

DOCKET NO. 00D-1384



Alliance Rubber Products Sdn.Bhd.

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Dockets Management Branch (HFA-305),
Food and Drug Administration [Docket No. 00D-1384]
5630 Fishers Lane, Room 1061,
Rockville, MD20852,
USA.

Dear Sir/Madam,

Re : Comment of Redicivist Policy for medical gloves “Guidance for Surveillance and Detention Without Physical Examination of Surgeons and/or Patient Examination Gloves”

We would like to submit our comments :

1. The redicivist policy include all kind of medical gloves as same item. For example, a manufacturer who manufacture latex exam. gloves and nitrile exam. gloves, powdered or powder free,.... etc, which may come out to 5-6 types of different examination gloves. If any one type of gloves failed FDA inspection, this means all types will be on detention list. Please note we need to have different 510K for each different gloves.

Which we find can be very unfair. For natural rubber latex exam. gloves and nitrile exam. gloves, these 2 items are produce from different machine, process, control, ASTM standard and material. Completely two different gloves. Moreover, from powdered to powder free, or polymer coated, there is an additional process or different process.

Our comment is natural rubber latex exam. gloves and nitrile exam. gloves should be separately. If nitrile exam. gloves is on detention, latex exam. gloves from the same manufacturer should not be on detention list.

And, if this can further differentiate as different type as powdered, powder free and polymer coated.

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2. Quantity export to USA : Manufacturers export different volume to US. For manufacturer like us which our export volume to US per month can be export volume of another manufacturer for a year. And we carry many types of different gloves, the chances for us to be on detention list is higher than manufacturer who export smaller volume or one type of gloves to USA

We hope FDA can look into this. As export volume is bigger, the effect will be more serious.

3. From our experience, the time taken for inspection and release from FDA, sometime can be very long time. Sometime, we as overseas manufacturer do not know what is the reason for such long delay. The same, we will only know that we are on detention list usually much later. In which, for a manufacturer like us, at anytime we will have shipment on sea or arriving in US port, the timing can be complicate and unfair to manufacturers.

We hope our comments can se seriously taken into consideration.

With best regards.

Alliance Rubber Products Sdn. Bhd.,

Chua Hooi Koon