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Docket No. 00D-1384
Dockets Management Branch
Division of Management Systems and Policy
Office of Human Resources and Management Services
Food and Drug Administration
5630 fishers Lane, Room 1061, HFA - 305
Rockville, MD 20857

Docket No. 00D-1384

Subject: Guidance for Surveillance and Detention Without Physical Examination of Surgeon's and/or Patient Examination Gloves (Recidivist Policy).

Comments:

1. The policy statement:

> Because the presence of defects/holes in surgeons' and/or patient examination gloves may present a possible hazard to health, only one (1) defective sample is needed to recommend detention without physical examination to FDA's Division of Import Operations & Policy (DIOP).

appears to not completely ignore the error in sampling plans because it is a recommendation to DIOP rather than the only factor. That is, the shipment rejected based on sampling results may actually be a good shipment. The Policy should indicate what other factors DIOP takes into consideration. For example, DIOP could consider facility inspection data, firm has never been on detention before, previous shipments, and excessive number of defectives when the sample failed.

2. The Policy considers the number and frequency of shipment failures and ignores the severity of the failures. A manufacturer should be placed on Level III for the first defective shipment if the gloves are bricks, non-donnable, "potato chips/flakes", covered with mold, or full of holes (excessive defectives).

3. The Policy needs to be modified in order to support the QS regulation. The present Policy waits to reach too high a level before advising the manufacturer/shipper about requirements in the Quality System Regulation and thus does not support the §820.100 CAPA requirements in the QS/GMP regulation. The QS regulation requires the firm to perform CAPA at Level I. FDA should

request and review the firm's CAPA actions at Level II instead of Level III. The Warning letter could remain at Level III.

4. The Recidivist Policy is very complex and needs to be simplified. One of the decision factors that complicates the Recidivist Policy is the time element. The time element is why the Recidivist Policy was originally created. However, the Quality System regulation primarily refers to non-conforming events in §820.90 and §820.100 rather than to time.

5. The present system of placing the manufacturer/shipper in Level I, Level II or Level II could possibly be replaced by a weighting and summing technique. Time is not used but rather non-conforming product. The three algorithms below are not intended to be used but rather are presented to show various weighting concepts.

Rejected shipments [RS] are counted
Accepted shipments [AS] are counted after the first failure;

If ACT <0 then ACT = 0
Firm is not on detention when ACT = 0
Detention decisions are based on the value of ACT.
The comments on the right are about limit conditions. The algorithm can have other values based on AS, the accepted shipments.

ACT = 4 + (RS)(RS) - AS is used to make decisions
Level I when ACT >4 (one rejected shipment plus other evidence)
Level II when ACT > 7 (for example, two rejected shipments and no good ones)
Level III when ACT > 12 (for example, 3 rejected shipments and no good ones)

Or

ACT = 4 +(RS)(RS+1)-AS is used to make decisions
Level I when ACT >5 (one rejected shipment plus other evidence)
Level II when ACT > 9 (for example, 2 rejected shipments and no good ones)
Level III when ACT > 15 (for example, 3 rejected shipments and no good ones)

Or

ACT = (RS)(RS+4)-AS is used to make decisions
Level I when ACT >4 (one rejected shipment plus other evidence)
Level II when ACT > 11 (for example, 2 rejected shipments and no good ones)
Level III when ACT > 20 (for example, 3 rejected shipments and no good ones)

ACT is reset to 0 when it goes negative.

Without a time element, it is possible for a firm to ship good product (subtracting good shipments AS causes ACT to eventually reach 0) and thus move in and out of

Level I detention which, of course, is not desirable. However, if the product is truly bad, is likely that other shipments will be rejected and the weighting of a suitable algorithm could quickly move ACT to a higher value.

Best Regards

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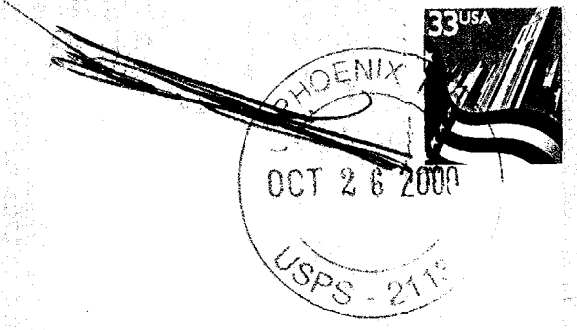

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