being audited, as required by 21 CFR 820.22. For example, the quality audit is conducted by individuals having direct responsibility for the matters being audited. The Supervisor of the QA department conducts audits of all Dumex departments, including the QA department.

6. Failure to establish and maintain requirements for the health, cleanliness, personal practices, and clothing of personnel if contact between such personnel and product or environment could reasonably be expected to have an adverse effect on product quality, as required by 21 CFR 820.70(d). For example, production personnel fail to follow the personnel sanitation standard operating procedure stating "All employees and visitors when entering production areas shall: ...wear head and beard covers (if applicable)". One day at least two manufacturing employees with beards were observed without beard covers. One employee was located in the clean room and another employee outside the clean room. The same employees did not have beard covers the next day.

Additionally, your devices are misbranded under section 502(t)(2) of the Act, in that your firm failed to submit information to the FDA as required by the Medical Device Reporting (MDR) regulation, as specified in 21 CFR Part 803. Specifically, you failed to implement a Medical Device Reporting (MDR) procedure. You should ensure that MDR reports are investigated and the cause of the problem is determined.

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 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 Food and Drug Administration. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

Our office has received your response to the FDA 483 dated August 14, 2001. Following our review of the response it is not possible to determine its adequacy. In order for us to determine the adequacy of each response, additional supporting documentation is needed. Any documentation, such as copies of all of the procedures you wrote or revised, supporting the establishment of the corrections stated in your response may be submitted to this office for further review. Please include any additional explanations of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur. 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 the English translation to facilitate our review. Please send another response in writing, within 15 working days of receipt of this letter.

Your response should be sent to the Food and Drug Administration, Center for Devices and Radiological Health, Office of Compliance, Division of Enforcement I, General Surgery Devices Branch, 2098 Gaither Road, Rockville, Maryland 20850, to the attention of Carol Shirk.

Sincerely yours,

Larry D. Spears
Acting Director
Office of Compliance
Center for Devices and
Radiological Health