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Our Ref. *MARGMA* Date : 23 JUN 2003

Your Ref.

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

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.

The Malaysian Rubber Glove Manufacturers Association (MARGMA) is an association of 52 manufacturers of medical gloves. See Attachment 1 for a list of current glove manufacturers who are members of MARGMA.

MARGMA manufacturers shipped about 1.2 billion pairs surgeons' gloves and 8.7 billion pairs examination gloves to the Unites States in year 2002.

The following comments are submitted by MARGMA, representing 52 manufacturers, and were developed with the collaboration of our US Regulatory Affairs Consultant, Mr. Andrew Lowery.

Sincerely Yours,

President
Malaysian Rubber Glove Manufacturers' Association

03N-0056

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Comments and Rationale

The Malaysian Rubber Glove Manufacturers Association (MARGMA) is privileged to review and comment on the Proposed Rule on 21 Code of Federal Regulations, Part 800.20 on Test Procedures and Acceptance Criteria for Medical Devices: Surgeons' Gloves and Patient Examination Gloves dated March 31, 2003.

MARGMA, taking into cognizance the various rationale and comments made in the Proposed Rule, would like to forward further suggestions and amendments to the Food and Drug Administration (the FDA) for its consideration. The suggestions and comments are made regarding the following pages on the Proposed Rule as given under the section Part 800 – General on pages 15414 to 15417 of the Federal Register/Vol 68, No. 61/Monday, March 31, 2003/Proposed Rules.

MARGMA notes that the present or proposed 800.20 is not a standalone regulation. It is implemented in conjunction with 21 CFR Part 820 GMP/QS and Import Alert #80-04. Therefore, MARGMA wishes to also propose that FDA review the current Import Alert #80-04 guidance, "Surveillance and Detention Without Physical Examination" [DWPE], Docket No. 00D-1384, together with this new proposed 800.20 rule.

The following are the concerns of MARGMA, the recommended changes, and the rationale for the suggested amendments to the Preamble and the Regulation. References to some key sections of the Preamble and proposed regulation are stated at the beginning of each of our comments. At the end of our comments, for convenient reading, we have also included a copy of the proposed regulation with our recommended changes incorporated into the proposed regulation.

1. See Preamble II. Proposed Changes, A. 1 Rationale and Summary of Changes; and 2 Harmonization With Consensus Standards. MARGMA recognizes the need by the FDA to review and revise the existing rule of the 21 CFR Part 800.20. MARGMA further commends the FDA for taking steps to harmonize the existing rule with those other international consensus standards and support the FDA's continuing effort to improve the healthcare standard through the distribution of safe and quality disposable/single-use medical gloves.

2. See Preamble II. Proposed Changes, A. 3. Interpretation of Defects. MARGMA, however, is deeply concerned over the implications the Proposed Rule will have on the glove manufacturers and the distribution channels in the United States. MARGMA further believes the implementation of the Proposed Rule in its current revision will impact upon the manner FDA inspectors will perform their duties.

3. See Preamble II. Proposed Changes, A. 2 Harmonization With Consensus Standards. While MARGMA sincerely agrees with the need to harmonize with ASTM and ISO, it realizes that bringing the AQL of the existing rule from 4.0 to 2.5 for patient examination gloves does not harmonize with ASTM's AQL 2.5 on the ground that ASTM's AQL 2.5 applies only to pinhole defects whereas FDA's proposal applies to both pinhole and visual defects. MARGMA is concerned that there will be situations whereby gloves that pass pinhole AQL on ASTM standard will be failed by the FDA due to presence of visually defective gloves sampled. That is, the visual defects actually would not impact the barrier integrity. The same comment and argument applies to surgeons' gloves.

4. See Preamble II, A. 3. Interpretation of Defects, and B, (Change 3) page 15406; See MARGMA proposed changes to regulation (b)(1) General Test Method, (b)(1)(ii) *Identification of defects,* all sections, (b)(3) *Visual defects and leak tests procedures*, and

(b)(3)(i) *Visual defects examination*, all sections. MARGMA is equally concerned over the revised definition of what constitute defects. It believes that the inclusion of the phrase, '*other defects visible upon initial examination that may affect the barrier integrity*' as part of the definition will bring about a lack of objectivity on how visual defects are classified. This is especially true in relation to how such defects may or may not affect barrier integrity. For example, an embedded rubber lump may not be viewed by one person as a threat to barrier integrity but viewed as a threat to the barrier integrity by another.

MARGMA wants a clearer definition of the various types of known defects that can threaten barrier integrity so that the manufacturers will take proactive steps to avoid shipment of such 'visually' defective products. In the absence of clear guidelines, MARGMA believes the new Proposed Rule will create serious anxiety over how the results of future random inspection of their gloves will be interpreted.

5. See Preamble II, A. 3. Interpretation of Defects, and B, (Change 3) page 15406; See MARGMA proposed changes to regulation (b)(1) General Test Method; (b)(1)(ii) *Identification of defects*, all sections; (b)(3) *Visual defects and leak tests procedures;* (b)(3)(i) *Visual defects examination,* all sections; and (d) *Compliance* (i)(C) and (D). In view of the above observations, MARGMA wishes to propose to the FDA to revise the test procedure and acceptance criteria to involve two sets of samples per lot, one set being to test for pinhole defects and the second set for testing or determining visual defects.

   MARGMA wishes to convey to the FDA the view that such a separation has been the industry practice for well over 15 years. Even today the glove trade is being regulated by issuing test certificates to the buyers that separately categorizes pinhole and visual defects. MARGMA observes that by separating the pinhole and visual defect AQL, the harmonization with the ASTM is more acceptable. It therefore proposes the following:

   a. For surgeons' gloves, a pinhole AQL of 1.5 and a visual defect AQL of 2.5
   b. For patient examination gloves, a pinhole AQL of 2.5 and a visual defect AQL of 4.0.

   MARGMA also recommends that FDA work with ASTM in a new program to better define the impact of visual defects on barrier integrity.

6. See Preamble II. Proposed Changes, A. 2 Harmonization With Consensus Standards. MARGMA further observes that whereas the ASTM standards specify the use of the single normal sampling plan for the test of pinhole defects, the FDA uses the multiple normal sampling plan. MARGMA believes that the AQL specified in both situations, although numerically the same, means differently when the sampling plan used is different.

7. General Comment: Because of the proposed requirements for visual defects, incompatibility with ASTM standards, and implementation with IA 80-04, MARGMA notes that the Proposed Rule without any modification will have a serious impact upon the ability of the manufacturers to deliver gloves that meet FDA's new requirements. Such impact may place more manufacturers into the automatic detention list and may cause a short supply of gloves to the US markets. MARGMA wishes to assure the FDA that while it looks upon the Proposed Rule from its positive impact upon the entire glove industry, it also wishes to draw the attention of the FDA to the likely negative scenario that can arise.

8. See Preamble IV. Analysis of Impacts, E. Cost of the Proposed Regulation. MARGMA believes that as efforts are made to improve the quality of gloves exported to the United States, there will be greater attention and cost to producing compliant gloves and managing

quality. The cost for the improved quality is not inconsequential [Preamble IV., E., 3. Withheld Lots, page 15410.] As such, the likelihood of supplying gloves without any price increase is unrealistic. MARGMA wishes to share the observation that manufacturers need to set in-house AQL standard very much tighter than FDA's new limits. [That is, manufacturers will need to release examination gloves at an AQL of 0.65 to 1.0]. Such new in-house standard is likely to lead to significant downgrading of some lots of gloves. Furthermore, the visual inspection protocol will have to be modified to match what the FDA requires. This is likely to give rise to further rejection of borderline visually defective gloves that may be inspected as defective by FDA.

9. See Preamble II., B., (Change 20) and (Change 21) page 15408; See MARGMA proposed changes to Proposed regulation (d)(2)(ii)(C). MARGMA commends the inclusion of Tightened Sampling Plans for reconditioned gloves. FDA's permission to manufacturers and importers to recondition a lot or part of a lot of gloves for re-testing will help to decrease the likelihood of false judgment regarding a statistical Type I sampling error, i.e., a good lot being rejected as a bad lot. At the moment, FDA has no policy to address a Type I sampling error, which could potentially put manufacturers at risk of being placed in damaging detention levels; and could potentially put distributors at risk of losing sales and customers.

   MARGMA believes FDA recognizes the consequences associated with sampling error risks and potentially damaging detention levels, a higher level of statistical certainty should be warranted. However, MARGMA is concerned over the allowable methodology for reconditioning and the conclusion made over from the subsequent analysis on retest results. MARGMA is proposing an additional criterion to the clause "(d)(2)(ii) *Adulteration levels and acceptance criteria for reconditioned gloves.*" under an additional Section (d)(2)(ii)(C) which states the following, or the legal equivalent of the following:

   " FDA considers the reconditioned lot of medical gloves tested by independent laboratory under tightened sampling to meet the AQLs which will provide additional assurance to the consumers. If the retest result has been determined to be acceptable, the initial analysis of the failed lot before reconditioning shall be nullified."

10. See Preamble IV. Analysis of Impacts D. Baseline Conditions, F. Benefits of the Proposed Regulation. MARGMA understands that AQL is defined as a level of acceptability of glove quality based on an agreed sampling plan. AQL is not related to percentage acceptability but is a number without a unit. MARGMA proposes that all reference to AQL as a percent value be rewritten to prevent misunderstanding by the readers.

11. See Preamble II. Proposed Changes; B, (Change 5); See Proposed regulation (b)(3)(iii)(A), etc. MARGMA suggests that, where possible, 800.20 be rearranged and re-numbered to reduce the complexity of the alphanumeric identifications for the sub-paragraphs because less complex notations make it easier to refer to in our documents, and to teach and discuss the new regulation with our employees.

12. For convenience, MARGMA has incorporated most of its proposed changes into the FDA Proposed Regulation in pages 4 and 5 below [next 2 pages]. MARGMA hopes that the FDA will consider the following revisions positively. The revisions as proposed by MARGMA are in red underlined text, and struck-out text.

Part 800 – GENERAL

1 The authority citation for 21 CFR part 800 continues to read as follows

Authority 21 U S C 321, 334, 351, 352, 355, 360e, 360i, 360k, 361, 362, 371

2 Section 800 20 is amended by revising paragraphs (b), (c), and (d) to read as follows

§800 20 Patient examination gloves and surgeons' gloves sample plans and test method for leakage defects, adulteration

* * * * *

(b)(1) *General test method* For the purposes of this part, FDA's analysis of gloves for leaks and certain other visual defects will be conducted by taking two separate samples, one for visual examination and the other by a water leak method, using 1,000 milliliters (ml) of water

(i) *Units examined* Each medical glove will be analyzed independently When packed as pairs, each glove is considered separately, and both gloves will be analyzed
(ii) *Identification of defects* For this test, defects are defined into the following categories
(A) leak
(B) tears or holes
(C) embedded foreign objects
(D) extruded glove material, embedded or on any glove surface, larger than 5mm diameter which breaks when the glove is inflated until the palm section is twice without applying any external pressure
(E) fused gloves that cannot be separated without tearing at least one of them
(F) sticky gloves that tear when separation is attempted (in this respect, a sticky glove that can be separated without tearing shall not be considered as defective within the definition of this section)

The following commonly known visual defects shall not be considered defective within the definition of this section as they do not affect the barrier integrity

(G) gloves with grip which are requested by customers for their frictional properties
(H) thickening of latex film caused by uneven spread during processing

A leak is defined as the appearance of water on the outside of the glove This emergence of water from the glove constitutes a watertight barrier failure
(iii) *Factors for counting defects* One defect in one glove is counted as one defect A defect in both gloves in a pair of gloves is counted as two defects If multiple defects, as defined in paragraph (b)(1)(ii) of this section, are found in one glove, they are counted as one defect Visual defects and leaks that are observed in the top 40 millimeters (mm) of a glove will not be counted as a defect for the purpose of this part

(2) *Leak test materials* The following materials are required for testing
(i) A 60mm by 380mm (clear) plastic cylinder with a hook on one end and a mark scored 40mm from the other end (a cylinder of another size may be used if it accommodates both cuff diameter and any water above the glove capacity),
(ii) Elastic strapping with Velcro or other fastening material,
(iii) Automatic water-dispensing apparatus or manual device capable of delivering 1,000 ml of water,
(iv) Stand with horizontal rod for hanging the hook end of the plastic tube The horizontal support rod must be capable of holding the weight of the total number of gloves that will be suspended at any one time, e g , five gloves will weigh about 5 kilograms (kg)

(3) *Visual defects and leak test procedures* For each sample lot, examine the sample and identify code/lot number, type, size, and brand as appropriate Perform ~~Continue~~ the visual examination using the following procedures
(i) *Visual defects examination* Inspect the gloves for visual defects by carefully removing the glove from the wrapper, box or package Visually examine each glove for defects As noted in paragraph (b)(1)(iii) of this section, a visual defect observed in the top 40mm of a glove will not be counted as a defect for the purpose of this part ~~Visually defective gloves do not require further testing, however, they must be included in the total number of defective gloves counted for the sample~~ Record the location and type of visual defect on the worksheet hand diagrams Record and total the number of visually defective gloves and refer to the tables following paragraph (c)(3) to determine if the lot passes or fails visual examination
(ii) *Leak test setup*
(A) During this procedure, ensure that the exterior of the glove remains dry Attach the glove to the plastic tube by bringing the cuff end to the 40mm mark and fastening with elastic strapping to make a watertight seal
(B) Add 1,000ml of room temperature water (i e , 20 °C to 30 °C) into the open end of the fill tube The water shall pass freely into the glove (With some larger sizes of long-cuffed surgeons' gloves, the water level may reach only the base of the thumb With some smaller gloves, the water level may extend several inches up the fill tube)
(iii) *Leak test examination* Immediately after adding the water, examine the glove for water leaks Do not squeeze the glove, use only minimum manipulation to spread the fingers to check for leaks Water drops may be blotted to confirm leaking
(A) If the glove does not leak immediately, keep the glove/filling tube assembly upright and hang the assembly vertically from the horizontal rod, using the wire hook on the open end of the fill tube (do not support the filled glove while transferring)
(B) Make a second observation for leaks 2 minutes after addition of the water to the glove Use only minimum manipulation of the fingers to check for leaks Record the location of the leaks on the worksheet hand diagrams and record the total number of water-leak defective gloves

(c) *Sampling, inspection, acceptance, and adulteration* In performing the test for leaks and other visual defects described in paragraph (b) of this section, FDA will collect and inspect samples of medical gloves, and determine when the gloves are acceptable as set out in paragraphs (c)(1) through (c)(3) of this section

(1) *Sample plans* FDA will collect samples from lots of medical gloves in accordance with agency sampling plans These plans are based on sample sizes, levels of sample inspection, and acceptable quality levels (AQLs) found in the International Standard Organization's standard, ISO 2859, Sampling Procedures for Inspection by Attributes

(2) *Sample sizes, inspection levels, and minimum AQLs* FDA will use single normal sampling for lots of 1,200 gloves or less and multiple normal sampling for all larger lots FDA will use general inspection level II in determining the sample size for any lot size As shown in the tables following paragraph (c)(3) of this section, for water leak defective gloves FDA considers a 1 5 AQL to be the minimum level of quality acceptable for surgeons' gloves and a 2 5 AQL to be the minimum level of quality acceptable for patient examination gloves

(3) *Adulteration levels and accept/reject criteria* FDA considers a lot of medical gloves to be adulterated when the number of water leak defective gloves found in the tested sample meets or exceeds the applicable rejection number at the 1 5 AQL for surgeons' gloves or the 2 5 AQL for patient examination gloves. The gloves are also considered adulterated if the number of gloves with visual defects , which could impact the integrity of the barrier, found in the tested sample meets or exceeds the applicable rejection number at the 2 5 AQL for surgeons' gloves or the 4 0 AQL for patient examination gloves. These waterleak and visual acceptance and rejection numbers are identified in the 4 tables following paragraph (c)(3) of this section as follows

Tables for Normal Gloves

(to include SEPARATE visual defects AQL table)

(d) *Compliances* Lots of gloves that are sampled, tested, and rejected using procedures in paragraphs (b) and (c) of this section, are considered adulterated within the meaning of section 501(c) of the act

(1) *Detention and seizure* Lots of gloves that are adulterated under section 501(c) of the act are subject to administration and judicial action, such as detention of imported products and seizure of domestic products

(2) *Reconditioning* FDA may authorize the owner of the product, or the owner's representative, to attempt to recondition, i e , bring into compliance with the act, a lot or part of a lot of foreign gloves detained at importation, or a lot or part of a lot of seized domestic gloves

(i) *Modified sampling, inspection, and acceptance* If FDA authorizes reconditioning of a lot or portion of a lot of adulterated gloves, testing to confirm that the reconditioned gloves meet AQLs must be performed by an independent testing facility The following tightened sampling plan must be followed, as described in ISO 2859 "Sampling Procedures for Inspection by Attributes "

(A) General inspection level II,
(B) Single sampling plans for tightened inspection,
(C) 1.5 pinhole AQL and 2.5 visual defect AQL for surgeons' gloves, and
(D) 2.5 pinhole AQL and 4.0 visual defect AQL for patient examination gloves

(ii) *Adulteration levels and acceptance criteria for reconditioned gloves* (A) FDA considers a lot or part of a lot of adulterated gloves, that is reconditioned in accordance with paragraph (d)(2)(i) of this section, to be acceptable when the number of defective gloves found in the tested sample does not exceed the acceptance number in the appropriate tables in paragraph (d)(2)(ii)(B) of this section for reconditioned surgeons' gloves or patient examination gloves

Tables for Reconditioned Gloves

(to include SEPARATE visual defects AQL table)

(B) FDA considers a reconditioned lot of medical gloves to be adulterated within the meaning of section 501(c) of the act when the number of defective gloves found in the tested sample meets or exceeds the applicable rejection number in the tables following paragraph (d)(2)(ii)(B) of this section

(C) FDA considers the reconditioned lot of medical gloves tested by independent laboratory under tightened sampling to meet the AQLs which will provide additional assurance to the consumers. If the retest result is determined to be acceptable, the initial analysis of the failed lot before reconditioning shall be nullified

Dated March 31, 2003
William K Hubbard
Associate Commissioners for Policy and Planning

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ATTACHMENT 1:

LIST OF MEMBER COMPANIES
[ORDINARY (Manufacturing) MEMBERS]

MALAYSIAN RUBBER GLOVE MANUFACTURERS' ASSOCIATION (MARGMA)

1. Alliance Rubber Products Sdn Bhd
2. Ansell (Kedah) Sdn Bhd
3. APL Healthcare Sdn Bhd
4. Apollo Rubber Sdn Bhd
5. Brightway Holdings Sdn Bhd
6. Comfort Rubber Gloves Industries Sdn Bhd
7. Concept Rubber Products Sdn Bhd
8. Contract Latex Dippers Sdn Bhd
9. Cranberry (M) Sdn Bhd
10. FELDA Rubber Products Sdn Bhd
11. Flexitech Sdn Bhd
12. GB Industries Sdn Bhd
13. Glovco (M) Sdn Bhd
14. Guthrie Medicare Products (NS) Sdn Bhd
15. Handsafe Products Sdn Bhd
16. Hartalega Sdn Bhd
17. IGA Overseas Sdn Bhd
18. JB Star Sdn Bhd
19. KL-Kepong Rubber Products Sdn Bhd
20. Koon Seng Sdn Bhd
21. Kossan Latex Industries (M) Sdn Bhd
22. Latexx Manufacturing Sdn Bhd
23. Longcane Industries Sdn Bhd
24. MAPA (gloves) Sdn Bhd
25. Marcon Rubber Industry Sdn Bhd
26. N.S. Uni-Gloves Sdn Bhd
27. Oon Corp Resources (M) Sdn Bhd
28. Pan Century Rubber Products Sdn Bhd
29. Perusahaan Getah Asas Sdn Bhd
30. Perusahaan Pelindung Getah (M) Sdn Bhd
31. Protection Gloves (M) Sdn Bhd
32. Purnabina Sdn Bhd
33. Quality Latex Products Malaysia Sdn Bhd
34. Riverstone Resources Sdn Bhd
35. Sanchem Corporation Sdn Bhd
36. Seal Polymer Industries Sdn Bhd
37. Seltom Pacific Sdn Bhd
38. Smart Glove Corporation Sdn Bhd
39. Sri Johani Sdn Bhd
40. SSN Gloves (M) Sdn Bhd
41. Super Latex Sdn Bhd
42. Supermax Corporation Berhad
43. Tekmedic (M) Sdn Bhd
44. Terang Nusa Sdn Bhd
45. TG Medical (M) Sdn Bhd
46. Top Glove Corporation Berhad
47. Ultrawin Sdn Bhd
48. Wear Safe (Malaysia) Sdn Bhd
49. WRP Asia Pacifc Sdn Bhd
50. WRP Senetimed Sdn Bhd
51. YTY Industry Sdn Bhd
52. Bonric Sdn Bhd