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#### List of Subjects in 21 CFR Part 800

Administrative practice and procedure, Medical devices,

Ophthalmic goods and services, Packaging and containers, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 800 be amended as follows:

#### PART 800—GENERAL

1. The authority citation for 21 CFR part 800 continues to read as follows:

**Authority:** 21 U.S.C. 321, 334, 351, 352, 355, 360e, 360i, 360k, 361, 362, 371.

2. Section 800.20 is amended by revising paragraphs (b), (c), and (d) to read as follows:

#### **§ 800.20 Patient examination gloves and surgeons' gloves; sample plans and test method for leakage defects; adulteration.**

\* \* \* \* \*

(b)(1) *General test method.* For the purposes of this part, FDA's analysis of gloves for leaks and certain other visual defects will be conducted by an initial visual examination and by a water leak method, using 1,000 milliliters (ml) of water.

(i) *Units examined.* Each medical glove will be analyzed independently. When packaged as pairs, each glove is considered separately, and both gloves will be analyzed.

(ii) *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. A leak is defined as the appearance of water on the outside of the glove. This emergence of water from the glove constitutes a watertight barrier failure.

(iii) *Factors for counting defects.* One defect in one glove is counted as one defect. A defect in both gloves in a pair of gloves is counted as two defects. If multiple defects, as defined in paragraph (b)(1)(ii) of this section, are found in one glove, they are counted as one defect. Visual defects and leaks that are observed in the top 40 millimeters (mm) of a glove will not be counted as a defect for the purposes of this part.

(2) *Leak test materials.* The following materials are required for testing:

(i) A 60 mm by 380 mm (clear) plastic cylinder with a hook on one end and a mark scored 40 mm from the other end (a cylinder of another size may be used if it accommodates both cuff diameter and any water above the glove capacity);

(ii) Elastic strapping with velcro or other fastening material;

(iii) Automatic water-dispensing apparatus or manual device capable of delivering 1,000 ml of water;

(iv) Stand with horizontal rod for hanging the hook end of the plastic tube. The horizontal support rod must be capable of holding the weight of the total number of gloves that will be suspended at any one time, e.g., five gloves suspended will weigh about 5 kilograms (kg).

(3) *Visual defects and leak test procedures.* Examine the sample and identify code/lot number, size, and brand as appropriate. Continue the visual examination using the following procedures:

(i) *Visual defects examination.* Inspect the gloves for visual defects by carefully removing the glove from the wrapper, box, or package. Visually examine each glove for defects. As noted in paragraph (b)(1)(iii) of this section, a visual defect observed in the top 40 mm of a glove will not be counted as a defect for the purpose of this part. Visually defective gloves do not require further testing, however, they must be included in the total number of defective gloves counted for the sample.

(ii) *Leak test set-up.* (A) During this procedure, ensure that the exterior of the glove remains dry. Attach the glove to the plastic fill tube by bringing the cuff end to the 40 mm mark and fastening with elastic strapping to make a watertight seal.

(B) Add 1,000 ml of room temperature water (i.e., 20 °C to 30 °C) into the open end of the fill tube. The water shall pass freely into the glove. (With some larger sizes of long-cuffed surgeons' gloves, the water level may reach only the base of the thumb. With some smaller gloves, the water level may extend several inches up the fill tube.)

(iii) *Leak test examination.*

Immediately after adding the water, examine the glove for water leaks. Do not squeeze the glove; use only minimum manipulation to spread the fingers to check for leaks. Water drops may be blotted to confirm leaking.

(A) If the glove does not leak immediately, keep the glove/filling tube assembly upright and hang the assembly vertically from the horizontal rod, using the wire hook on the open end of the fill tube (do not support the filled glove while transferring).

(B) Make a second observation for leaks 2 minutes after addition of the water to the glove. Use only minimum manipulation of the fingers to check for leaks. Record the number of defective gloves.

(c) *Sampling, inspection, acceptance, and adulteration.* In performing the test