

that have failed to meet the 1.5 or 2.5 AQL level. These reconditioned gloves would have to be sampled under a more stringent inspection standard in order to provide additional assurance that they meet the AQLs. This practice is consistent with the ISO sampling plans, which allow for tightened sampling when failures occur under normal sampling.

B. Paragraph by Paragraph Changes

1. Current Test Method (§ 800.20(b)) as Proposed General Test Method (§ 800.20(b)(1))

(Change 1) FDA proposes to rename and renumber current § 800.20(b), *Test method* as § 800.20(b)(1), *General test method*. FDA is revising the substance of the first sentence of current paragraph (b) to add the following language: "For the purposes of this regulation, 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 test method, using 1,000 milliliters (ml) of water." The purpose of these changes is to recognize that there are other visual defects addition to leaks, and that these defects can sometimes be detected by visual examination.

(Change 2) For clarification, FDA would reorganize the remaining elements of current paragraph (b) into paragraphs (b)(1)(i) through (b)(1)(iii) of proposed § 800.20(b)(1), as follows:

- The current second and third sentences would be reorganized, without revision, in proposed § 800.20(b)(1)(i), *Units examined*.
- The current fifth, sixth, and seventh sentences would be reorganized and revised in proposed § 800.20(b)(1)(ii), *Identification of defects*.
- The current fourth sentence would be revised and reorganized, together with the current seventh and eighth sentences, in proposed § 800.20(b)(1)(iii).

(Change 3) Proposed § 800.20(b)(1)(ii) changes 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 in accordance with paragraph (b)(3) of this section."

FDA is proposing to remove "mold" as a defect in proposed § 800.20(b)(1)(ii). The agency considers the presence of visible mold on sampled gloves as evidence that the lot is adulterated under section 501(a) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 351(a)), in that it consists in

whole and/or in part of any filthy, putrid, or decomposed substance. The revised section removes the abbreviation, "etc.", as being indeterminate.

The phrase, "other defects visible upon initial examination that may affect the barrier integrity," would be added in proposed § 800.20(b)(1)(ii), to encompass various other defects that may arise, including, but not limited to:

a. Extrusions of glove material on the exterior or interior surface of, or within, the film of the glove. FDA believes that such extrusions or material lumps can contribute to rips or tears near the site of the lump, during routine donning or other stretching of the glove.

b. Gloves that are fused together so that individual glove separation is impossible.

c. Gloves that adhere to each other and tear when separated into individual gloves.

(Change 4) In proposed § 800.20(b)(1)(iii), the fourth sentence in current paragraph (b) would be revised and reorganized into two sentences for clarity, reading, "One defect in one glove is counted as one defect. A defect in both gloves in a pair is counted as two defects." Other proposed changes to § 800.20(b)(1)(iii) include:

- To confirm current counting practices, FDA would add the clarifying sentence, "If multiple defects, as defined in paragraph (b)(1)(ii) of this section, are found in one glove, they are counted as one defect."
- For further clarification, FDA is adding the sentence, "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." The substance of this sentence is in current § 800.20(b)(2); however, FDA is changing the unit of measure, 1 1/2 inches, to the corresponding metric unit of measure, 40 millimeters (mm), used by most standards setting organizations.

2. Current Untitled (§ 800.20(b)(1)) as Proposed Leak Test Materials (§ 800.20(b)(2))

(Change 5) FDA proposes to rename current § 800.20(b)(1) as proposed § 800.20(b)(2), *Leak test materials*. To conform current U.S. measurement units to metric measurement units used by most standards setting organizations, FDA proposes to change the current language, "2 3/8 inch by 15-inch" to "60 mm by 380 mm" and "11 pounds" to "5 kilograms (kg)." No other change would be made to current § 800.20(b)(1).

3. Current Untitled (§ 800.20(b)(2)) as Proposed Visual Defects and Leak Test Procedure, Visual Defects Examination, and Leak Test Set-Up (§ 800.20(b)(3)(i) through (b)(3)(ii))

(Change 6) FDA is proposing to renumber and revise current § 800.20(b)(2) into the following new paragraphs:

- (b)(3) *Visual defects and leak test procedures*.
- (b)(3)(i) *Visual defects examination*.
- (b)(3)(ii) *Leak test set-up*.

(Change 7) FDA is also proposing to revise current § 800.20(b)(2) in proposed paragraph (b)(3) to reorganize the section for clarity to read, "(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:"

(Change 8) FDA is also proposing to revise current § 800.20(b)(2) in proposed paragraph (b)(3)(i) to incorporate metric units of measure, reflecting the harmonization of the test method to international standards. The revisions would read as follows:

(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.

(Change 9) In proposed § 800.20(b)(3)(i) in the third sentence, "1 1/2 inches" would be changed to "40 mm", to reflect the corresponding metric unit of measure used by most standards setting organizations.

(Change 10) FDA proposes to add the following statement to § 800.20(b)(3)(ii) *Leak test set up*, "During this procedure, ensure that the exterior of the glove remains dry." This method conforms to the "Standard Test Method for Detection of Holes in Medical Gloves" found in ASTM D5151. The reason for including this step is that a leak can be detected more easily on a dry surface.

(Change 11) For ease of reading, FDA is proposing to reorganize current § 800.20(b)(3) into three paragraphs in proposed (b)(3)(iii) *Leak test examination*. The first three current sentences would be in the first paragraph, the current fourth sentence would be in the second paragraph, and the remaining three current sentences would be in the third paragraph.