

4. Current Sample Plan (§ 800.20(c)) as Proposed Sampling, Inspection, Acceptance, and Adulteration (§ 800.20(c))

(Change 12) FDA is proposing to rename current paragraph § 800.20(c) paragraph, “(c) Sampling, inspection, acceptance, and adulteration,” and to reorganize the section as follows:

- (c)(1) *Sample plans.*
- (c)(2) *Sample sizes, inspection levels, and minimum AQLs.*
- (c)(3) *Adulteration levels and accept/reject criteria.*

(Change 13) Proposed introductory paragraph § 800.20(c) would retain the element of current paragraph (c), which identifies how FDA will sample and examine lots of gloves to determine whether the gloves are considered adulterated under section 501(c) of the act. Proposed paragraph § 800.20(c) would be revised as follows: “(c) *Sampling, inspection, acceptance, and adulteration.* In performing the test for leaks and other visual defects described in paragraph (b) of this section, FDA will collect and inspect samples of medical gloves, and determine when the gloves are acceptable as set out in paragraphs (c)(1) through (c)(3) of this section.”

(Change 14) Proposed § 800.20(c)(1) retains the elements of current paragraph (c) that identify the sampling plans, inspection, and AQLs used by the agency in its determination of adulteration. In § 800.20(c)(1), FDA is proposing to change the standard of sampling procedures and inspection tables from “MIL–STD–105E” to “ISO 2859” because “MIL–STD–105E” is no longer in effect. The use of ISO 2859 is consistent with the agency’s recognition of this standard as provided in section 514 of the act (21 U.S.C. 360d) (see FDA’s Internet Web site at <http://www.fda.gov/cdrh/stdsprog.html>).

(Change 15) Proposed § 800.20(c)(2) retains the same “single normal sampling,” “multiple normal sampling,” and “general inspection level II” that are in current paragraph (c). In proposed paragraph (c)(2), FDA proposes lowering the minimum AQL for surgeons’ gloves from the current 2.5 AQL to a 1.5 AQL. Additionally, FDA proposes to lower the minimum AQL for patient examination gloves from a 4.0 AQL to a 2.5 AQL. These changes would reduce the allowable level of defective gloves in sampled lots of medical gloves and harmonize FDA adulteration criteria with the recognized consensus standards for medical gloves.

(Change 16) FDA is proposing to remove the current table entitled “ADULTERATION LEVEL AT 2.5 FOR

SURGEONS’ GLOVES” and the current table entitled “ADULTERATION LEVEL AT 4.0 FOR PATIENT EXAMINATION GLOVES,” and replace them with the table entitled “ACCEPT/REJECT CRITERIA AT 1.5 AQL FOR SURGEONS’ GLOVES” and the table entitled, “ACCEPT/REJECT CRITERIA AT 2.5 AQL FOR PATIENT EXAMINATION GLOVES,” following proposed § 800.20(c)(3).

5. Current Untitled (§ 800.20(d)) as Proposed Compliance (§ 800.20(d))

(Change 17) For purposes of clarification, FDA is proposing to revise § 800.20(d) as follows:

- (d) *Compliance.*
- Add (d)(1) *Detention and seizure.*
- Add (d)(2) *Reconditioning.*
- Add (d)(2)(i) *Modified sampling, inspection, and acceptance.*
- Add (d)(2)(ii) *Adulteration levels and acceptance criteria, and adulteration levels for reconditioned gloves;* and
- Add tables, “ACCEPT/REJECT CRITERIA AT 1.5 AQL FOR RECONDITIONED SURGEONS’ GLOVES” and “ACCEPT/REJECT CRITERIA AT 2.5 AQL FOR RECONDITIONED PATIENT EXAMINATION GLOVES,” following paragraph (d)(2)(ii).

(Change 18) Proposed introductory § 800.20(d) retains the regulatory element of current paragraph (d), which establishes that medical gloves that are “rejected,” i.e., fail to meet acceptance criteria in proposed § 800.20(c)(3) when tested as described in proposed § 800.20(b), are adulterated in accordance with section 501(c) of the act.

(Change 19) Detention under section 801(a) of the act (21 U.S.C. 381(a)) and seizure under section 304(b) of the act (21 U.S.C. 334(b)) are common administrative or enforcement actions FDA has taken against medical gloves that are in violation of section 501(c) of the act. FDA may detain and refuse entry to medical gloves that are presented for import and found to be adulterated under section 501(c) of the act. Medical gloves found to be adulterated while in domestic interstate commerce are subject to seizure. Agency regulatory procedures for the reconditioning of domestically manufactured gloves seized in interstate commerce are found in the FDA/ORA (Office of Regulatory Affairs) Regulatory Procedures Manual (RPM), Chapter 6 Judicial Actions, Subchapter—Seizure, Disposition of Seized Articles, Reconditioning Operations. Regulatory procedures for detained imported gloves are in RPM Chapter 9 Import

Operations/Actions, Subchapter—Reconditioning. When appropriate, FDA may take other regulatory actions, such as injunction, civil money penalties, or criminal prosecution of manufacturers and individuals responsible for adulterated products. FDA is proposing to add revised § 800.20(d)(1) to include the detention and seizure of gloves that are adulterated under section 501(c) of the act because the quality falls below the level it is represented to have. Under the authority of section 801(b) of the act for imported gloves and section 304(d)(1) of the act for seized domestic articles, FDA is proposing to add revised § 800.20(d)(2) to provide the importer of record, owner, or consignee an opportunity to recondition the gloves as a lot or part of a lot, whether they are foreign or domestic gloves.

(Change 20) In § 800.20(d)(2)(i), FDA is proposing a modified sampling plan. The rationale for the plan is based on the agency’s experience with reconditioned gloves, the need for greater assurance that reconditioned gloves meet minimum AQLs given the initial finding of adulteration, and the provisions in ISO 2859 for tightened sampling plans.

FDA samples medical gloves that are often presented for import in large quantities. When the “sampling lots” are large and include several glove sizes and manufacturing lots, FDA attempts to have each sample adequately represent each size in the proportion it occurs in the “sampling lot.” On occasion, manufacturers and importers have claimed that a single size or lot code may have contributed to a disproportionate number of defects that caused the sample to fail, and have requested FDA to allow the rest of the shipment to be salvaged, based on retesting of each of the segregated sizes or lot codes. Such segregation and retesting is considered reconditioning.

FDA district offices review reconditioning proposals on a case by case basis. In determining, whether to approve a reconditioning proposal, the district offices exercise discretion in considering the nature and type of defects, the degree of noncompliance with minimum AQLs, the compliance history of the manufacturer, the qualifications and reliability of the independent testing laboratories, and any other relevant factors.

When FDA has permitted manufacturers/importers of gloves that have failed FDA or private laboratory analysis to segregate and retest portions of the lot(s)/size(s), the agency’s experience has been that the segregated lot(s)/size(s) almost always pass the retest, resulting in two contradictory