



RB 10/26/98

October 23, 1998

Food and Drug Administration  
Kansas City District Office  
11630 West 80th Street  
P.O. Box 15905  
Lenexa, Kansas 66285-5905

MARTIN

Telephone: (913) 752-2100

**WARNING LETTER**

Edward Gerson, President  
Certified Safety Manufacturing, Inc.  
1400 Chestnut  
Kansas City, MO 64127

KAN #99-002

Dear Mr. Gerson:

During an inspection of your firm located in Kansas City, Missouri, on July 9 through 16, 1998, our investigator determined that your firm manufactures and distributes first aid kits which contain assorted sterile packaged bandages. Sterile bandages are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (Act).

The above-stated inspection revealed that these devices are adulterated within the meaning of Section 501(c) of the Act, in that their quality falls below that which is purported or is represented to possess in that they are represented to be sterile, when, in fact, they are not sterile because of defective packaging.

In addition, 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 current good manufacturing practice (CGMP) requirement of the Quality System Regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

1. Failure to establish and maintain procedures, and to document finished device acceptance to ensure each lot of finished devices meets specified requirements [21 CFR 820.80(d) & (e) and 820.86]. For example:

Between 6-2-98 and 7-6-98, 111 lots equaling over 500,000 devices, was missing required documentation specified in your procedure QA-007, Release of Sterile Product Processed In-house, before being released from quarantine.

On 6-11-98 sterilization load 80611.6 failed to meet the criteria for release, yet the load was released anyway.

There is no written procedure or documentation that inspections are covered on product packaged prior to sterilization.

2. Failure to validate the sterile packaging process on any of the equipment used to package all of your sterile medical devices [21 CFR 820.75].
3. Failure to justify your choice of using a MIL-STD 105E inspection level II reduced sampling plan for post-sterilization package integrity inspection [21 CFR 820.250].
4. Failure to establish and maintain procedures for implementing corrective and preventive action, and failure to document such activities [21 CFR 820.100]. For example:

No investigation and preventative action was done when sterile package integrity inspections found defective seals on 6-12-98.

No investigation of failing results from a creep test performed on 1-16-98.

5. Failure to justify the placement of biological indicators during the sterilization cycle [21 CFR 820.75(b)].
6. Failure to establish and follow production processes to ensure a device conforms to its specifications [21 CFR 820.70]. For example:

Your procedure TP-004, Bioburden Testing, states testing is to be performed semi-annually. The last testing conducted by your firm was August, 1997.

You are not following your procedure IP-005, Adhesive Bandage Inspection, in that you are selecting 5 samples rather than the required 10 samples. In addition, you are imposing the rejection level of 2 on the 5 samples, which was meant to be used for 10 samples.

7. Failure to ensure that device packaging and shipping containers are designed and constructed to protect the device from alteration or damage during the customary conditions of processing, storage, handling, and distribution [21 CFR 820.130]. For example, field examinations for sterile package integrity conducted by our FDA investigator during the inspection revealed the following:
  - a. Two units out of 50 units examined from lot 80623.9 of 4" x 4" Non-Stick Pads had open/incomplete seals of the primary sterility barrier.

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- b. Eight units out of 200 units examined from lot 80706.8 of 3" x 4" Non-Stick Pads had open/incomplete seals of the primary sterility barrier.

In addition, nonconforming packaging were found during packaging inspections performed after the inspection by the FDA Winchester Engineering and Analytical Center (WEAC), as follows:

- c. Sixteen of seventeen packages sampled from lot 80707.6 of 2" compress bandages had wrinkles in or across the package seal and 8 of 17 packages had two or more holes in the package seal.
- d. Six of eight packages sampled from lot 80706.8 of 3" x 4" Non-Stick Pads were defective in that they had totally or partially incomplete seals or wrinkles in the seals.
- e. Two of two packages sampled from lot 80623.5 of 4" x 4" Non-Woven Pads had incomplete seals.

Furthermore, these devices are misbranded within the meaning of Section 502(a) of the Act, in that the labeling for the devices contain statements which are false and misleading since the labeling claims the devices are sterile when, in fact, they are not sterile because of defective packaging.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. Violations were previously brought to your attention in a Warning Letter issued to your firm on October 26, 1995. 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.

Your response of July 20, 1998, to the Form FDA 483 issued at the close of the inspection was received and reviewed. We will address your response by separate letter. While we acknowledge your commitment to correct the identified deficiencies, we note that your firm has in the past, promised to correct deficiencies noted during FDA inspections, and our subsequent inspections, in particular the most recent inspection, have found your efforts to be ineffective.

Therefore, in order to facilitate FDA in making the determination that such corrections have been made and thereby enabling FDA to withdraw its advisory to other federal agencies concerning the award of government contracts, and to resume marketing clearance, and export clearance for

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products manufactured at your facility, we are requesting that you submit to this office on the schedule below, certification by an outside expert consultant that it has conducted an audit of your firm's manufacturing and quality assurance systems relative to the requirements of the Quality System Regulation, 21 CFR, Part 820. You should also submit a copy of the consultant's report, and certification by your firm's CEO (if other than yourself) that he or she has reviewed the consultant's report and that your firm has initiated or completed all corrections called for in the report. The enclosed guidance may be helpful in selecting an appropriate consultant.

The initial certifications of audit and corrections should be submitted to this office by Friday, March 1, 1999. A time frame should be provided for corrections and subsequent audits that will be completed after March 1, 1999.

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 requests for Certificates For Products For Export will be approved until the violations related to the subject devices have been corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office in writing, within fifteen (15) working days of receipt of this letter, of the specific steps you will be taking to comply with our request.

Your reply should be sent to Clarence R. Pendleton, Compliance Officer, at the above address.

Sincerely,

*Mary Walske*  
W. Michael Rogers *for*  
District Director  
Kansas City District

Attachment - Selecting a Consultant?