MARGMA

MALAYSIAN RUBBER GLOVE MANUFACTURERS' ASSOCIATION

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Our Ref. *MARGMA* Date :

Your Ref.

Date: .. July, 2003

FROM: **Malaysian Rubber Glove Manufacturers' Association (MARGMA)**
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TO: **Dockets Management Branch (HFA-305),**
Food and Drug Administration,
5630 Fishers Lane, Rm. 1061,
Rockville, MD 20852, USA

Reference : Docket: No. 00D-1384. **Additional Comments by MARGMA**

Subject: Import Alert IA 80-04

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

MARGMA notes that the present or proposed 800.20 is implemented with 21 CFR Part 820 GMP/QS and Import Alert #80-04. Therefore, MARGMA respectfully requests that FDA review the current Import Alert #80-04 guidance, "***Surveillance and Detention without Physical Examination" [DWPE***] together with the new proposed rule identified immediately below:

800.20 Medical Devices; Patient Examination and Surgeons' Gloves; Test Procedures and Acceptance Criteria.
Reference: Docket No. 03N-0056.

00D-1384

C9

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

Sincerely Yours,

Andrew Tan
Executive Director
Malaysian Rubber Glove Manufacturers' Association

Attachments 2

ADDITIONAL COMMENTS ON IA 80-04

MARGMA has submitted comments on IA 80-04 and we would like to submit the additional following comments.

Comment: Where IA 80-04 calls for 5 or 10 consecutive good shipments to get off DWPE after a failure, please make it **clear** that it is 5 or 10 good shipments after the failure and not 5 or 10 consecutive good shipments to get off DWPE after FDA places the manufacturer/shipper on the alert list.

Rationale: The additional delay is much more punitive. While under detention, a manufacturer pays the cost of testing; however, much more important, is the loss of business and loss of customers because they move, and must move, to other suppliers if it appears that there will be continued delays in getting gloves released.
The delays have and extremely serious negative impact on the 'detained' manufacturer. That is, MARGMA believes that the Recidivist Policy was intended to achieve corrective action rather than forcing a manufacturer out of the glove business.

Comment: Where IA 80-04 calls for 5 or 10 consecutive good shipments to get of DWPE after a failure, please make it **clear** that it is not consecutive good shipments for 6 months or more to get off DWPE after FDA places the manufacturer/shipper on the alert list.

Rationale: One of our manufacturers has been subjected to 6 months of good shipments before getting off DWPE rather than the required 5 good shipments with no reason given for the private requirements. The additional delay is devastating and is not in IA 80-04. While under detention, this manufacturer pays the cost of testing; however, much more important, is the loss of business and loss of customers because their customers move, and must move, to other suppliers if delays in getting gloves released will **continue for more than 6 months**. MARGMA believes that FDA employees should follow the text and intent of IA 80-04 rather than setting arbitrary and devastating policy. Such arbitrary policy destroys the FDA promoted concept of a level playing field.

Copy of IA 80-04 for reference.
IA #80-04

REVISED 9/11/97, IMPORT ALERT #80-04, "SURVEILLANCE AND DETENTION WITHOUT PHYSICAL EXAMINATION OF SURGEON'S AND OR PATIENT EXAMINATION GLOVES

ATTACHMENT A - 3/15/01, ATTACHMENT B - 8/1/00

(NOTE: This import alert represents the Agency's current guidance to FDA field personnel regarding the manufacturer(s) and/or product(s) at issue. It does not create or confer any rights for or on any person, and does not operate to bind FDA or the public.

REASON FOR REISSUANCE: A new procedure was developed for detention without physical examination of gloves manufactured by firms who repeatedly import non-compliant products.

TYPE OF ALERT: Surveillance (Physical Examination), and Detention Without Physical Examination

PRODUCT: Surgeon's and Patient Examination Gloves

PRODUCT CODE: 80LZA, 80FMC, 80LYY, 80LZC, 80LYZ, 79KGO

PAC: 82Z003

PROBLEM: Defective per 21 CFR 800.20 - Leaks, tears, mold, embedded foreign objects

COUNTRY: Surveillance - All Countries - (ZZ) Detention Without Physical Examination - See Attachments (A & B)

MANUFACTURER/ SHIPPER: See Attachments (A & B)

MANUFACTURER/ SHIPPER ID#: N/A

IMPORTER'S ID #: N/A

CHARGE: "The article is subject to refusal of admission pursuant to section 801(a)(3) in that it appears to contain defects/holes [Adulteration, section 501(c).]"

When FDA has documented repeated violations, and the manufacturer/shipper has been issued a Warning Letter and listed in Attachment B of the Recidivist Policy described below, future shipments may be detained charging the following:

"The article is subject to refusal of admission pursuant to section 801(a)(1) in that it appears that the methods used in, or the facilities and controls used for, the manufacture, packaging, storage, or installation of the device do not conform with Good Manufacturing Practices [Adulteration, section 501(h), Good Manufacturing Practices, Section 520(f).]"

RECOMMENDING OFFICE: Center for Devices and Radiological Health (CDRH)

REASON FOR ALERT: CDRH has determined that many foreign manufacturers and shippers of medical gloves have failed to consistently provide medical gloves of adequate quality for distribution in the U. S. Surgeon's and examination gloves are widely used by health care professionals and others as a barrier to blood-borne diseases and pathogens. Defective medical gloves present a potential hazard to health for users as well as patients. Therefore, continuous monitoring of these medical gloves is needed.

GUIDANCE: Districts may detain without physical examination, all shipments of surgeon's and patient examination gloves from the manufacturers/shippers listed on the attachments to this alert.

Surveillance sampling of other manufacturers/shipper's surgeon's and patient examination gloves per the most recent guidance is indicated.

NOTE: Because the presence of defects in medical gloves represents a potential hazard to health, only one (1) violative sample is needed to submit a recommendation for detention without physical examination to the Division of Import Operations & Policy (DIOP). DIOP has direct reference authority for detention without physical examination of these medical gloves. Violative medical gloves are subject

to RPM Chapter 9, Detention Without Physical Examination, subchapter "Recommendations Based on One Sample."

The following strategy has been established to address those manufacturers/shippers who are found to repeatedly ship violative medical gloves to the U.S. (recidivist firms.)

Level 1 Detention (INDICATED BY * IN ATTACHMENT A)

When a district encounters a shipment of medical gloves which is found violative for defects by FDA analysis, the shipment should be detained and a recommendation for detention without physical examination should be forwarded to DIOP, HFC-170.

If the recommendation meets current guidance, the manufacturer/shipper will be placed on attachment "A" with a single asterisk(*), and subsequent medical glove shipments from that manufacturer/shipper may be detained without physical examination under this import alert. This is referred to as "Level 1 detention." The manufacturer/ shipper may obtain admission of subsequently detained shipments of medical gloves by presenting evidence that the individual shipments are not adulterated, such as sample analyses performed by an independent testing laboratory, following the sampling plan and test method contained in FDA guidance.

In order for the responsible manufacturer's/shipper's name to be removed from attachment "A," documentation should be provided with sufficient evidence that their medical gloves are not adulterated (for example, five consecutive non-violative shipments analyzed as described in the preceding paragraph may be considered adequate evidence for manufacturers/shippers to be removed from Level 1 detention).

Level 2 Detention -- (Recidivist firms which are currently on Level 1 detention, or which have been removed from Level 1 detention) (INDICATED BY ** IN ATTACHMENT A)

If a manufacturer/shipper, while on Level 1 detention, has a violative sample analyzed by a private laboratory, the district should notify DIOP and submit supporting documentation. DIOP will place the firm on Level 2 detention and identify the manufacturer/shipper on attachment "A" with two asterisks (**).

Similarly, if a manufacturer/shipper that has been removed from Level 1 detention has a violative sample analyzed by FDA within 24 months from the date they were removed from Level 1 detention, the district should notify DIOP and submit supporting documentation. DIOP will verify the manufacturer/shipper was listed under Level 1 detention during the past 24 months and if confirmed will place the manufacturer/shipper on Level 2 detention and identify the manufacturer/shipper on attachment "A" with two asterisks(**).

DIOP will bring this action to the attention of CDRH.

Based on this second listing within 24 months, CDRH has agreed to notify the foreign firm in writing of FDA's concerns about potential deficiencies in the manufacturing practices and process controls which may be affecting the quality of the medical gloves shipped to the U.S. A copy of the Good Manufacturing Practices (GMP) Regulations will be provided with the letter for their information.

Once a manufacturer/shipper is placed on Level 2 detention, FDA may need greater assurance that the medical gloves are not adulterated before removing the manufacturer/shipper from detention without physical examination status. For example, 10 consecutive non-violative shipments, analyzed by an independent testing laboratory, may be considered adequate evidence that the manufacturer/shipper is

shipping medical gloves to the U.S. which are not adulterated. Other types of evidence to remove the appearance of a violation will be evaluated by CDRH on a case-by-case basis.

Level 3 Detention -- (Recidivist firms which are currently on Level 2 detention, or which have been removed from Level 2 detention) (** * IN ATTACHMENT A DENOTES A WARNING LETTER IS BEING CONSIDERED BY CDRH)

If a manufacturer/shipper, while on Level 2 detention, has another violative sample analyzed by an independent testing laboratory, the district should notify DIOP and submit supporting documentation.

Similarly, if a manufacturer/shipper removed from Level 2 detention has another violative sample analyzed by FDA within 24 months from the date they were removed from Level
1 detention, or the date they were placed on Level 2 detention, DIOP will bring these instances to the attention of CDRH.

Based on the failure of the manufacturer's/shipper's medical gloves to pass FDA analysis [Section 501(c)] after being listed on Level 2 detention, or having failed an independent testing laboratory examination while under Level 2 detention, CDRH may then issue a Warning Letter to the firm.
Additionally, after reviewing the manufacturer/shipper's export and inspectional history, CDRH may elect to charge the firm for failure to conform with GMP's [Section 501(h)], based on the recurring GMP deficiencies as revealed by the repeated failures of analyses.

If CDRH determines a warning letter should issue to the foreign manufacturer/shipper, DIOP will place the manufacturer/shipper on Level 3 detention (attachment B).

Non-violative analyses may not be sufficient to remove the appearance of a violation for manufacturers/shippers on attachment B. Manufacturers/shippers will remain on Level 3 detention until evidence is provided to CDRH which demonstrates that the medical gloves are being manufactured in accordance with Good Manufacturing Practices (for example, an acceptable FDA inspection or a written certification from the manufacturer/shipper together with the results of an independent audit performed by a qualified third party).

Once a foreign manufacturer/shipper satisfactorily demonstrates that the apparent GMP deviations have been corrected, the manufacturer/shipper will be removed from attachment "B" and placed on attachment "A" under the Level 1 detention for individual shipment analysis to confirm their medical gloves do not contain defects until they provide adequate evidence to be removed from Level 1 detention (see above).

For questions or issues concerning science, science policy, sample collection, analysis, preparation, or analytical methodology, contact the Division of Field Science at (301)
443-3320 or 3007.

For questions concerning 21 CFR 800.20, CPG 7124.31, medical glove labeling, or other compliance issues, contact CDRH, Office of Compliance, Division of Enforcement II at (301)
594-4618.

SAMPLING: See 21 CFR 800.20(c) for sample plans.

All sizes should be represented as closely as feasible to the proportion which they exist in the shipment, however, exact statistical representation is not necessary. If the sample is found violative, all sizes should be detained.

When an entry consists of only one size, attempt to collect as many lot numbers as possible. For example, if during a random sample collection three lot numbers are observed, represent them all as subs within one sample. If the sample is found violative, all lots should be detained.

If a shipment is detained based on the analysis of one lot and subsequently it is learned that there were 10 lot numbers present, the detention stands.

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