JM GLOVES CO., LTD.
No. 48, Kong Yeh Road, kuan Tien Shiang,
Tainan Hsien, Taiwan
TEL: (02) 27162828 Fax: (02) 27187588

Dockets Management Branch (HFA-305),
Food and Drug Administration,
5630 Fishers Lane, Rm. 1061,
Rockville, MD 20852.

Date: June 25,2003

REFERENCE: Docket No. 03N-0056

[Federal Register: March 31, 2003 (Volume 68, Number 61)] [Proposed Rules] [Page 15404-15417]
21 CFR Part 800

Proposed rule: 800.20 Medical Devices; Patient Examination and Surgeons' Gloves; Test Procedures and Acceptance Criteria

COMMENTS

General comments: FDA implements 21 CFR Part 800.20 regulation with Import Alert 80-04. Thus, the Preamble should cover the relationship between Import Alert 80-04 and 800.20.

Add to the Preamble:

When we have a failed shipment, we need to know about it as soon as possible in order to take corrective action (CAPA) at our factory. Therefore, we request that FDA collect manufacturers contact information in order to send us failure information such as a copy of the FDA analyses worksheet.

II Proposed Changes

4. Tightened Sampling Plans for Reconditioned Gloves

This section implies that the assurance of the quality of gloves passed by enhanced sampling and testing is lower than for an original pass on first test. We believe that the assurance is higher because of the enhanced sampling and testing.

03N-0056

C 4

5. Proposed Reclassification of Medical Gloves

We recommend that gloves that have passed enhanced sampling and testing without any re -work such as air testing be considered a pass under IA 80-04. Gloves that are distributed as allowed by the Food, Drug and Cosmetic are not adulterated and should not be considered adulterated under IA 80-04. We further recommend that this point be covered by the regulation 800.20

(change 3) b.
This section should also cover gloves that cannot be donned.

(Change 8) page 15406
The Preamble should emphasize that visual defects include large holes, tears, and other visual defects that have a high probability of negatively impacting the barrier integrity of the glove. Otherwise, the requirement can result in good gloves being rejected.

Sec. 800.20 Patient examination gloves and surgeons' gloves; sample plans and test method for leakage defects; adulteration.

In paragraph (b)(3) *Visual defects and leak test procedures*
Change heading to: *Obvious Visual barrier defects and leak test procedures*
Visual defects should be limited to those defects that are an obvious barrier defect or appear to have a high probability of reducing the barrier integrity of the glove.

Add (d)(ii)(C) Gloves that are reconditioned by enhanced sampling and testing according to (d)(2)(i) without any air testing or other rework are not rejects under Import Alert 80-04.

Sincerely,
JM GLOVES CO.,LTD.

P. M. YEH
Marketing Director