



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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VIA FEDERAL EXPRESS

Food and Drug Administration
Rockville MD 20857

JAN 6 2000

WARNING LETTER

Mr. Gary E. Player
Vice President of Operations
Ansell Perry de Mexico, SA de CV
C. Hertz #7, Bermudez Industrial Park
Cuidad Juarez
Chihuahua, Mexico 32470

Dear Mr. Player:

During an inspection of your firm located in Cuidad Juarez, Chihuahua, Mexico 32470 on October 12 through 15, 1999, our investigator determined that your firm manufactures sterile latex surgical and examination gloves. 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 manufacturing, packing, storage, or installation are not in conformance with the Good Manufacturing Practice (GMP) for Medical Devices Regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as listed below. Your response, dated December 3, 1999, to the investigator's findings was also reviewed. Comments on your response follow each observation.

1. Failure to develop, conduct, control, and monitor production processes to ensure that a device conforms to its specifications, and to establish and maintain process control procedures that describe any process controls necessary to ensure conformance to specifications, where deviations could occur as a result of the manufacturing process, as required by 21 CFR 820.70(a). For example:
 - a. The Encore Glove Chlorination SOP-PRO02-JZ, Rev. 13, specifies pre-chlorination tumble and post-chlorination drying temperatures as 140°F-150° and 140°-160°F respectively. The most recent chlorination process validation study specifies these temperatures as 110°F and 140°F-150°F respectively. There is no rationale provided for this.
 - b. Ansell Perry, Juarez (Ansell) is conducting the American Society for Testing in Materials (ASTM) 1000mL water leak test only to validate its own "Visual and Water Test" method against the ASTM method. Most styles of gloves receive "leak" tests and the packages

receive "peel" tests. The "cut resistant" and "radiation attenuation" style gloves are manually packed and get "peel" tested only. The Ansell "leak" method consists of filling a sink with water, submerging a glove into the sink to fill it with water, then removing the filled glove from the sink to look for leaks. The method has the operator squeeze the glove, increasing the pressure past the point that a hanging 1000mL of water creates. The validation method re-runs a randomly selected 50 gloves through both test methods every month. Ansell has conducted this "leak" test since 12/96, and states that in this time no differences in the method's respective abilities to detect "leakers" have been observed. This is inadequate.

Your response to item 2(a) above is adequate. A new procedure for establishing process parameters has been created and is in place.

You did not comment on issue 2(b) in your response of December 3, 1999. This leak test method is not in accordance with the ASTM leak test method as described in 21 CFR 800.20, nor the ASTM D5151 test method. You may respond to this issue and provide details explaining the decision not to follow the ASTM leak test methods.

2. Failure to establish and maintain procedures for implementing corrective and preventive action including requirements for identifying the action(s) needed to correct and prevent recurrence of non-conforming product and other quality problems, as required by 21 CFR 820.100(a)(3). For example, the procedure "Environmental Survey" states that if a microbial location/slide reads 200.0 colony forming units (CFU) or more, a corrective action shall be taken. There were six readings above 200.0 CFU in the summer of 1999, but the assessment indicated no corrective action was indicated. The available data reviewed suggested some of the readings in facility locations during the summer of 1999 readings were problematic areas and no corrective action was taken. Also, the microbes are not identified.

Your response is not adequate. Since the inspection the procedures have been changed to include procedures and processes to follow should the count be greater than 200.0 CFU. All organisms must be identified.

3. Failure to establish and maintain procedures for acceptance of incoming product, including that the incoming product shall be inspected, tested, or otherwise verified as conforming to specified requirements, and documenting

acceptance or rejection, as required by 21 CFR 820.80(b). For example, there are no incoming acceptance specifications for chlorine or thiosulfate used in glove processing. There is no procedure mentioning how warehouse or quality assurance (QA) personnel should accept or reject chlorine or thiosulfate, which are two raw materials used in the glove chlorination process.

Your response is adequate. A new procedure has been created establishing a method for the acceptance of chemicals.

4. Failure to establish the appropriate responsibility, authority, and interrelation of all personnel who manage, perform, and assess work affecting quality, and provide the independence and authority necessary to perform these tasks, as required by 21 CFR 820.20(b)(1). For example, the environmental monitoring procedure does not specify which duties are Ansell Perry, Ohio's and which duties are Ansell Perry de Mexico's.

Your response is adequate. You acknowledged the problem during the inspection and created new procedures that establish appropriate management QA responsibility for environmental monitoring duties.

5. Failure to establish and maintain procedures for receiving, reviewing, and evaluating complaints by a formally designated unit, ensuring that all complaints are processed in a uniform and timely manner, as required by 21 CFR 820.198(a)(1). For example, the existing complaint procedures do not state that all complaint failure investigation results are forwarded to the Massillon, Ohio corporate headquarters. All complaints are initially received at Massillon, Ohio, and those related to packaging or contamination are forwarded to the Juarez facility for investigation.

Your response is adequate. The modified complaint procedures include instructions for forwarding the failure investigation results to Massillon, Ohio.

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

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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 devices manufactured by Ansell Perry de Mexico, SA de CV, C. Hertz #7, Bermudez Industrial Park, Cuidad Juarez, Chihuahua, Mexico 32470 may be detained without physical examination upon entry into the United States (U.S.) until these violations are corrected.

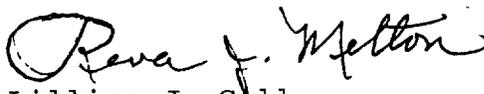
In order to remove the devices from detention, it will be necessary for you to provide a written response to the charges in this Warning Letter for our review where we have judged your response as less than adequate. Note that item number 1 in the Warning Letter cites an issue regarding leak testing which was not mentioned on the FDA 483. After we notify you that the response is adequate, a re-inspection will be required to verify that your corrective actions have been implemented. As soon as the inspection has taken place, and the implementation of your corrections has been verified, your products may resume entry into this country.

Please notify this office in writing of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections 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.

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 Shirck.

Sincerely yours,

for/

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