June 20, 2003

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. 03N-0056: Proposed Rule (March 31, 2003): 21CFR Part 800 "Medical Devices; Patient Examination and Surgeon's Gloves; Test Procedures and Acceptance Criteria"

Dear Sir / Madam:

We are providing comments with regard to the proposed changes to 21CFR Part 800.20 " Patient Examination gloves and surgeon's gloves; sample plans and test method for leakage defects; adulteration. This response will address each of the four (4) major proposed revisions to this regulation:

1. **Lower the AQL to which the level of defects in lots of gloves is tested, thereby assuring improved quality of gloves.** The proposed changes are as follows:

Glove Type	FDA's Current AQL	FDA's Proposed AQL
Surgeon's Glove	2.5%	1.5%
Examination Glove	4.0%	2.5%

Comment: This proposed change is appropriate to align AQL levels with current ASTM and ISO requirements for medical gloves. These same ASTM and ISO requirements are currently being used for Premarket Notification submissions to the FDA for medical gloves.

2. **Lower the AQL's, convert units of measure to the metric system; eliminate references to obsolete sampling plans, and reference current ISO standards thereby harmonizing with recognized consensus standards.**

Comment: This proposed change is also appropriate to harmonize FDA's requirements with appropriate ASTM and ISO standards.

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3. **Clarify visual defects and current methodology for conducting water leak testing.**

   Comment: The following represents a comparison of the current language defining the term "defects" and that from the proposal:

   Current language: "Defects are defined as leaks, tears, mold, embedded foreign objects, etc."

   Proposed language: "Identification of defects. For this test, defects are defined as tears, embedded foreign objects, or other defects visible upon initial examination that may affect the barrier integrity, or leaks detected when tested in accordance with paragraph (b) (3) of this section."

   We have added an underline to a critical phrase in the proposed language for the definition of a "defect". As written, this statement represents a subjective determination regarding a possible failure vs. an objective determination based upon an actual test failure. In our opinion subjectivity should be removed from any decision counting an observed undefined "defect" that might affect barrier integrity, as an actual failure. Absent a visual tear or hole in a glove that obviously would be a failure during a water leak test, all other glove samples should be tested with the water leak test to confirm whether or not the observed "defect' actually constitutes a failure. This would remove subjectivity and possible differences in judgment across testing laboratories and among testing personnel.

4. **Provide tightened sampling plans for testing reconditioned lots of medical gloves that have already failed one analysis.**

   Comment: We are in agreement with this proposed rule, and as part of an effective implementation strategy, FDA sampling and testing records must be accurately maintained and made available in a timely manner to the importer of record. This would allow both the FDA and importer of record to agree when additional testing is appropriate.

Additional Comments: In light of the proposed tightening of the acceptance criteria for patient examination and surgeon's gloves under 21CFR Part 820, we request that the Center review its current policy for imported medical gloves. Many foreign manufacturers of medical gloves have a thousand or more containers of gloves imported into the U.S. each year, and each lot of product is released, based in part, upon satisfactory physical test results at the factory. Current FDA policy is that one test failure during surveillance sampling **requires** that a foreign manufacturer be automatically placed on "Detention without Physical Examination (*Import Alert*)". Being placed on "*Import Alert*" has severe ramifications regarding the ability of a foreign manufacturer to provide an uninterrupted flow of quality product to its U.S. customers. It must be noted that no similar type of surveillance sampling is conducted on gloves from domestic manufacturers.

It is our opinion that any single test failure be viewed in the context of the details regarding the specific test results for that entry, and the historical FDA surveillance test profile for the manufacturer. For foreign manufacturers that have a historical profile of acceptable test results over a large number of entries, a recommended alternative to a single test failure requiring placement on "*Import Alert*", would be for the FDA to increase the percentage of future entries that would need to be sampled over a specific number of entries, and require that the additional testing be performed by an independent 3rd party, at the manufacturer's expense. As the majority of medical gloves are now manufactured outside of the U.S., this would assure a consistent supply of high quality medical gloves into the U.S. marketplace, and not unfairly penalize a foreign manufacturer, based upon a single test failure.

We appreciate the opportunity to comment on this proposed change to an existing regulation. We request that the FDA provide due consideration to all comments received on this proposal, to assure the revised regulation is fair and objective in achieving its goal of improving the barrier quality of medical gloves in the U.S. market.

Sincerely,

Richard V. Wolfe
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Health Care
Kimberly-Clark Corporation