TO: www fda gov/dockets/ecomments

FROM: Harry F. Bader harryb@ardl.com

E-MAILED 4-8-03

DATE: April 8, 2003

SUBJECT: Proposed revision to 21CFR 800.20-Medical Glove-Docket No. 03N-0056

CC: Jim Drummond

Thanks for sending me the Subject document.

I haven't yet read it word for word. However, four things got my attention.

1) On page 25 of 28
Lot size 1201-3200
The first sample should be Accept # Reject 4
No decision can be made on the first sample.

2) On pages 26, 27 and 28 of 28
There are no Accept/Reject figures shown. I assume they would be the same as what was previously shown for Surgeon's gloves..
    a. 2.5 adulteration level.

3) On pages 25 through 28.
For both Surgeon's gloves and Examination gloves the tables are for increasing quantities top to bottom. Previously the tables were decreasing quantities top to bottom. What is the rationale for the change?

4) The leak test materials and the set up described in 800.20 are an example of what might be used in a situation where small and infrequent testing was being done. However, to use this in a high volume situation where both testing accuracy and low unit cost are important, just is not done.

    I've visited dozens of manufacturing plants and commercial laboratories and none are using what is described in 800.20. The process is the same, but the materials and the set up are quite different. I'm certain FDA inspectors are aware of that Shouldn't 800.20 (b) (2) and 800.20 (b) (3) (ii) mention that they are only examples.

Please contact me if the above requires discussion

Regards,

Sincerely,

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