

Date : 20 October 2000

To : Dockets Management Branch
Division of Management System and Policy,
Food and Drug Administration

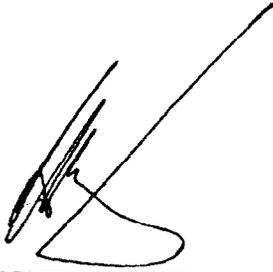
From : C.E. Lim

Re : *Comment on Recidivist Policy (Docket No : 00D-1384)*

We are pleased to submit our comments on the proposed Draft Guidance – RECIDIVIST POLICY.

Our comments are per attached.

Yours faithfully,



C.E. Lim (Mr)
General Manager - QA

- C.C
1. Mr Andrew Tan
Malaysian Rubber Glove Manufacturer's Association
 2. Dr Esah Yip
Malaysian Rubber Export Promotion Council

00D-1384

Comment 1

(a) Draft guidance states:

Firms will be placed on Import Alert # 80-04 only for two categories of gloves : “surgeon’s gloves” and / or “patient examination gloves “. Specific types / styles of gloves (powdered , powder-free , vinyl , nitrile ,etc.) are not considered separate glove categories for the purposed of the Recidivist Policy and should not be referenced in a recommendation for detention.

(b) Proposal

Since FDA categories Patient Examination Gloves and Surgeon’s gloves into product codes according to the glove material or area of application, it is suggested that detention should be based upon such categories.

The product codes are namely:

(i) Patient Examination Gloves

| | |
|-------|--|
| 80LYY | Latex (all types) |
| 80LZA | Polymer (nitrile , polyurethane, etc.) |
| 80LZC | Specialty (chemotherapy) |
| 80LYZ | Vinyl (PVC) |

(ii) Surgeon’s gloves

| | |
|--------|------------------------------|
| 79 KGO | Surgeon’s gloves (all types) |
| 79 KGQ | Autopsy gloves |

The process of manufacturing and control for each materials is different . If a firm produces Latex (80LYY) and Polymer (80LZA) gloves, and have trouble with polymer gloves, it does not necessary mean that they will have problem with the latex gloves

Hence the detention should be based on the product code which determines the capability of the firm to produce such device.

Comment 2

Level 2 Detention

(a) Draft guidance states:

Firms that fail FDA or private lab analysis while on Level 1 detention, or firms that have a violate shipment within 24 months after being removed from Level 1, will be placed on Level 2 detention.

(b) Proposal :

It is agreed that a firm that fail FDA or private lab analysis (for the five consecutive shipments) while on Level 1 detention will be placed on Level 2 detention .

However, after the firm has been removed from Level 1 detention, a violate shipment within 24 months will cause the firm to be placed on level 2 detention.

It is felt that the 24 months period is too long. This is a long period for firms that export 30 to 40 containers per month to the United States. It will mean that at least 720 to 960 shipments were made during the 24 months period.

The chances of shipments being sampled by FDA is higher as compared to the smaller manufacturers who make 10 containers per month. With all due respect to the Quality Controls implemented by the manufacturer , sometimes "bad" luck may strike. As all the manufacturer perform statistical sampling of the gloves instead of 100 % check, an escape of "bad" sub-lot may occur.

With huge volumes of export, the chances of failing one or two containers may be there.

We would like to propose a reduction on the monitoring period of 24 months to 12 months.

Comment 3

Level 3 Detention

(a) Draft guidance states:

Level 3 detention includes firms that fail FDA or private lab analysis while on Level 2 detention, or firms that were removed from Level 2 detention , and have another violate shipment within 24 months from the date FDA either removed the firm from Level 1 detention status or increased the status to level 2 detention.

(b) Proposal

It is agreed that a firm that fails FDA or private lab analysis (during the 10 consecutive shipment) while on Level 2 detention will be placed on Level 3 detention.

The shaded portion from the above statement is causing some confusion

We recommend for FDA to make the statement (shaded sentences) simple . It is suggested that the “observation” period to be stated the same as for Level 2 detention.

i.e. an example of the rephrase of the shaded sentences to be as follows:

“...firms that were removed from Level 2 detention and have another violate shipment within XX months after removed from Level 2 detention”.

The XX months is also recommended to be 12 months period.

In this manner, manufacturer will have a clear understanding that eventhough they are removed from detention (either level 1 or 2) they have XX months to ensure that their product is not adulterated.

Comment 4

1. The recidivist policy did not mention the status for a firm which has been cleared from Import Alert # 80-04 (Level 2) and has no violate shipment after the 24 months period.

Does the firm go back to Level 1 ? or the firm is "clear" to start again from "zero" ?

What happen if there is another violate shipment after the 24 months? The firms will be on Level 1 or Level 2 ?