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สมาคมผู้ผลิตถุงมือยางไทย

THAI RUBBER GLOVE MANUFACTURERS ASSOCIATION

REF NO. TRGMA 087/2003

25th June 2003

The Dockets Management Branch (HFA-305)
Food and Drug Administration,
5630 Fishers Lane, rm.1061,
Rockville, MD20852.
U.S.A.

RE: Docket No. 03N-0056

Dear Sirs,

With the reference to the new FDA Proposed Rules, on behalf of The Thai Rubber Gloves Manufacturers Association members, we would like to make some comments on the following points:

1) The Definition of Defects

The FDA proposed of changing the definition of defects from the current "leaks, tears, mold, embedded foreign objects, etc " to " tears, embedded foreign objects, or other defects visible upon initial examination that may affect the barrier integrity or leaks detected when tested." Defects visible upon the initial examination is rather broad defined definition and inspector's decision is relied solely on individual judgement.

The Association would like to propose to the FDA to test all samples by using The current FDA's standard for Visual and water leak test method.

2) The Acceptable Quality Level (AQL)

The FDA proposed of the AQL for patient examination gloves = 2.5 % and the AQL for surgeons' gloves = 1.5%

In principal, we are willing to support the proposed rules, however, since most manufacturers in Thailand have faced difficulties due to the Economics Crisis during the past 5 years , therefore, we will need more time in implementing and improving our machineries and Quality Control Procedures in order to achieve the AQL 2.5% target . We wish to propose that this adoption of the new proposed should be postponed until the year 2010.

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3) The switching from Multiple Normal Sampling Plan to Single Tightened Sampling Plans for reconditioned lots.

The Tightened Plan at the same AQL for Normal Plan is merely to reduce accepted number (in order to reduce consumer's risk). The true quality of the lots are still the same. There is always the possibility of our making type I and type II error when we take samples from a lot. To guarantee most of the lots will pass the FDA's water leak test, the whole industries by no means have to use the Tightened Sampling Plan to control their outgoing products instead of the current Multiple Normal Sampling Plan.

The Association wishes to propose to the FDA to reconsider to adopt The Single Normal Sampling Plan for reconditioned lots as the Normal Inspection for the original submitted lots and the optimum sampling plan should be taken into account both technical and economical aspects.

In summary, we , on behalf of the major manufacturers of Examination Gloves in Thailand wishes to pledge our full support of the new proposed rules for the benefit of the worldwide consumers. However, in achieving the new rules for mutual benefits of the manufacturers and consumers, we on the manufacturers side would have to invest in new machineries and train more efficient staffs which are time consuming , especially in Thailand where we have just stepped out of the economic crisis since last 5 years. Therefore, we would like to propose that the adoption of the above rules should be gradually implemented and targeted for total achievement in the year 2010.

We would like to thank you for your kind consideration and assure that all manufacturers in Thailand are ready and willing to cooperate with the U.S. FDA.

Yours sincerely,
The Thai Rubber Glove Manufacturers Association

สมาคมผู้ผลิตถุงมือยางไทย
THAI RUBBER GLOVE MANUFACTURERS ASSOCIATION

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