

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