

PERUSAHAAN PELINDUNG GETAH (M) SDN BHD (Company No. 169997-P)

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Dockets Management Branch (HFA-305)

Food and Drug Administration

5630 Fishers Lane, Rm 1061,

Rockville, MD 20852,

United States of America.

Ref: Docket No. 00D-1384

October 06, 2000

Dear Sir,

Comment and Proposals on 'Guidance for Surveillance and Detention without Physical Examination of Surgeon's and/or Patient Examination Gloves' Recidivist Policy.

We are a registered latex examination glove manufacturer since 1988 and we are exercising our privilege to comment on the recidivist policy and make our proposals for your consideration.

1. Generally we find the policy carrying a punitive direction without an opportunity for the exporter or manufacturer concerned to apply a right to recall his defective products.
2. We do not object to the manner of classification under 3 levels of detention but we appeal on reducing the 'good performance' period from 24 months to 6 months. A manufacturer who is in automatic detention at any level will make serious efforts to bail out of the list and improve on his quality system management or risk his business dealing with his American buyers. 24 months is too long a time frame and too punitive a measure. In any case he should have a right to recall any shipments on water without the FDA taking actions on such shipments. A recall policy will benefit the United States in safe guarding her consumers from defective products in circulation.
3. We are of the view that FDA should not combine all the products and all the 510k's of the same manufacturer in the enforcement of the recidivist policy. There are different control measures for the different types of products even produced by the same manufacturer, hence a violation in one product line need not necessary means violation in the other product lines. We appeal that automatic detention be based on product type and 510k. A manufacturer whose powder-free latex exam gloves are under automatic detention should not be penalized further by having his powdered gloves blocked as well.

We wish to submit the following revision to the policy for debate and consideration.

- a. The manufacturers need to have an efficient communication channel with the FDA. We propose that all glove manufacturers, foreign and domestic, be registered with the FDA as a mandatory requirement. FDA will maintain e-mail and fax addresses of all registered manufacturers for prompt communication especially when a violation has been detected. Presently we only get the information from your web-site.

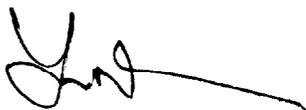
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- b. A manufacturer with one violation and under automatic level 1 detention shall have the right to recall his subsequent shipments on water to the United States. Such shipments, after arrival in the U.S. ports, should be allowed to be re-exported back or elsewhere, even though FDA may have collected samples or even commence testing on these shipment samples. FDA shall not consider these recalled shipments against the manufacturer as part of its compliance exercise. Rather the FDA shall consider this a responsible attitude taken by the manufacturer concerned to avoid further troubles as well as ensure only compliant gloves are imported into the United States. However, FDA shall continue to exercise her right to require sufficient evidence of non-adulteration, such as 5 consecutive non-violative shipments, before the manufacturer can be removed from level 1 detention. The manufacturer while on level 1 detention has a violative sample analyzed by a private laboratory will be placed on level 2 detention.
- c. A manufacturer who has been removed from the level 1 detention has a violative sample analyzed by FDA within 6 months from the date of removal shall be placed under level 2 detention. However, if the manufacturer do not have a violative sample analyzed during the 6 months period after removal from level 1 detention, the said manufacturer's detention file is closed and any subsequent violation shall be treated as a first violation and the procedure is applied from the start.
- d. A manufacturer who has been removed from the level 2 detention has a violative sample analyzed by FDA within 6 months from the date of removal shall be placed under level 3 detention. FDA shall exercise her current recidivist policy for this stage of non-compliance.
- e. In the case of a shipment that comprises more than one type of medical gloves, for example, powdered and powder-free latex examination gloves, the shipment shall be considered in 2 parts and violation of one type shall not compromise the second if the second type of medical gloves passes the examination. It is agreed that all sizes of the glove type that fails the examination shall be considered to have failed together.
- f. All non-compliant shipments shall be refused entry into the U.S. but be re-exported. This is to stabilize the medical glove market integrity and regulate its pricing mechanism independent of the non-medical glove supply.

We sincerely hope that this proposal will receive its due consideration and review for the overall benefits of the industry and the U.S. medical glove market. Thank you.

Yours sincerely,
Perusahaan Pelindung Getah (M) Sdn Bhd



Peter Yew Nieng Choon
Managing Director

Copy: President, Malaysian Rubber Gloves Association
CEO, Malaysian Rubber Export Promotion Council

FedEx International Air Waybill

1 From
 Date 10/07/2000 Sender's FedEx Account Number 1634-3040-0

Sender's Name Mrs. Yaw Niang Chyan Phone 06-677 2781

Company CAREPLUS (P) SIA WHD

Address SERAWANG 4, SERAWANG IND EST

SERAWANG 4, SERAWANG IND EST

ZIP Postal Code 70051

2 Your Internal Billing Reference

3 To
 Recipient's Name _____ Phone _____

Company _____

Address DOCKET'S MANAGEMENT BRANCH (HFA-305)

FOOD & DRUG ADMINISTRATION, 5630 FISHERS LANE,
RD 1061, ROCKVILLE,

City ROCKVILLE State Province _____

Country J.S.A. ZIP Postal Code MD 20852

Recipient's Tax I.D. number for Customs purposes
 e.g. GST/RFC/VAT/IN/EIN, or as locally required

4 Shipment Information

For EU Only. Tick here if goods are not in free circulation and provide C.I. ALL shipments are subject to Customs charges.

Total Packages 1 Shipper's Load and Count/SLAC
 Total Weight 0.2 lbs. 0 kg DIM 1 / 1 / 1 in. 0 cm

Commodity Description	Harmonized Code	Country of Manufacture	Value for Customs
<u>the</u>		<u>MY WPD</u>	
For U.S. Export Only: Check One <input type="checkbox"/> No SED required per Exemption <input type="checkbox"/> No SED required, value \$200 or less per Schedule B Commodity number			
Total Declared Value for Customs			Total Value for Customs (Specify Currency)
<input type="checkbox"/> SED attached (provide export license no. and exp. date or license exception symbol, w/ECCN if applicable)			

FedEx Tracking Number **8224 7149 6854** Form I.D. No. **0402**

5 Express Package Service

Packages up to 150 lbs. / 68 kg
 For packages over 150 lbs. (68 kg), use the FedEx Expanded Service Intl. Air Waybill.

Not all services and options are available to all destinations.

1 FedEx Intl. Priority 6 FedEx Intl. First
Available to select locations. Higher rates apply.

3 FedEx Intl. Economy
FedEx Envelope/Letter and FedEx Pak rate not available.

6 Packaging

These unique brown boxes with special pricing are provided by FedEx for FedEx Intl. Priority only.

6 FedEx Envelope/Letter 2 FedEx Pak 1 Other Pkg.
Includes FedEx box, FedEx Tube, and customer pkg. PW FedEx 10kg Box PX FedEx 25kg Box

7 Special Handling

1 HOLD at FedEx Location 3 SATURDAY Delivery
Available to select locations

Shipper must check / tick

This shipment does not contain Dangerous Goods.
Dangerous Goods cannot be shipped using this Air Waybill.

8a Payment Bill transportation charges to:

1 Sender Acct. No. in Section 1 will be billed. 2 Recipient 3 Third Party 4 Credit Card 5 Cash Check/Cheque
Total Transportation

FedEx Acct. No. _____ Credit Card No. _____
 Credit Card Exp. Date _____ Specify Currency _____

8b Payment Bill duties and taxes to: *FedEx cannot estimate Customs charges

1 Sender Acct. No. in Section 1 will be billed. 2 Recipient 3 Third Party 5 Cash Check/Cheque
 FedEx Acct. No. _____

9 Required Signature

Use of this Air Waybill constitutes your agreement to the Conditions of Contract on the back of this Air Waybill, and you represent that this shipment does not require a U.S. State Department License. Certain international treaties, including the Warsaw Convention, may apply to this shipment and limit our liability for damage, loss, or delay, as described in the Conditions of Contract. **WARNING:** These commodities, technology, or software were exported from the United States in accordance with Export Administration Regulations. Diversion contrary to U.S. law prohibited.

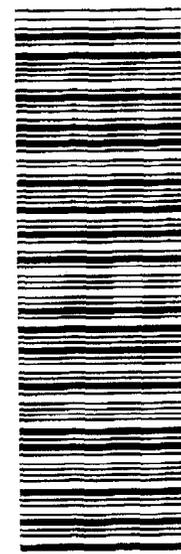
Sender's Signature: _____ Date Executed: 7/10/200
This is not authorization to deliver this shipment without a recipient signature.

Received above shipment in good order and condition. We agree to pay all charges, including Customs duties and taxes as applicable, and we agree to the Conditions of Contract as stated on the reverse side of the Recipient's Copy.

Recipient's Signature: _____

FedEx Tracking Number **8224 7149 6854** Form I.D. No. **0402**

Origin Station I.D. <u>M4KW</u>	Destination Station I.D. <u>MS-GA</u>	UBSA Routing <u>02-GA</u>	Handling Units
Received At: <input type="checkbox"/> 1 Reg. Stop <input type="checkbox"/> 2 Ad-Call Stop <input type="checkbox"/> 3 Drop Box <input type="checkbox"/> 4 World Service Center <input type="checkbox"/> 5 Station			Forms Attached: <input type="checkbox"/> CI <input type="checkbox"/> SED <input type="checkbox"/> CO
Base Charges	Declared Val. Chrg.	Other	Del. Courier
FedEx Emp. #	Audit Emp. #	Date	Time



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