DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 800

[Docket No. 03N–0056]

Medical Devices; Patient Examination and Surgeons' Gloves; Test Procedures and Acceptance Criteria

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend the sampling plans, test method, and acceptable quality levels (AQLs) for medical gloves contained in its medical device regulations. As prescribed by its regulation, FDA samples patient examination and surgeons' gloves and examines them for visual defects and water leaks. Glove lots are considered adulterated if they do not meet the specified quality levels. The objective of the proposed regulation is to improve the barrier quality of medical gloves on the U.S. market. The updated regulation would accomplish this by reducing the acceptable level of defects observed during FDA testing of medical gloves. By reducing the AQLs for medical gloves, FDA would also harmonize the level with consensus standards developed by the International Organization for Standardization (ISO) and the American Society for Testing Materials (ASTM).

DATES: Submit written or electronic comments by [*insert date 90 days after date of publication in the* **Federal Register**]. See section VII of this document for the proposed effective date of a final rule based on this proposal.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments.

FOR FURTHER INFORMATION CONTACT: Casper E. Uldriks, Office of Compliance, Center for Devices and Radiological Health (HFZ–300), Food and Drug Administration, 2094 Gaither Rd., Rockville, MD 20850, 301–594–4692.

SUPPLEMENTARY INFORMATION:

I. Background

With the advent of the human immunodeficiency virus (HIV) infections and the progression of infections into acquired immune deficiency syndrome (AIDS), scientists and medical and public health experts developed risk reduction strategies, including protective and preventive strategies for health care workers. These strategies were based on the etiology, and mechanisms and routes of transmission, of HIV infections.

A. Routes and Mechanisms of HIV Transmission

HIV is transmitted primarily through sexual contact. However, nonsexual transmission occurred in health care settings as a result of contact with infected blood. HIV was also isolated from other body fluids. The prevalence of HIV infections in health care settings and the risk of clinical transmission of other infections increased the importance of using effective procedures and barriers. The potential for infection heightened the importance of the quality of the barriers selected for protection.

B. The Need for Precautions in Health Care Settings

On August 21, 1987, the Centers For Disease Control (CDC) published a report emphasizing the need for all health care workers to routinely use appropriate universal precautions when they expect to come into contact with blood or other body fluids of any patient (Ref. 1). This report recommended that health care workers wear medical gloves when: (1) Touching blood or other body fluids, mucous membranes, or non-intact skin of patients; (2) handling items or surfaces soiled with blood or other bodily fluids; and (3) performing venipuncture and other vascular access procedures. The collective term, medical gloves, includes patient examination and surgeons' gloves (see 21 CFR 880.6250 and 878.4460).

C. The Need for Testing

After the publication of the CDC's recommendations, and the rise in HIV infections, health care workers increasingly relied on surgeons' gloves and patient examination gloves as a barrier to the transmission of HIV and other blood- and fluid-borne infectious agents. The CDC's recommendations clearly recognized that defects in medical gloves had the potential of resulting in transmission of HIV between patients and health care workers.

Consequently, FDA reviewed and evaluated the quality control procedures that manufacturers used in making medical gloves. FDA concluded that manufacturers could only meet reasonable expectations of barrier protection by establishing adequate specifications for medical gloves, and adequate test procedures to detect defects in gloves. Glove defects include rips, tears, embedded foreign objects in the glove that may cause the glove to rip or tear upon stretching, or holes that allow the passage of fluids and fluid-borne microorganisms. Each of these defects compromises the glove barrier integrity

and may expose health care workers and patients to infectious agents. Articles written by health care professionals who studied glove quality and the use of gloves as a barrier to infectious agents noted that gloves with defects may not provide this protection (Refs. 2 through 6). In 1989, when FDA proposed § 800.20 (21 CFR 800.20), FDA's position was that existing consensus standards did not establish adequate test methods and acceptance criteria for patient examination or surgeons' gloves (54 FR 48218, November 21, 1989). Therefore, the agency concluded that it needed to communicate clearly the test procedures and the acceptance levels it would use to determine whether medical gloves were adulterated.

D. The Setting of Adulteration Levels

In the **Federal Register** of December 12, 1990 (55 FR 51254), FDA issued a final rule that identified minimum AQLs for both patient examination and surgeons' gloves, and established the sample plans and test method for determining whether a lot of gloves were acceptable. This rule defined defects as ''leaks, tears, mold, embedded foreign objects, etc.'' The definitions, sampling plans, test methods, and adulteration levels identified in the 1990 **Federal Register** are currently codified in title 21 of the Code of Federal Regulations in § 800.20.

II. Proposed Changes

A. Rationale and Summary of Changes

1. Continuing HIV/AIDS Incidence and Need for Protective Measures for Health Care Workers

In a May 1998 report, CDC reaffirmed its expectation that health care workers should use medical gloves as an effective barrier to HIV, hepatitis B

virus, and other blood-borne infections, and that these gloves should provide effective protection against exposure to pathogenic microorganisms in blood and other body fluids (Ref. 7).

In the December 10, 1999, *Morbidity and Mortality Weekly Report* (MMWR), CDC estimated that the prevalence of HIV at the end of 1998 ranged from 800,000 to 900,000 infected persons. CDC estimated that, of these 800,000 to 900,000 persons, HIV infection or AIDS was diagnosed in approximately 625,000 of the individuals (Ref. 8). In a fact sheet posted on the Internet in June 1999, CDC reported that 54 documented cases of HIV seroconversion resulted from occupational exposure to HIV (Ref. 9). In April 2002, CDC reported that, as of December 31, 1999, 22,218 out of 437,407 adults reported diagnosed with AIDS were health care workers (Ref. 10). FDA concluded that medical gloves play an important role in the prevention of infectious disease transmission in health care settings, and that lowering the acceptable level of defects is necessary to further reduce the risk of transmission of such diseases and to harmonize the quality of gloves sold in the United States with international consensus standards.

2. Harmonization With Consensus Standards

Following the publication of § 800.20, several consensus standards organizations, such as the ISO and the ASTM, adopted the FDA test methodology and acceptance criteria for patient examination and surgeons' gloves. As glove manufacturing capabilities improved, these consensus standards organizations lowered the minimum acceptance criteria for holes/ leaks for these gloves. In 1994, ISO published standards for surgeons' and patient examination gloves with AQLs of 1.5 and 2.5, respectively. ASTM adopted these same acceptance criteria in April 1998, and March 1999, for

surgeons' and patient examination gloves, respectively. Because the standards organizations updated their standards to reflect the improvement in manufacturing technology, the consensus standards currently have lower AQLs for medical gloves than FDA's regulation (§ 800.20).

The consensus standards differ from the current FDA regulation in two other respects: (1) They use metric units for specifying dimensions, and (2) they refer to sampling plans from the ISO's document ISO 2859, ''Sampling Procedures for Inspection by Attributes,'' instead of the MIL–STD–105E sampling plan that is currently referenced in § 800.20.

FDA believes that, whenever feasible, it is important to harmonize its requirements with consensus standards. Harmonization helps ensure an acceptable standard of safety and effectiveness for all manufacturers and allows manufacturers to market their products more efficiently in a global economy. FDA has recognized the ASTM standards for patient examination and surgeons' gloves for the purpose of premarket notification submissions (510(k)s), and believes that it is appropriate to use the same standards for determining the acceptability of lots of medical gloves.

3. Interpretation of Defects

Since issuing § 800.20, FDA has received many questions from FDA field laboratories, glove manufacturers, importers, and private laboratories regarding the definition of defects in the current regulation. Many questions concerned whether lumps of latex material on or beneath the glove surface are considered defects. These questions arise because the definition of defects in § 800.20 refers to ''embedded foreign objects,'' and latex is not ''foreign'' to a latex glove. Other questions were whether ''mold'' is an appropriate defect to be included in a sampling plan intended primarily to detect physical defects. FDA believes

these questions are valid and has addressed them in the proposed amendments.

4. Tightened Sampling Plans for Reconditioned Gloves

FDA recognizes the difficulty of adequately representing a large lot of gloves with a relatively small sample size. FDA has sometimes allowed manufacturers and importers to segregate and retest portions of the lot(s) or sizes of reconditioned gloves that initially failed FDA or private laboratory analysis to identify those portions of the larger lot(s) or sizes that meet quality requirements. The agency recognizes, however, that passing a retest does not provide the same assurance of quality as when the lot passes the initial analysis. This is due, in part, to the nature of the standard sampling plans, and in part to the fact that retesting is performed to identify acceptable portions of the larger lot(s) after failing the initial test. Recognized consensus standard sampling plans address the issue of previous test failures by allowing tightened sampling during retesting in order to provide additional assurance to the consumer. FDA proposes to apply this principle to testing of reconditioned lots that have failed an initial analysis.

5. Proposed Reclassification of Medical Gloves

On July 30, 1999, FDA published a proposed rule in the **Federal Register** (64 FR 41710) that addressed several issues pertaining to medical examination gloves, including their reclassification from class I to class II in order to provide reasonable assurance of safety and effectiveness. To provide this assurance, appropriate special controls (applicable to class II medical devices) were also proposed. The proposal to reclassify medical examination gloves reflects the increased importance of these devices in the health care arena and is consistent with the changes FDA is now proposing for § 800.20. However,

this proposal to lower the acceptable level of defects in medical gloves is an independent initiative that will go forward as FDA continues to review the comments it received on the reclassification proposal.

Therefore, in summary, FDA is proposing to: (1) Lower the AQL to which the level of defects in lots of gloves is tested, thereby assuring improved quality of gloves; (2) lower the AQLs, 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; (3) clarify visual defects and current methodology for conducting water leak testing; and (4) provide tightened sampling plans for testing reconditioned lots of medical gloves that have already failed one analysis.

Specifically, FDA is proposing to lower the AQL for surgeons' gloves from 2.5 to 1.5, and is proposing to base the sampling plans on the tables in the ISO sampling standard, ISO 2859–1995.

FDA is also proposing to lower the AQL for patient examination gloves from 4.0 to 2.5, and is proposing to base the sampling plans on the tables in ISO sampling standard, ISO 2859–1995. Lowering the AQLs for medical gloves will reduce the allowable defect level for patient examination gloves. Further, FDA is proposing to amend the regulation to tighten sampling plans for reconditioned lots of medical gloves 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.

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)/ sizes(s) almost always pass the retest, resulting in two contradictory conclusions about the analyzed lot. Statistically, a passing retest result is not unexpected due to the nature of the normal sampling plans, which minimize producer risk. When failures occur under normal sampling, ISO 2859 recommends the use of tightened sampling plans for resubmitted lots in order to reduce the risk to the consumer (see part 1 section 7.4 of ISO 2859). FDA is proposing that single normal sampling plans and the tightened level of inspection, found in ISO 2859, be used in resampling and retesting medical gloves that have been reconditioned. The proposed modifications would increase the size of the sample and the number of units examined, while lowering the number of defects required for rejection. FDA believes that this would provide greater statistical assurance that reconditioned lots meet minimum AQLs.

(Change 21) FDA proposes to add § 800.20(d)(2)(ii) to establish accept/ reject criteria and adulteration levels for reconditioned surgeons' gloves and patient examination gloves based on the tightened sampling plans proposed in paragraph (d)(2)(i). For convenience, FDA is adding tables following § 800.20(d)(2)(ii), which describe the number of units to examine and the accept/reject criteria for various lot sizes.

III. Environmental Impact

The agency has determined under 21 CFR 25.30(i) that this action is of a type that does not individually or cumulatively have a significant effect on

the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IV. Analysis of Impacts

A. Introduction

FDA has examined the proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612) (as amended by subtitle D of the Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104–121)), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, distributive impacts and equity). Under the Regulatory Flexibility Act, if a regulation has a significant economic impact on a substantial number of small entities, the agency must analyze regulatory options that would minimize the impact on small entities. Section 202(a) of the Unfunded Mandates Reform Act requires that agencies prepare a written statement of anticipated costs and benefits before proposing any regulation that may result in expenditure by State, local, and tribal governments, or by the private sector of $100 million in any one year (adjusted annually for inflation). Currently, such a statement is required if costs exceed $110 million for any one year.

The proposed regulation is consistent with the principles set forth in Executive Order 12866 and the two statutes. As explained in the following paragraphs, FDA does not believe the proposed regulation is a significant regulatory action, as defined in Executive Order 12866. In addition, FDA certifies under the Regulatory Flexibility Act that the proposed regulation

would not result in a significant economic impact on a substantial number of small entities. The expected cost of this proposed regulation is under $110 million in any one year and is therefore not considered a major regulatory action as defined by the Unfunded Mandates Reform Act.

B. Objective of the Proposed Regulation

The objective of the proposed regulation is to reduce the risk of transmission of blood-borne pathogens (particularly HIV and hepatitis B (HBV) and C (HBC) infections). The regulation would accomplish this objective by ensuring that medical gloves (surgeons' and patient examination gloves) maintain a high level of quality with respect to the level of noted defects. By so doing, FDA also would harmonize its standard for acceptable defects with consensus quality standards developed by ISO and ASTM.

C. Current Risks of Blood-Borne Illness

Unnecessary exposures to blood-borne pathogens are of great importance to the health care community because contact with contaminated human blood or tissue products has led to increased cases of HIV, HBV, and HCV infections.

Available data cannot precisely quantify the number of new HIV cases that this proposed rule would prevent. This analysis, however, attempts to derive a conservative estimate. For the year 2000, the CDC reported a cumulative total of approximately 900,000 persons in the United States who had contracted HIV, of which 775,000 cases had progressed to AIDS (Ref. 1). Of those patients whose conditions had progressed to AIDS, almost 450,000 (58 percent) had died as of December 2000. For the year 2000, the CDC identified 21,704 new cases of HIV infection.

Approximately 5 percent of the reported HIV/AIDS cases were among health care personnel (Ref. 2). However, in an indepth analysis of occupational

risk, the CDC reported that, since 1992, there have been only 56 identified incidents of occupational transmission of the HIV pathogen and all but 7 of these cases (12.5 percent) were due to percutaneous cuts or needle sticks. In addition, there were 138 other cases of HIV infection or AIDS among health care workers with occupational exposures to blood who had not reported other risk factors for HIV infection (Ref. 2). Assuming the same 12.5 percent rate for these workers implies that 17 additional cases of HIV transmission to health care personnel during this period might have been caused by cutaneous contact in an occupational setting. Consequently, a total of 24 incidents of occupational transmission of HIV to health care personnel may have occurred over the 10-year period (or 2.4 per year) due to problems with the glove barrier protection properties of gloves used in health care settings.

The CDC also reports approximately 80,000 new cases of HBV for the latest available reporting period (1999) (Ref. 3). There are approximately 1.25 million people in the United States chronically infected with HBV. While only 6 percent of those who contract HBV after the age of 5 will develop chronic conditions, 15 to 25 percent of those that do will die prematurely. Health care personnel are at some risk of this pathogen, but the availability of a vaccine has reduced the risk of negative outcomes due to exposure.

FDA has no direct data for estimating the rate of new HBV infections in health care personnel. While the CDC has reported the risk to health care workers as ‘‘low,’’ there is no definition of that term (Refs. 3 and 4). FDA estimates that as many as 4,000, or 5 percent, of all new incidents of HBV occur in health care personnel. Because occupational transmission of HBV may be approximately 5 times more likely than for HIV, FDA imputes approximately 140 annual cases of occupational transmission of HBV to health

care personnel. (HIV rate of 7.3 /1,085 x 5 x 4,000.) CDC analyses have stated that ‘‘most’’ of the occupational transmissions are due to percutaneous injuries (cuts) (Ref. 4). Because 2.4 of the 7.3 annual HIV cutaneous contact transmissions (33 percent) were believed to be attributable to glove defects, FDA similarly expects that about one-third of the 140 annual occupational transmissions of HBV infections (approximately 40 cases) may potentially be associated with the current quality level of medical gloves. If only 6 percent of these cases develop chronic conditions, then an average of 2.4 annual cases of chronic HBV are associated with defective medical gloves.

HBV currently infects 3.9 million persons (Ref. 3). Over 2.7 million patients have reported chronic conditions. More than 40,000 new cases were reported during 1999. The risk of exposure to health care workers, however, appears to be extremely low. In fact, according to the CDC, for other than needle stick punctures, no transmission of HCV for health care personnel has been documented from intact or no intact skin exposures to blood or other fluids or tissues (Ref. 4). Thus, there is little evidence that glove defects are associated with HCV exposures.

As a result, FDA estimates the overall annual transmission of blood-borne pathogens due to defects in glove barrier protection in health care settings to include 2.4 cases of HIV infection and 2.4 cases of HBV infection. Increasing the AQL of gloves by lowering the rate of acceptable defects would reduce the transmission rates of these pathogens.

D. Baseline Conditions

The current AQL for medical gloves allows a defect rate of 4.0 percent (0.04) for patient examination gloves and 2.5 percent (0.025) for surgeons’ gloves. The AQL represents the proportion of sampled gloves from a given lot

that may include defects such as leaks or foreign material and still be accepted for entry into the marketplace. Currently, if more than 4 percent of the sampled patient examination gloves exhibit defects, the entire lot of gloves may not be sold as medical devices. Surgeons' gloves are sampled to a higher quality level (the lower AQL requires a higher proportion of nondefective gloves in order to pass inspection), because these products have a higher likelihood of contact with bodily fluids. Of course, medical glove lots that fail to meet the AQL may be marketed as household or other products. If a sample of gloves fails to meet the AQL, the marketer may petition for resampling of the lot. The required resampling plan for a lot originally found to be out of compliance is more intensive than the original sampling plan for a randomly selected lot. Lots initially found to be out of compliance are either resampled and subsequently offered as medical gloves after meeting the current AQL, offered as nonmedical gloves, or sold in foreign markets.

Approximately 30.8 billion medical gloves were sold in the United States during the year 2000 (Ref. 6). According to FDA records, there are 417 manufacturers of medical gloves. Of these, only six are domestic firms. Malaysian manufacturers supply almost 44 percent of the medical gloves in the United States (Ref. 7). Only 250 million surgical gloves are imported each year (0.8 percent of the medical glove market) and the impact on this sector is negligibly different from overall patient examination gloves. Therefore, this analysis focuses exclusively on patient examination gloves.

FDA expects the demand for medical gloves to increase by the same rate as employment in the medical services industry. The Bureau of Labor Statistics (BLS) projects annual employment growth of 2.6 percent for this industry (NAICS 6200) (Ref. 8), which implies an annual demand for almost 40 billion

medical gloves within 10 years. (A 2.6 percent annual growth rate results in an expected increase of 29.3 percent in 10 years).

Medical glove lot sizes may vary from as few as 25 gloves to as many as 500,000. According to discussions with manufacturers (Eastern Research Group, Inc. (ERG); 2001), a typical production or import lot from a foreign manufacturer contains an average of 325,000 gloves (either patient examination or surgeons'). This implies that the U.S. medical glove market currently imports about 95,000 lots of gloves per year. FDA currently samples only about 1.5 percent (0.015) of all glove lots, or 1,400 lots per year. Within 10 years, FDA expects the number of lots offered for import to increase to 122,500 per year. If the compliance sampling rate remains constant, FDA would sample 1,850 lots during that year.

FDA's Winchester Engineering and Analysis Center (WEAC) analyzed results from samples collected from 2000 and 2001. These samples represent approximately one-third of FDA's total sampling effort for that period. A total of 98,067 gloves were tested from 942 separate lots. Of these gloves, 2,354 (0.024) were defective, which implies that 2.4 percent of marketed gloves are likely to be defective. If so, then approximately 740 million defective medical gloves are currently marketed (30.8 billion gloves x 0.024). At the current AQL of 4.0 percent, 28 lots failed (0.0297) the WEAC analysis. Consequently, approximately 42 of the annually sampled lots are defective (1,400 x 0.0297). By the 10th year, in the absence of the proposed regulation, 955 million defective gloves would be marketed and 55 percent of the sampled lots would fail to meet the AQL.

FDA allows glove lots that fail to meet the AQL to be resampled. Sponsors usually attempt to resample the glove lot rather than divert the entire lot to

alternative markets. According to discussions with industry sources and testing laboratories, the cost of domestic lot resembling and retesting for leakage and tensile strength equals approximately $1,400. The current annual industry cost of resampling glove lot failures with the current AQL, therefore, is approximately $59,000 (42 lots x $1,400 per lot). This resampling and retesting cost would equal $77,000 within 10 years.

E. Costs of the Proposed Regulation

FDA expects that the proposed regulation would result in changed shipping practices by medical glove manufacturers. Currently, manufacturers use the target AQLs as a guide for releasing production lots of gloves for export to the United States because the release criteria are lower in the United States. Manufacturers attempt to avoid having three lot inspection failures within a 24-month period, because this results in rejection of future imports under FDA's current recidivist policy. Thus, to maintain an uninterrupted supply of gloves to customers, and to guard brand loyalty while avoiding the recidivist list, manufacturers would be expected to raise their level of quality control to at least maintain the current average lot rejection rate of 2.97 percent. FDA also expects the regulation to increase the costs of sampling by requiring larger and more detailed sampling plans to assure that the lower AQL is met for each inspected glove lot. FDA does not envision increased regulatory oversight costs because the number of inspections is not expected to change.

1. Costs of Quality Control

Manufacturers currently conduct quality control tests on glove lots prior to release. These tests include water-tight leak and tensile strength assays. According to interviews with glove manufacturers, the current cost of conducting these tests at the manufacturing site is approximately $310 per lot,

whereas more stringent quality control testing may cost an additional $45 per lot. The additional cost is for increased inventory and larger sample sizes to ensure more precise measurements at the lower AQL. Because approximately 95,000 lots of medical gloves are imported per year, the expected costs are $4.3 million (95,000 lots x $45 per lot). Due to the expected increase in the demand for medical gloves by the 10th evaluation year, the compliance cost of meeting this increased quality level will equal $5.5 million. Over the 10-year period, the average annualized cost of this increased level of testing (at a 7 percent discount rate) is $4.9 million.

2. Increased Sampling Costs

A lower AQL would result in increased sampling costs for imported glove lots. The increased sampling costs would result from the need to test greater quantities of gloves to ensure sufficient statistical power. Based on reported costs from U.S. testing laboratories, ERG, an independent economic contractor, estimated that increased testing would add approximately $200 to the current costs of $1,400 per sample. (The difference between this increased cost and the $310 increased import sampling cost is attributable to lower costs in the foreign countries that produce medical gloves.) FDA currently samples about 1.5 percent of the 95,000 annual imported lots, or 1,400 samples. Thus, the increased sampling costs due to the proposal are $0.3 million ($1,400 x $200). Within 10 years, this increased cost will equal $0.4 million (due to expected increases in the number of inspected glove lots) and the average annualized sampling cost (at a 7 percent discount rate) increase is $0.3 million.

3. Withheld Lots

In addition, the proposed AQL is likely to result in an increase in the number of lots of medical gloves that are not released for shipment to the U.S.

medical market. For example, manufacturers may attempt to maintain a target compliance level in order to avoid FDA's recidivist listing. FDA's WEAC research laboratory sampled 942 lots and discovered that 28 failed using the current AQL while 79 lots failed using the proposed AQL. To maintain the original 0.0297 (28/942) lot failure rate, the 53 lots with the highest defect rate would have to be held back by the affected manufacturers (.056)[1]. Therefore, FDA expects, that under the proposed AQL, approximately 5,500 lots would be held back by manufacturers. In order to meet the expected demand in 10 years, 7,000 lots would be held back. FDA believes that glove lots that fail to meet the proposed AQL medical quality standards would most likely be sold as nonmedical gloves. Manufacturers and distributors would experience some loss of revenue from this shift, because of the price premium commanded by medical gloves. FDA believes this loss would be inconsequential.

4. Costs of FDA Inspections

FDA does not envision increased inspection costs due to the proposed regulation. The rate of sampled glove lots is not expected to change and FDA resources are not expected to increase over the evaluation period.

5. Total Costs

In sum, therefore, FDA estimates that the proposed regulation would have an average annualized cost of about $5.2 million.

F. Benefits of the Proposed Regulation

The proposed regulation would result in public health gains by reducing the frequency of blood-borne pathogen transmissions due to defects in the

[1] The current lot failure rate (28/942=0.0297) is reached by removing 53 defective lots from the sample. If only the 51 additional failing lots are removed, the overall failure rate is 0.0314 (28/891). The expected future failure rate is 0.0292 (26/889). FDA expects the withheld lots to include those with the highest defect rates.

barrier protection provided by medical gloves. Based on an implied societal willingness to pay (WTP), an annualized monetary benefit of $12.3 million would be saved due to fewer pathogen transmissions and unnecessary blood screens. Moreover, fewer glove defects would reduce the number of, and, therefore, the cost and anxiety associated with, unnecessary blood screens (i.e., those that yield negative results for health care personnel).

1. Reductions in Marketed Defective Gloves

As noted in the previous paragraphs, FDA finds that approximately 740 million defective gloves are marketed each year in the United States, or 2.4 percent of all medical gloves. In the absence of this regulation, FDA expects that the number of defective medical gloves marketed in the United States each year would increase to 955 million gloves within 10 years. The proposed regulation would substantially reduce this figure.

WEAC's analysis of 98,067 medical gloves from 942 sampled lots collected in 2000 and 2001 resulted in approximately 3 percent lot failures under the current AQL of 4 percent (28 failed lots). This lot failure rate was associated with 2,356 defective gloves, or 2.4 percent of the total number of sampled gloves. Under the proposed AQL of 2.5 percent, the WEAC analysis concluded that 51 additional lots would fail (a total of 79 failed lots), increasing the lot failure rate from 2.97 percent to 8.39 percent.

As discussed earlier, FDA maintains a recidivist policy under which manufacturers are denied import entry if three lots fail statistical sampling within a 24-month period. To avoid the denial of entry, manufacturers may be expected to hold a sufficient number of defective lots from shipment in order to maintain the same target lot failure rate (approximately 3 percent) with a new AQL. For example, removing the 53 most defective lots in the testing

sample would result in 26 lot failures from 889 total lots, thereby maintaining the original 2.92 percent lot failure rate. This scenario leaves 85,172 total gloves in the sample, of which 1,512 gloves were defective, resulting in a glove defect rate of 1.78 percent. The proposed regulation, therefore, could reduce the proportion of marketed defective medical gloves from 2.4 percent of all marketed gloves to 1.78 percent of all marketed gloves.

The implications of this expected reduction in defective gloves are significant. The current AQL is associated with 740 million glove defects in the present year and within 10 years would result in 955 million annually marketed defective medical gloves. If the proposed AQL were in place, the current annual number of defective gloves would approximate 548 million and within 10 years would reach 709 million. The number of defective gloves, therefore, would be reduced by more than 25 percent due to the new AQL.

2. Reductions in Blood-Borne Pathogens

FDA has estimated that, on average, there are potentially 4.8 annual transmissions of blood-borne pathogens associated with medical glove defects (section IV.C of this document). These transmissions include 2.4 cases of HIV and 2.4 cases of chronic HBV. Because there are currently no documented cases of cutaneous transmission of HCV that would be affected by improving glove quality levels, this analysis does not consider potential HCV cases.

a. *Reductions in HIV transmission*. While the direct relationship between defective medical gloves and HIV is unknown, FDA believes it is reasonable to apply the proportional reduction in the number of defective gloves due to the proposed regulation (about 25 percent) to the annual transmission rate of the HIV pathogen to health care personnel. In the absence of this regulation, the current expectation of 2.4 annual cases of HIV transmission to health care

personnel would likely increase to 3.1 annual cases within 10 years due to the expected growth of employment in the health services industry. However, if the proposed AQL were in place, FDA forecasts the expected value of the annual transmission of HIV in health care personnel to equal 1.8 cases during the first effective year and 2.3 cases by the 10th year (based on the expected proportionate decrease in marketed defective gloves). Over the entire 10-year evaluation period, these assumptions suggest that the regulation would prevent approximately seven cases of HIV transmission to health care personnel.

b. *Reductions in HBV transmissions*. Hepatitis B transmissions to health care personnel are more common than cutaneous HIV transmissions. However, little specific data are available to identify affected patient populations. FDA has estimated that as many as 2.4 cutaneous transmissions of chronic HBV may be due to defective medical gloves each year. In the absence of this rule, this number is expected to increase to 3.1 annual transmissions within 10 years, based on the expected employment growth in the health services industry.

Implementation of the proposed regulation would decrease these transmissions by about 25 percent. Under the new standard, FDA expects 1.8 HBV transmissions during the first evaluation year, a reduction of 0.6 transmissions from baseline conditions. By the 10th evaluation year, FDA expects 2.3 chronic HBV transmissions under the proposed AQL, a total of 0.8 fewer cases. Overall, about seven transmissions of chronic HBV would be avoided due to the proposed regulation over a 10-year period.

3. Reductions in the Number of Blood Screening Tests

As the number of defective gloves marketed in the United States decreases due to this regulation, corresponding reductions would be expected in the

number of unnecessary blood screens. FDA contacted several research hospitals to ascertain how frequently health care personnel identify glove failure as a reason for initiating blood screens. Respondents stated that about 5 percent of all glove failures are noticed by the user and about 1 percent of these identified failures are reported to the facility for additional screening (Refs. 9 and 10). Respondents noted that the glove failure could occur prior to patient contact. The additional screening may apply to the affected health care personnel or the patient if identified. The great majority of these screens result in negative findings.

As shown in the previous paragraphs, during the first evaluation year under the new rule, FDA projects the number of defective gloves marketed in the United States to decrease from 740 to 548 million, a reduction of 192 million defective gloves. By the 10th year, the annual number of defective gloves is expected to decrease from 955 to 709 million, a reduction of 246 million defective gloves. At the rates of potential identification (5 percent) and reports of contact with pathogens (1 percent) obtained from the research hospital sector, the proposed regulation would result in 96,000 fewer unnecessary blood screens during the first year (192 million fewer defects x 0.05 x 0.01). By the 10th year, 123,000 fewer annual blood screens are expected. Over the entire period, the regulation could result in 1,095,000 fewer unnecessary blood screens.

4. Value of Avoiding Blood-Borne Pathogen Transmissions

a. *Quality adjusted life-years*. The economic literature includes many attempts to quantify societal values of health. A widely cited methodology assesses wage differentials necessary to attract workers to riskier occupations. This research indicates that society is willing to pay approximately $5 million

to avoid a statistical death (Refs. 11, 12, and 13). That is, social values appear to show that people are willing to pay a significant number of dollars to reduce even a small risk of death; or similarly, to demand significant payments to accept even marginally higher risks.

Because this estimate is predominantly based on blue-collar occupations that mainly attract males between the ages of 30 and 40, FDA adjusted the life-expectancy of a 35 year-old male to account for future bed and nonbed disability (Refs. 14, 15, and 16), and amortized the $5 million (at a 7 percent discount rate) over the resulting quality-adjusted life span. The result yields an estimate of $373,000 per quality adjusted life-year (QALY), which implies that society is willing to pay $373,000 for the statistical probability of a year of perfect health.

b. *Value of morbidity losses*. In theory, loss of health reduces the willingness to pay for additional longevity. Many studies have attempted to estimate the relative loss of health for different conditions of morbidity. One method utilizes the Kaplan-Bush Index of Well-Being. This index assigns relative weights to functional states, and then adjusts the resulting weighted value by the problem/symptom complex that contributed to loss of function (Refs. 16 and 17). Functional state is measured in three areas: Mobility, social activity, and physical activity. For example, with treatment, chronic HBV may not have a major impact on any of these functions; a patient could drive a car, walk without a physical problem, and participate in work, school, housework, and other activities. However, because a patient with HBV has an ongoing problem/symptom complex, the relative weight of this functional state is estimated at 0.7433.[2]

[2] Note: The implication is that an ideal health state is valued as 1.0000 and mortality at 0.0000.

This methodology then adjusts the weighted value of the functional state by the most severe problem/symptom complex contributing to that state. In the case of HBV, the most common symptom is general tiredness, weakness, or weight loss. This complex has a derived relative weight of +0.0027, which when added to the weighted functional state value results in a relative weight of 0.7460. The loss of relative health due to HBV, therefore, is expected to equal 1.0000 minus 0.7460, or 0.2540 of perfect health. When this relative health loss is applied to the derived value of a QALY, it implies that society is willing to pay $93,000 per year to avoid a case of HBV ($373,000 times 0.2540). This value includes the potential costs of treatment and additional prevention, as well as any perceived pain and suffering.

FDA compared this methodology to a variety of published estimates of preference ratings of morbidity prepared by the Harvard Center for Risk Analysis (HCRA) (Ref. 17a). The published ratings of 14 studies of chronic HBV ranged from 0.75 to 1.00 (no impact). While the estimate used in this analysis (0.746) is in the low end of the collected published studies, FDA notes that most of the expressed preferences that were derived from time trade-off and standard gamble methodologies as compared to author judgment were closer to the FDA estimate. A health care worker who may contract HBV may typically have a life expectancy of approximately 40 years (as of 2000, a 40-year old female has a future life expectancy of 41.1 years (Ref. 14)). The present value of $93,000 per year for 40 years at a 7 percent discount rate implies that society is willing to pay $1.24 million to avoid the statistical likelihood of a case of chronic HBV in health care personnel.

Deriving society's implied WTP to avoid HIV is more complicated. The CDC has published data indicating that approximately 80 percent of all HIV

infections progress to AIDS within 5 years. Of the cases of AIDS, over half (approximately 60 percent) result in mortality within an additional 5 years. Thus, for a 10 year period, FDA tracked three potential outcomes: Patients who contract HIV but do not progress to AIDS (20 percent); patients who contract HIV and progress to AIDS in 5 years and survive (32 percent); and patients who contract HIV, progress to AIDS within 5 years, and then die within the next 5 years (48 percent).

HIV infection may not affect either mobility or social activity. However, such an infection may somewhat inhibit physical activity. HIV patients are able to walk, but with some physical limitations. This functional state has a relative weight of 0.6769. The main problem/symptom complex of HIV is general tiredness (as for HBV), so the selected functional weight is adjusted by +0.0027 to result in relative well-being of 0.6796. As a result, the relative societal willingness to pay to avoid the statistical probability of a case of HIV in health care personnel is estimated at approximately $120,000 per year ($373,000 times [1.0000 minus 0.6796]). According to the collected preference scores (Ref. 17a) in the Car's Catalog of Preference Scores, the average estimated published preference rating for HIV infection was 0.7 (range 0.3 to 1.00).

If HIV progresses to AIDS, a patient's functional state is likely to be more restricted. An AIDS patient requires some assistance with transportation, is limited in physical activity, and is limited in work, school, or household activity. The relative weight for this functional state is 0.5402. The main problem/symptom of AIDS remains general tiredness and loss of weight (as with HIV and HBV), so the adjusted health state is 0.5429. This results in a derived societal willingness to pay to avoid the statistical probability of a case of AIDS of about $170,000 per year ($373,000 times [1.0000 minus 0.5429]).

The Car's Catalog of Preference Scores (Ref. 17a) reports average preference ratings of 0.375 for cases of AIDS with ranges from 0.0 to 0.5.

As discussed earlier, the derived societal willingness to pay to avoid a statistical mortality has been estimated to equal approximately $5 million.

Using these estimates, the WTP to avoid the statistical probability of an HIV transmission in health care personnel is calculated as the sum of:

- 20 percent of the percent value (PV) (at 7 percent discount rate) of avoiding 40 years of HIV infection.
- 32 percent of the sum of the PV of avoiding 5 years of HIV infection plus the PV of avoiding 35 years of AIDS infection occurring 5 years in the future.
- 48 percent of the sum of the PV of avoiding 5 years of HIV infection plus the PV of avoiding 5 years of AIDS infection occurring 5 years in the future plus the discounted WTP of avoiding a statistical mortality occurring 10 years in the future.

The PV of avoiding 40 years of health loss valued at $120,000 per year is approximately $1.6 million (at 7 percent discount). Twenty percent of this figure equals $320,000. The PV of avoiding 5 years of health loss to due HIV infection is equal to $492,000. The PV of avoiding the health loss expected from 35 years of AIDS infection (valued at $170,000 per year) is equivalent to $2.2 million. The present value of this amount occurring 5 years in the future (at 7 percent) is $1.6 million. When added to the PV of avoiding the health loss associated with 5 years of HIV infection ($492,000), the total estimated present value of the societal willingness to pay to avoid a statistical case of this outcome is about $2.1 million. Thirty-two percent of this figure equals $660,000. The PV of avoiding the health loss expected from 5 years

of AIDS infection ($700,000) occurring 5 years in the future is equivalent to $497,000 (at 7 percent discount rate). The PV of avoiding a statistical mortality ($5 million) 10 years in the future is $2.54 million (at 7 percent discount). The total societal WTP to avoid a case of HIV with mortality as an outcome, therefore, is $3.5 million ($493,000 plus $497,000 plus $2.54 million). Forty-eight percent of this figure equals approximately $1.7 million. Summing the weighted amounts of the three expected outcomes for a case of HIV infection ($320,000 plus $660,000 plus $1,700,000) equals an estimated societal willingness to pay $2.68 million to avoid a statistical transmission of HIV.

In sum, the estimated societal values of avoiding morbidity and mortality due to the transmission of blood-borne pathogens are estimated to be equivalent to $1.24 million per transmission of chronic HBV and $2.68 million per transmission of HIV. FDA notes that other recent cost-effectiveness research (Ref. 18) has reported cost-effectiveness estimates (excluding pain and suffering) of $2.1 million per avoided case of HIV.

FDA believes the methodology to estimate the value of avoided HBV and HIV infection is reasonable and supportable. Nevertheless, comparison with reported published preferences show some estimates to place higher values on avoidance and some lower than the average collected weight. FDA acknowledges these differences and solicits comment on other appropriate measures for estimating the societal value of avoiding blood-borne infections.

c. *Benefits of morbidity and fatality avoidance*. The proposed regulation would reduce both HBV and HIV transmissions by reducing the prevalence of defective medical gloves used as barrier protection. During the first evaluation year, the regulation would result in 0.6 fewer chronic HBV transmissions to health care personnel. Applying the assumed societal WTP

of $1.24 million to avoid the statistical probability of one chronic HBV infection, the expected benefit of avoiding these transmissions is $0.7 million. By the 10th evaluation year, 0.8 annual transmissions would be avoided at a value of $1.0 million. The PV of avoiding almost seven chronic HBV transmissions over a 10 year period equals $6.1 million (at a 7 percent discount rate), which is equivalent to an average annualized value of $0.9 million for the entire 10-year evaluation period.

Also, in the first evaluation year, FDA expects that the proposed regulation would result in the probability of 0.6 fewer transmissions of HIV caused by defective gloves. Assuming that society is willing to pay $2.68 million to avoid the probability of a single HIV transmission, the benefit of avoiding these transmissions equals $1.6 million. By the 10th evaluation year, FDA expects the proposed regulation to result in 0.8 fewer HIV transmissions, which are valued at over $2.1 million. The societal PV of avoiding seven transmissions of HIV over the 10-year evaluation period is $12.9 million (at 7 percent discount rate) and is equivalent to an average annualized benefit of $1.8 million.

In sum, FDA estimates that the reduction in blood-borne pathogen transmissions due to this proposed rule would produce health benefits valued at $2.7 million per year. Much of this benefit (almost 67 percent) is attributable to reducing the incidence of HIV.

5. Value of Avoiding Unnecessary Blood Screens

The expected decline in the number of defective medical gloves would lead to a smaller number of unnecessary blood screens and thereby provide two potential benefits. First, the direct cost of conducting screens to determine whether the pathogen was transmitted to health care personnel would fall.

Second, the psychological anxiety and stress that accompanies the possibility that a pathogen was transmitted to an individual would decrease.

a. *Cost of conducting blood screens*. FDA has collected data from the American Red Cross (Ref. 5) on the costs of conducting blood screening tests designed to ensure the safety of the blood supply. These estimates include the costs of collection (including personnel, needles, bags, and other supplies) at $47.66 per sample; sample testing at $25.16 per sample; and overhead at $3.26 per sample. The estimated direct testing cost per blood sample is the sum of these amounts, or $76 per test.

b. *Anxiety and stress associated with potential transmission of pathogens*. The psychological literature has noted that levels of anxiety and stress impact participation in public health screening programs and thereby affect physiological health (Refs. 19, 20, and 21). Also, patients who experience high levels of uncertainty due to the possibility of contracting serious, threatening diseases experience heightened levels of stress and anxiety until the results of the testing screens are negative (Ref. 20). According to one measurement scale of well-being, reduced mental lucidity, depression, crying, lack of concentration, or other signs of adverse psychological sequence may detract as much as 8 percent from overall feelings of well-being (Ref. 16) and have outcomes similar to physiological morbidity. Scaling of the relative stress caused by events shows that concerns of personal health, by themselves, are likely, on average, to contribute approximately one-sixth of the total weighting required to trigger a major stressful episode (Refs. 20, 21 and 22). Thus, FDA approximates that increased stress and anxiety concerning possible exposure to pathogens may reduce overall sense of well-being and result in health loss of approximately 1.3 percent (0.013).

As described earlier, FDA has calculated an assumed WTP of $373,000 for a statistical QALY. This figure implies that the probability of each day of quality adjusted life has a social value of $1,022 ($373,000/365). If blood test results are usually obtained within 24 hours, the resultant loss of societal well-being for each test subject is valued at approximately $13 ($1,022 times 0.013).

c. *Benefit of test avoidance*. By combining the avoided direct cost of tests and the value of avoided anxiety and stress, FDA estimates that the societal benefit of avoiding an unnecessary blood test is $89 per sample. During the first evaluation year, FDA expects 96,000 fewer unnecessary blood screens because of the expected reduction in defective medical gloves due to the proposed regulation. The implied societal WTP to avoid these unnecessary screens is $8.5 million. During the 10th evaluation year, approximately 123,000 fewer unnecessary blood screens are expected with a resultant benefit of $10.9 million. The PV of each year's reduced cost of testing and anxiety totals $66.5 million for the entire period (at a 7 percent discount rate) and an average annualized amount of $9.6 million. Of the average annualized amount, $8.2 million represents reductions in the direct testing costs and $1.4 million represents reduced anxiety associated with possible infection by a contagious agent.

6. Total Benefits

FDA estimates that the proposed regulation would reduce the availability of defective medical gloves by over 25 percent, resulting in over 2.2 billion fewer defective gloves over a 10-year period. During this time, FDA expects that reduction in defective gloves would result in almost 7 fewer cases of chronic HBV, 7 fewer cases of HIV, and 1.1 million fewer unnecessary blood screens. Based on an implied societal WTP, the average annualized benefits

of the fewer pathogen transmissions and unnecessary blood screens would equal $12.3 million.

G. Small Business Impact—Initial Regulatory Flexibility Analysis

FDA finds that the proposed regulation would not have a significant impact on a substantial number of small entities. There are currently 417 manufacturers of medical gloves, of which 411 are foreign. Because medical gloves are almost exclusively manufactured by foreign firms, there would not be a significant economic impact on a substantial number of domestic small entities. Moreover, FDA does not expect the increased manufacturer costs to be directly passed on to end users, because the cost increases would affect only a minority of global manufacturers and, therefore, competition would require these manufacturers to absorb these costs.

H. Conclusion

FDA has conducted an analysis of the proposed regulation, using outside economic consultants. The estimated annualized costs equal $5.2 million, while the estimated annualized benefits equal $12.3 million. FDA certifies that the proposed regulation would not have a significant economic impact on a substantial number of small entities because medical gloves are imported from foreign manufacturers not subject to the Regulatory Flexibility Act. All six domestic manufacturers of medical gloves employ more than 1,200 workers. The Small Business Administration designates as small any entity with fewer than 500 employees in this industry.

V. Submission of Comments and Proposed Effective Date

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**), written or electronic comments regarding this document. Submit

a single copy of electronic comments to http://www.fda.gov/dockets/ecomments or two copies of any mailed comments, except that individuals may submit one hard copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

FDA proposes that any final rule that may issue based on this proposal become effective 90 days after its date of publication in the **Federal Register**.

VI. Paperwork Reduction Act of 1995

This proposed rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520). No burden has been estimated for the requirements in § 800.20 because recordkeeping of tests and samples is a usual and customary business practice. Under 5 CFR 1320.3(b)(2), the time, effort, and financial resources necessary to comply with a collection of information are excluded from the burden estimate if the reporting, recordkeeping or disclosure activities needed to comply are usual and customary because they would occur in the normal course of activities.

VII. References

The following references have been placed on display in the Dockets Management Branch and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. FDA has verified the Web site addresses, but is not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**.

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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 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.

(1) *Sample plans*. FDA will collect samples from lots of medical gloves in accordance with agency sampling plans. These plans are based on sample sizes, levels of sample inspection, and acceptable quality levels (AQLs) found in the International Standard Organization's standard, ISO 2859, Sampling Procedures For Inspection By Attributes.

(2) *Sample sizes, inspection levels, and minimum AQLs*. FDA will use single normal sampling for lots of 1,200 gloves or less and multiple normal sampling for all larger lots. FDA will use general inspection level II in determining the sample size for any lot size. As shown in the tables following paragraph (c)(3) of this section, FDA considers a 1.5 AQL to be the minimum level of quality acceptable for surgeons' gloves and a 2.5 AQL to be the minimum level of quality acceptable for patient examination gloves.

(3) *Adulteration levels and accept/reject criteria*. FDA considers a lot of medical gloves to be adulterated when the number of defective gloves found in the tested sample meets or exceeds the applicable rejection number at the 1.5 AQL for surgeons' gloves or the 2.5 AQL for patient examination gloves. These acceptance and rejection numbers are identified in the tables following paragraph (c)(3) of this section as follows:

ACCEPT/REJECT CRITERIA AT 1.5 AQL FOR SURGEONS' GLOVES

Lot Size	Sample	Sample Size	Number Examined	Number Defective	
				Accept	Reject
8 to 90	Single sample		8	0	1
91 to 280	Single sample		32	1	2
281 to 500	Single sample		50	2	3
501 to 1,200	Single sample		80	3	4
1,201 to 3,200	First	32	32	0	4
	Second	32	64	1	5
	Third	32	96	2	6
	Fourth	32	128	3	7
	Fifth	32	160	5	8
	Sixth	32	192	7	9
	Seventh	32	224	9	10
3,201 to 10,000	First	50	50	0	4
	Second	50	100	1	6
	Third	50	150	3	8
	Fourth	50	200	5	10
	Fifth	50	250	7	11
	Sixth	50	300	10	12

ACCEPT/REJECT CRITERIA AT 1.5 AQL FOR SURGEONS' GLOVES—Continued

Lot Size	Sample	Sample Size	Number Examined	Number Defective	
				Accept	Reject
	Seventh	50	350	13	14
10,001 to 35,000	First	80	80	0	5
	Second	80	160	3	8
	Third	80	240	6	10
	Fourth	80	320	8	13
	Fifth	80	400	11	15
	Sixth	80	480	14	17
	Seventh	80	560	18	19
35,000 and above	First	125	125	1	7
	Second	125	250	4	10
	Third	125	375	8	13
	Fourth	125	500	12	17
	Fifth	125	625	17	20
	Sixth	125	750	21	23
	Seventh	125	875	25	26

ACCEPT/REJECT CRITERIA AT 2.5 AQL FOR PATIENT EXAMINATION GLOVES

Lot Size	Sample	Sample Size	Number Examined	Number Defective	
				Accept	Reject
5 to 50	Single sample		5	0	1
51 to 150	Single sample		20	1	2
151 to 280	Single sample		32	2	3
281 to 500	Single sample		50	3	4
501 to 1,200	Single sample		80	5	6
1,201 to 3,200	First	32	32	0	4
	Second	32	64	1	6
	Third	32	96	3	8
	Fourth	32	128	5	10
	Fifth	32	160	7	11
	Sixth	32	192	10	12
	Seventh	32	224	13	14
3,201 to 10,000	First	50	50	0	5
	Second	50	100	3	8
	Third	50	150	6	10
	Fourth	50	200	8	13
	Fifth	50	250	11	15
	Sixth	50	300	14	17
	Seventh	50	350	18	19
10,001 to 35,000	First	80	80	1	7
	Second	80	160	4	10
	Third	80	240	8	13
	Fourth	80	320	12	17
	Fifth	80	400	17	20
	Sixth	80	480	21	23
	Seventh	80	560	25	26
35,000 and above	First	125	125	2	9
	Second	125	250	7	14
	Third	125	375	13	19
	Fourth	125	500	19	25
	Fifth	125	625	25	29
	Sixth	125	750	31	33
	Seventh	125	875	37	38

(d) *Compliance*. Lots of gloves that are sampled, tested, and rejected using procedures in paragraphs (b) and (c) of this section, are considered adulterated within the meaning of section 501(c) of the act.

(1) *Detention and seizure*. Lots of gloves that are adulterated under section 501(c) of the act are subject to administrative and judicial action, such as detention of imported products and seizure of domestic products.

(2) *Reconditioning*. FDA may authorize the owner of the product, or the owner's representative, to attempt to recondition, i.e., bring into compliance with the act, a lot or part of a lot of foreign gloves detained at importation, or a lot or part of a lot of seized domestic gloves.

(i) *Modified sampling, inspection, and acceptance*. If FDA authorizes reconditioning of a lot or portion of a lot of adulterated gloves, testing to confirm that the reconditioned gloves meet AQLs must be performed by an independent testing facility. The following tightened sampling plan must be followed, as described in ISO 2859 ''Sampling Procedures for Inspection by Attributes:''

(A) General inspection level II,

(B) Single sampling plans for tightened inspection,

(C) 1.5 AQL for surgeons' gloves, and

(D) 2.5 AQL for patient examination gloves.

(ii) *Adulteration levels and acceptance criteria for reconditioned gloves*. (A) FDA considers a lot or part of a lot of adulterated gloves, that is reconditioned in accordance with paragraph (d)(2)(i) of this section, to be acceptable when the number of defective gloves found in the tested sample does not exceed the acceptance number in the appropriate tables in paragraph (d)(2)(ii)(B) of this section for reconditioned surgeons' gloves or patient examination gloves.

(B) FDA considers a reconditioned lot of medical gloves to be adulterated within the meaning of section 501(c) of the act when the number of defective

gloves found in the tested sample meets or exceeds the applicable rejection number in the tables following paragraph (d)(2)(ii)(B) of this section:

ACCEPT/REJECT CRITERIA AT 1.5 AQL FOR RECONDITIONED SURGEONS' GLOVES

Lot Size	Sample	Sample Size	Number Examined	Number Defective	
				Accept	Reject
13 to 90	Single sample		13	0	1
91 to 500	Single sample		50	1	2
501 to 1,200	Single sample		80	2	3
1,201 to 3,200	Single sample		125	3	4
3,201 to 10,000	Single sample		200	5	6
10,001 to 35,000	Single sample		315	8	9
35,000 and above	Single sample		500	12	13

ACCEPT/REJECT CRITERIA AT 2.5 AQL FOR RECONDITIONED PATIENT EXAMINATION GLOVES

Lot Size	Sample	Sample Size	Number Examined	Number Defective	
				Accept	Reject
8 to 50	Single sample		8	0	1
51 to 280	Single sample		32	1	2
281 to 500	Single sample		50	2	3
501 to 1,200	Single sample		80	3	4
1,201 to 3,200	Single sample		125	5	6
3,201 to 10,000	Single sample		200	8	9
10,001 to 35,000	Single sample		315	12	13
35,000 and above	Single sample		500	18	19

Dated: March 21, 2003.

William K. Hubbard,

Associate Commissioner for Policy and Planning.

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