cargo information requirements as provided in section 343(a) of the Trade Act of 2002. Truck Carrier Accounts participating in the test were given the ability to electronically transmit the truck manifest data and obtain release of their cargo, crew, conveyances, and equipment via the ACE Portal or electronic data interchange messaging.

A series of notices announced additional deployments of the test, with deployment sites being phased in as clusters. Clusters were announced in the following notices published in the **Federal Register**: 70 FR 30964 (May 31, 2005); 70 FR 43892 (July 29, 2005); 70 FR 60096 (October 14, 2005); 71 FR 3875 (January 24, 2006); 71 FR 23941 (April 25, 2006); 71 FR 42103 (July 25, 2006); and 71 FR 77404 (December 26, 2006).

CBP continues to test ACE at various ports. CBP will continue, as necessary, to announce in subsequent notices in the **Federal Register** the deployment of the ACE truck manifest system test at additional ports.

Designation of ACE Truck Manifest System as the Approved Data Interchange System

In a notice published October 27, 2006, (71 FR 62922), CBP designated the Automated Commercial Environment (ACE) Truck Manifest System as the approved EDI for the transmission of required data and announced that the requirement that advance electronic cargo information be transmitted through ACE would be phased in by groups of ports of entry.

ACE will be phased in as the required transmission system at some ports even while it is still being tested at other ports. However, the use of ACE to transmit advance electronic truck cargo information will not be required in any port in which CBP has not first conducted the test.

The October 27, 2006, document identified all land border ports in the states of Washington and Arizona and the ports of Pembina, Neche, Walhalla, Maida, Hannah, Sarles, and Hansboro in North Dakota as the first group of ports where use of the ACE Truck Manifest System is mandated.

ACE Mandated at Ports of Entry in California, Texas and New Mexico

Applicable regulations (19 CFR 123.92(e)) require CBP, 90 days prior to mandating advance electronic information at a port of entry, to publish notice in the **Federal Register** informing affected carriers that the EDI system is in place and fully operational. Accordingly, CBP is announcing in this document that, effective 90 days from the date of publication of this notice, truck carriers entering the United States at any land border port of entry in the states of California, Texas, and New Mexico will be required to present advance electronic cargo information regarding truck cargo through the ACE Truck Manifest System.

Although other systems that have been deemed acceptable by CBP for transmitting advance truck manifest data will continue to operate and may still be used in the normal course of business for purposes other than transmitting advance truck manifest data, use of systems other than ACE will no longer satisfy advance electronic cargo information requirements at a port of entry in California, Texas and New Mexico as of April 19, 2007.

Compliance Sequence

CBP will be publishing subsequent notices in the **Federal Register** as it phases in the requirement that truck carriers utilize the ACE system to present advance electronic truck cargo information at other ports. ACE will be phased in as the mandatory EDI system at the ports identified below in the sequential order in which they are listed. The sequential order provided below is somewhat different from that announced in the October 27, 2006, notice. Although further changes to this order are not currently anticipated, CBP will state in future notices if changes do occur. In any event, as mandatory ACE is phased in at these remaining ports, CBP will always provide 90 days' notice through publication in the **Federal Register** prior to requiring the use of ACE for the transmission of advance electronic truck cargo information at a particular group of ports.

The remaining ports at which the mandatory use of ACE will be phased in, listed in sequential order, are as follows:

1. All ports of entry in the state of New York and Michigan.

2. All ports of entry in the states of Vermont, New Hampshire, and Maine.

3. All ports of entry in the states of Idaho and Montana.

4. The remaining ports of entry in the state of North Dakota and the land border port of Minnesota.

5. All ports of entry in the state of Alaska.

Dated: January 16, 2007.

Deborah J. Spero,

Acting Commissioner, Customs and Border Protection.

[FR Doc. E7–762 Filed 1–18–07; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 800

[Docket No. 2003N–0056 (formerly 03N–0056)]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a final regulation that appeared in the **Federal Register** of December 19, 2006 (71 FR 75865). The document issued a final regulation that improves the barrier quality of medical gloves marketed in the United States (U.S.). The rule will accomplish this by reducing the current acceptable quality levels (AQLs) for leaks and visual defects observed during FDA testing of medical gloves. By reducing the AQLs for medical gloves, FDA will also harmonize its AQLs with consensus standards developed by the International Organization for Standardization (ISO) and ASTM International (ASTM). The document was published with some errors in the use of references. This document corrects those errors.

DATES: This correction is effective on January 19, 2007.

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, 240–276–0100.

SUPPLEMENTARY INFORMATION: In FR Doc. E6–21591, appearing on page 75865 in the **Federal Register** of Tuesday, December 19, 2006, the following corrections are made to the **SUPPLEMENTARY INFORMATION**.

1. On page 75868, in the second column, section III of the document is corrected to read:

''III. Analysis of Impacts

A. Introduction

FDA has examined the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), 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, and other advantages; distributive impacts; and equity). The agency believes that this final rule is not a significant regulatory action under the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of the rule on small entities. Because this final rule will not result in economic impacts on domestic small entities, the agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any Federal mandate that may result in the expenditure of State, local and tribal governments, in the aggregate, or the private sector of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $122 million, using the most current (2005) implicit price deflator for the Gross National Product. FDA does not expect this final rule to result in any 1-year expenditure that would meet or exceed this amount.

The information in the following sections sets forth the bases for the previous conclusions. We show the expected annual costs and benefits of this final rule next in table 1. The average annualized costs of the final rule are estimated to be $6.6 million using either a 3-percent or 7-percent discount rate. Average annualized benefits are expected to be between $14.8 million and $15.1 million, depending on the discount rate. Average annualized net benefits are between $8.2 million and $8.5 million.

TABLE 1.—AVERAGE ANNUALIZED COSTS AND BENEFITS (IN MILLIONS)[1]

Annual Discount Rate	Costs	Benefits	Net Benefits
3 Percent	$6.6	$14.8	$8.2
7 Percent	$6.6	$15.1	$8.5

[1]Annualized over a 10-year evaluation period.

B. Objective of the Final Rule

The objective of the final rule is to reduce the risk of transmission of blood-borne pathogens (particularly human immunodeficiency virus (HIV), hepatitis B (HBV), and hepatitis C (HCV) infections). The rule accomplishes 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. FDA is also harmonizing its level 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 final rule will prevent. This analysis, however, attempts to derive a conservative estimate. For the year 2000, the Centers for Disease Control (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 Acquired Immunodeficiency Syndrome (AIDS). 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 (Ref. 1).

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 between 1992 and 2002 there had been 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 needlesticks. 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. 3). Assuming the same 12.5-percent rate for these workers implies that 17 additional cases of HIV transmission to health care workers 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 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 (2001) (Ref. 4). There are approximately 1.25 million people in the United States chronically infected with HBV. While only 6 percent of those who contract hepatitis B 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 from this pathogen, but the availability of a vaccine has reduced the risk of negative outcomes due to exposure. (Ref. 5).

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 (Ref. 6). FDA estimates that as many as 4,000, or 5 percent, of all new incidents of HBV occur in health care personnel. Because occupational transmissions for HBV may be approximately 5 times more likely than that 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 communicate that a large portion of HBV infections in health care personnel are the result of direct or indirect blood or bodily fluid exposures that inoculated HBV into cutaneous scratches, abrasions, burns, other lesions, or on mucosal surfaces (Ref. 7). 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 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.

HCV currently infects 3.9 million persons in the United States. Over 2.7 million patients have reported chronic conditions. (Ref. 8). More than 40,000 new cases were reported in 1999. The risk of exposure to health care workers, however, appears to be extremely low. In fact, according to the CDC, other than from needle stick punctures, there has been no documented transmission of HCV to health care personnel from intact or non-intact skin exposures to blood or other fluids or tissues (Ref. 9). 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 should reduce the transmission rates of these pathogens.

D. Baseline Conditions

The previous AQL (being replaced by this rule) for medical gloves allowed a defect rate of 4.0 percent for patient examination gloves and 2.5 percent 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 in accordance with the sampling criteria, the entire lot of gloves is considered adulterated. Surgeons' gloves are sampled to a higher quality level (lower AQL requires a higher proportion of non-defective 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 request resampling of the lot. The required sampling 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 devices after meeting the current AQL, offered as nonmedical gloves, or sold in foreign markets.

Approximately 39.5 billion medical gloves were imported into the United States during 2004 (Ref. 10). According to FDA records, there are over 400 manufacturers of medical gloves. Malaysian manufacturers supply almost 40 percent of the medical gloves in the United States while Thailand manufacturers supply approximately 30 percent (Ref. 11). Surgeons' gloves accounted for only about 15 percent of all imported medical gloves during 2004, and the impact of the final rule 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 has projected annual employment growth of 2.6 percent for this industry (North American Industry Classification System 6200) (Ref. 12), which implies an annual volume of over 50 billion medical gloves in 10 years. (A 2.6 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 over 120,600 lots of gloves per year. FDA currently samples only about 1.5 percent of all glove lots, or 1,800 lots per year. Within 10 years, FDA expects the number of lots offered for import to increase to 156,000. If the compliance sampling rate remains constant, FDA would sample about 2,300 lots during that year.

FDA's Winchester Engineering and Analytical Center (WEAC) analyzed results from samples collected from 2000 and 2001. These samples represent approximately one-third of FDA's total sampling effort for the period. (Ref. 13). A total of 98,067 gloves were tested from 942 separate lots. Of these gloves, 2,354 were defective, which implies that 2.4 percent of marketed gloves are likely to be defective. (Ref. 14) If so, then approximately 940 million defective medical gloves are currently marketed (39.2 billion gloves x 0.024). At the current AQL of 4.0, 28 lots (2.97 percent) failed. Consequently, approximately 53 annually sampled lots are defective (1,800 sampled lots x 0.0297). By the 10th year, in the absence of the final regulation, 1.21 billion defective gloves would be marketed and 68 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 glove lot resampling and retesting for leakage and tensile strength is approximately $1,400. The current annual industry cost of resampling glove lot failures with the current AQL is approximately $74,000 (53 lots times $1,400 per lot). This resampling and retesting cost would equal $95,000 within 10 years.

E. Costs of the Final Rule

FDA expects that the final rule will 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 than in other markets. Manufacturers attempt to avoid having three failures within a 24–month period, because this may result in refusal of future imports under Level 3 detention described in FDA's current policy, ''Surveillance and Detention Without Physical Examination of Surgeon's and/or Patient Examination Gloves.'' Thus, to maintain an uninterrupted supply of gloves to customers, and to guard brand loyalty while avoiding Level 3 detention, 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 rule to increase the costs of sampling by requiring larger and more detailed sampling plans to assure the lower AQL is met for each inspected glove lot. FDA does not envision increased regulatory oversight costs because the rate of inspections is not expected to change. Costs have been analyzed and discounted using the methodology suggested by the Office of Management and Budget's (OMB's) Circular A–4 (September 2003).

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, while the more stringent quality control testing required by this rule 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 120,600 lots are currently imported per year, the expected costs are $5.4 million (120,600 lots x $45 per lot). The expected increase in the demand for medical gloves by the 10th evaluation year will result in a compliance cost of meeting this increased quality level of $7.0 million. Over the 10-year period, the average annualized cost of this increased level of testing, at a 3-percent annual discount rate, is $6.2 million and, at a 7-percent annual discount rate, is $6.2 million.

2. Increased Sampling Costs

A lower AQL will result in increased sampling costs for imported glove lots. The increased sampling costs will result from the need to test greater quantities of gloves in order 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 $45 increased quality control cost is attributable to lower costs in foreign countries that produce medical gloves.) FDA currently samples about 1.5 percent of the 120,600 lots imported annually, or 1,800 samples. Thus, the increased sampling costs due to this final rule are $0.4 million (120,600 lots x 0.015 x $200). Within 10 years, this increased cost will equal $0.5 million (due to expected increases in the number of inspected glove lots). The average annualized sampling cost increase at a 3-percent annual discount rate is $0.4 million, and at a 7-percent annual discount rate is $0.4 million.

3. Withheld Lots

The lower AQL in this final rule is also 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 Level 3 detention under ''Surveillance and Detentions Without Physical Examination of Surgeon's and or Patient Examination Gloves.'' FDA's WEAC laboratory sampled 942 lots and discovered that 28 failed using the current AQL while 79 lots failed using the lower AQL in this final rule. (Ref. 15) 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 anticipates that under the lower AQL in the final rule, approximately 6,900 lots will be held back by manufactures. In order to meet the expected demand in 10 years, FDA expects that 9,000 lots will be held back. FDA believes that glove lots that fail to meet the lower AQL in this final rule for medical quality standards will most likely be sold as nonmedical gloves. FDA believes that, although manufacturers and distributors may experience some loss of revenue from this shift (because of the price premium commanded by medical gloves), the loss will be inconsequential.

4. Costs of FDA Inspections

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

5. Total Costs

In sum, FDA estimates that the final rule will have an average annualized cost of about $6.6 million using either a 3-percent or 7-percent annual discount rate. Table 2 of this document presents the costs for each year of the evaluation period.

TABLE 2.—COSTS PER YEAR OF THE FINAL RULE (IN MILLIONS)

Year	Costs for Quality Control	Costs for Sampling	Total Costs
Current	$5.4	$0.4	$5.8
1	$5.6	$0.4	$6.0
2	$5.7	$0.4	$6.1
3	$5.9	$0.4	$6.3
4	$6.0	$0.4	$6.4
5	$6.2	$0.4	$6.6
6	$6.3	$0.4	$6.7
7	$6.5	$0.4	$6.9
8	$6.7	$0.4	$7.1
9	$6.8	$0.5	$7.3
10	$7.0	$0.5	$7.5
Present Values	3%–$53.2 7%–$43.4	3%–$3.6 7%–$2.9	3%–$56.8 7%–$46.3

F. Benefits of the Rule

The final rule will result in public health gains by reducing the frequency of blood-borne pathogen transmissions due to defects in the barrier protection provided by medical gloves. Based on an implied societal willingness to pay (WTP), FDA expects that an annualized monetary benefit of $14.8 million (using a 3-percent discount rate) or $15.1 million (using a 7-percent discount rate) will be realized due to fewer pathogen transmissions and unnecessary blood screens. Fewer glove defects will reduce the cost and anxiety associated with unnecessary blood screens (i.e., those that would yield negative results for health care personnel). Benefits have been analyzed and discounted using the methodology suggested by OMB's Circular A–4 (September 2003).

1. Reductions in the Number of Marketed Defective Gloves

As noted in the previous paragraphs, FDA has determined that approximately 940 million defective gloves are marketed each year in the United States, or 2.4 percent of all medical gloves. In the absence of this rule, FDA expects that the number of defective medical gloves marketed in the United States would increase to 1.21 billion per year within 10 years. The final rule will 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 with an AQL of 4.0 (28 lots would fail). This lot failure rate was associated with 2,356 defective gloves, or 2.4 percent of the total number of sampled gloves. (Ref. 16). Under the lower AQL of 2.5 in the rule, the WEAC analysis concluded that 51 additional lots would fail (a total of 79 failed lots), increasing the lot failure rate from 2.91 percent to 8.39 percent.

As previously mentioned, FDA provides a Level 3 detention status in its guidance, ''Surveillance and Detentions Without Physical Examination of Surgeon's and or Patient Examination Gloves.'' Manufacturers on Level 3 detention are not allowed to import medical gloves because they have repeatedly failed analysis. 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. If so, removing the 53 most defective lots in the testing sample would result in 26 lot failures from 880 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 were defective, resulting in a glove defect rate of 1.78 percent. The final rule, 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 940 million glove defects during the present year (based on 2004) and within 10 years would result in 1.21 billion marketed defective medical gloves. When the lower AQL is in place, the current number of defective gloves will approximate 700 million and within 10 years will result in 900 million defective marketed gloves. The number of defective gloves,

[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.

therefore, should be reduced by more than 25 percent due to the new AQL.

2. Reductions in Blood-Borne Pathogens

FDA has estimated that there are potentially 4.8 annual transmissions of blood-borne pathogens associated with medical glove defects (section III.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 transmission.

a. *Reductions in HIV transmission.* While the direct relationship between defective medical gloves and the transmission of HIV is unknown, FDA believes it is reasonable to apply the proportional reduction in the number of defective gloves due to the final rule (about 25 percent) to the annual transmission rate of the HIV pathogen to health care personnel. In the absence of this rule, 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, with the new AQL in place, FDA forecasts the expected annual transmission of HIV to health care personnel to equal 1.8 cases in current conditions and 2.3 cases by the 10th evaluation year (based on the expected proportionate decrease in marketed defective gloves). Over the entire 10-year evaluation period, these assumptions suggest that the rule should 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 and routes of transmission. 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 would be 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 final rule should decrease these transmissions by about 25 percent. FDA expects 1.8 HBV transmissions under current conditions, a reduction of 0.6 transmissions from baseline conditions. By the 10th evaluation year, FDA expects that there will be 2.3 chronic HBV transmissions with the lower AQL, or a total of 0.8 fewer cases. Overall, about 7 transmissions of chronic HBV will be avoided due to the final rule over a 10 year evaluation 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 rule, 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 (Ref. 17). Respondents noted that the glove failure could occur prior to patient contact. Therefore, the additional screening may apply to the affected health care personnel or the patient. The great majority of these screens result in negative findings.

As shown in the previous paragraphs, when the final rule is in effect, FDA expects the number of defective gloves marketed to decrease from 940 million to 700 million, a reduction of 240 million defective gloves. By the 10th year, the number of defective gloves is expected to decrease from 1.21 billion to 900 million, a reduction of 310 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 final rule should result in 120,000 fewer unnecessary blood screens under current conditions (240 million fewer defects x 0.05 x 0.01). By the 10th year, 155,000 fewer annual blood screens are expected. Over the entire evaluation period, the rule could result in over 1.4 million fewer unnecessary blood screens.

4. Cost-Effectiveness of the Final Rule

We analyzed the cost-effectiveness of the final rule using both the cost per transmission of blood-borne pathogen avoided and the cost per unnecessary blood screen avoided. The annual numbers of future avoided transmissions and tests were compared to the present values of the costs for the evaluation period and shown in table 3. Table 3 of this document shows the expected annual reductions in blood-borne pathogens and unnecessary blood screens due to the final rule.

TABLE 3.—EXPECTED ANNUAL REDUCTIONS IN BLOOD-BORNE PATHOGEN TRANSMISSIONS AND UNNECESSARY BLOOD SCREENS

Year	Reduction in Blood-Borne Pathogen Transmission	Reduction in Unnecessary Blood Screens
Current	1.2	120,000
1	1.2	120,000
2	1.2	125,000
3	1.4	135,000
4	1.4	135,000
5	1.4	140,000
6	1.4	145,000
7	1.6	150,000
8	1.4	145,000
9	1.6	155,000
10	1.6	155,000

Although these reductions should continue beyond the evaluation period, we have analyzed only through the 10th year. Each year's expected number of reduced blood-borne pathogen transmissions and unnecessary blood screens are discounted (using both a 3-percent annual discount rate and a 7-percent annual discount rate) to arrive at an equivalent number of reductions if valued during the first evaluation year. The present values of the regulatory costs (shown in table 4 of this document) are divided by the present values of the expected reductions to arrive at the cost per avoided event. This is shown in table 4 of this document.

TABLE 4.—REGULATORY COST-EFFECTIVENESS PER INCIDENCE OF BLOOD-BORNE PATHOGEN TRANSMISSION AVOIDED AND UNNECESSARY BLOOD SCREEN AVOIDED

Annual Discount Rate	Present Value of Costs (in millions)	Present Value of Blood-Borne Pathogens Avoided	Cost per Blood-Borne Pathogen Avoided (in millions)	Present Value of Blood Screens Avoided	Cost per Blood Screen Avoided
3 percent	$56.8	12.2	$4.7	1,191,000	$48
7 percent	$46.3	9.8	$4.7	971,000	$48

The cost-effectiveness of the final rule is $4.7 million per transmission of blood-borne pathogen avoided, or $48 per unnecessary blood screen avoided for both discount rates. We note that both reductions should occur and the allocation of costs to each outcome would reduce the costs per avoided event for both.

5. Value of Avoiding Blood-Borne Pathogens

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 labor to riskier occupations. This research indicates that society appears to be WTP approximately $5 million to avoid the probability of a statistical death (Ref. 18). That is, social values appear to show that people are WTP a significant amount to reduce even a small risk of death; or similarly, to demand significant payments to accept 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 non-bed disability (Ref. 19), and amortized the $5 million (at both 3-percent and 7-percent discount rates) over the resulting quality-adjusted life span. The results were estimates of $213,000 per quality adjusted life-year (QALY) using a 3-percent discount rate and $373,000 per QALY using a 7-percent discount rate, which implies that society is WTP between $213,000 and $373,000 for the statistical probability of a year of perfect health, depending on the discount rate.

b. *Value of morbidity losses.* In theory, loss of health reduces the WTP for additional longevity. Many studies have attempted to estimate the relative loss of health for many 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 (Ref. 20). Functional state is measured in three areas: Mobility, social activity, and physical activity. For example, with most treatment, chronic HBV is unlikely to have a major impact on any of these functions; a patient could drive a car, walk without a physical problem, and conduct 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 0.7433[2]. (Ref. 21).

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 chronic 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 would be WTP between $54,000 (3 percent) and $93,000 (7 percent) per year to avoid a case of HBV (QALY value x 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). The published ratings of 14 studies of chronic HBV ranged from 0.75 to 1.00 (no impact) (Ref. 22). While the estimate used in this analysis (0.746) is in the low end of 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 the year 2000, a 40-year-old female had a future life expectancy of 41.1 years (Ref. 23)). The present value (PV) of $54,000 (3 percent) and $93,000 (7 percent) for 40 years implies that society is WTP $1.25 million (3 percent) or $1.24 million (7 percent) 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 3 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 an additional 5 years (48 percent).

HIV infection is not expected to affect either mobility or social activity. However, such an infection is likely to somewhat inhibit physical activity. HIV patients are expected to be 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 WTP to avoid the statistical probability of a case of HIV in health care personnel is approximately $68,000 (3 percent) or $120,000 (7 percent) per year (QALY value x (1.0000 minus 0.6796)). According to the collected preference scores in the HCRA's Catalog of Preference Scores, the average estimated published preference rating for HIV infection was 0.7 (range 0.3 to 1.00). (Ref. 24).

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

[2]The implication is that an ideal health state is valued as 1.0000 and mortality at 0.0000. Each functional state between these extremes is a proportionate value of ''perfect'' health.

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 WTP to avoid the statistical probability of a case of AIDS of about $97,000 (3 percent) or $170,000 (7 percent) per year (QALY value x (1.0000 minus 0.5429)). The HCRA's Catalog of Preference Scores reports average preference ratings of 0.375 for cases of AIDS with ranges from 0.0 to 0.5. (Ref. 25).

As discussed earlier, the derived societal WTP 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 PV (at 3-percent and 7-percent discount rates) of avoiding 40 years of HIV infection.
- 32 percent of the sum of the PV of avoiding 5 years of a 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 $68,000 per year (3 percent) is approximately $1.6 million and if valued at $120,000 per year (7 percent) is also approximately $1.6 million. Twenty percent of this figure equals $320,000.

The PV of avoiding 5 years of health loss to due HIV infection is equal to $311,000 (3 percent) or $492,000 (7 percent). The PV of avoiding the health loss expected from 35 years of AIDS infection (valued at $97,000 (3 percent) and $170,000 (7 percent) per year) is equivalent to $2.1 million (3 percent) and $2.2 million (7 percent). The present values of these amounts occurring 5 years in the future are $1.8 million (3 percent) and $1.6 million (7 percent). When added to the PV of avoiding the health loss associated with 5 years of HIV infection ($311,000 (3 percent) and $492,000 (7 percent)), the total estimated PV of the societal WTP to avoid a statistical case of this outcome is about $2.1 million (for both 3-percent and 7-percent discount rates). Thirty-two percent of this figure equals $660,000.

The PV of avoiding the health loss associated with 5 years of AIDS infection ($445,000 (3 percent) and $700,000 (7 percent)) occurring 5 years in the future is equivalent to $384,000 (3 percent) and $497,000 (7 percent). The PV of the societal value of avoiding a statistical mortality ($5 million) 10 years in the future is $3.72 million (at 3 percent) and $2.54 million (at 7 percent). The total societal WTP to avoid a case of HIV with mortality as an outcome, therefore, is $4.4 million using a 3-percent discount rate ($311,000 plus $384,000 plus $3.72 million) and $3.5 million using a 7-percent discount rate ($493,000 plus $497,000 plus $2.54 million). Forty-eight percent of these figures equals approximately $2.1 million (3 percent) and $1.7 million (7 percent).

Summing the weighted amounts of the three expected outcomes for a case of HIV infection equals an estimated societal WTP of $3.08 million using a 3-percent discount rate ($320,000 plus $660,000 plus $2.1 million) and $2.68 million using a 7-percent discount rate ($320,000 plus $660,000 plus $1,700,000).

In sum, the estimated societal values of avoiding morbidity and mortality due to transmission of blood-borne pathogens are estimated to be equivalent to $1.25 million per transmission of chronic HBV and $3.08 million per transmission of HIV using a 3-percent discount rate and $1.24 million per transmission of HBV and $2.68 million per transmission of HIV using a 7-percent discount rate. FDA notes that other cost-effectiveness research has determined cost-effectiveness estimates (excluding pain and suffering) of $2.1 million per avoided case of HIV. (Ref. 26).

FDA believes the methodology used to estimate the value of avoided HBV and HIV infection is reasonable and supportable. However, comparative methodologies that demonstrate both higher and lower values on avoidance have been reported. FDA acknowledged these differences in the proposed rule and solicited comment on other appropriate measures for estimating the societal value of avoiding blood-borne pathogens. FDA received no responses.

c. *Benefit of morbidity avoidance*. The rule is expected to reduce both HBV and HIV transmissions by reducing the prevalence of defective medical gloves used as barrier protection. During the first evaluation year, the rule is expected to result in 0.6 fewer chronic HBV transmissions to health care personnel. Applying the assumed societal WTPs of $1.25 million (3 percent) and $1.24 million (7 percent) to avoid the probability of an HBV infection, the expected benefit of avoiding these transmissions is $0.8 million (3 percent) and $0.7 million (7 percent). By the 10th evaluation year, 0.8 annual transmissions are expected to be avoided at a value of $1.0 million for either discount rate. The PV of avoiding approximately 7 chronic HBV transmissions over a 10-year period equals $7.6 million (at 3-percent discount rate) and $6.1 million (at 7-percent discount rate). This is equal to an average annualized value of $0.9 million for the entire 10-year evaluation period at either discount rate.

Also, in the first evaluation year, FDA expects that the final rule will result in the probability of 0.6 fewer transmissions of HIV caused by defective gloves. Assuming that society is WTP $3.08 million (at 3-percent discount rate) and $2.68 million (at 7-percent discount rate) to avoid the probability of a single HIV transmission, the benefit of avoiding these transmissions equals $1.8 million (3 percent) and $1.6 million (7 percent). By the 10th evaluation year, FDA expects the final rule to result in 0.8 fewer HIV transmissions, which are valued at $2.5 million (3 percent) and $2.1 million (7 percent). The societal PV of avoiding seven transmissions of HIV over the 10-year evaluation period is $18.8 million (at 3-percent discount rate) and $13.1 million (at 7-percent discount rate). These values are equivalent to average annualized benefits of $2.2 million (at 3-percent discount rate) and $1.9 million (at 7-percent discount rate).

In sum, FDA estimates that the reduction in blood-borne pathogen transmissions due to this final rule should produce health benefits valued at $3.1 million (at 3-percent discount rate) and $2.8 million (at 7-percent discount rate) per year. Most of this benefit (over 67 percent) is attributable to reducing the incidence of HIV.

6. Value of Avoiding Unnecessary Blood Screens

The expected decline in the number of defective medical gloves should lead to fewer 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 should decrease. Second, the psychological anxiety and stress that accompanies the possibility that a pathogen was transmitted to an individual should also decrease.

a. *Cost of conducting blood screens*. FDA has collected data from the American Red Cross on the costs of conducting blood screening tests in order 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 (Ref. 27).

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 (Ref. 28). Also, patients with high levels of uncertainty about whether they have contracted serious, threatening diseases experience heightened levels of stress and anxiety until they learn the results of any testing screens are negative (Ref. 29). According to one measurement scale of well-being, reduced mental lucidity, depression, crying, lack of concentration, or other signs of adverse psychological sequelae may detract as much as 8-percent from overall feelings of well-being and have outcomes similar to physiological morbidity (Ref. 30). Scaling of the relative stress caused by events shows that concerns about personal health, by themselves, are likely, on average, to contribute approximately one-sixth of the total weighting required to trigger a major stressful episode (Ref. 31). 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 $213,000 (at 3 percent) and $373,000 (at 7 percent) for a statistical QALY. These figures imply that the probability of each day of quality adjusted life has a social value of about $585 (at 3-percent discount rate; $213,000 divided by 365) and $1,020 (at 7-percent discount rate; $373,000 divided by 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 $8 (at 3-percent discount rate; $585 x 0.013) and $13 (at 7-percent discount rate, $1,020 x 0.013).

c. *Benefit of test avoidance.* By combining avoided direct costs of tests and the value of avoided anxiety and stress, FDA estimates that the societal benefit of avoiding an unnecessary blood test is $84 per sample (at 3-percent discount rate) and $89 per sample (at 7-percent discount rate). During the first evaluation year, FDA expects that there will be 120,000 fewer unnecessary blood screens because of the expected reduction in defective medical gloves due to the final rule. The implied societal WTP to avoid these unnecessary screens is $10.1 million (3 percent) and $10.7 million (7 percent). During the 10th evaluation year, approximately 155,000 fewer unnecessary blood screens are expected with a resultant benefit of $13.0 million (3 percent) and $14.0 million (7 percent). The PV of each year's reduced cost of testing and anxiety totals $100.0 million (at 3-percent discount rate) and $86.4 million (at 7-percent discount rate). The average annualized equivalent amounts are $11.7 million (3 percent) and $12.3 million (7 percent). Between 85 percent and 90 percent of the average annualized amounts represent reductions in the direct testing costs rather than the reduced anxiety associated with possible infection by a contagious agent.

7. Total Benefits

FDA estimates that the final rule will reduce the availability of defective medical gloves by over 25 percent, resulting in over 2.8 billion fewer defective gloves over a 10-year period. During this time, FDA expects that the reduction in defective gloves will result in approximately 7 fewer cases of chronic HBV, 7 fewer cases of HIV, and 1.4 million fewer unnecessary blood screens. Based on an implied societal WTP, the average annualized benefits of the fewer pathogen transmissions and unnecessary blood screens should equal $14.8 million (at 3-percent annual discount rate) and $15.1 million (at 7-percent discount rate).

G. Conclusion

As noted in the introduction to the analysis of impacts section, FDA is certifying that the final rule will not have a significant impact on a substantial number of small entities. We provided the above information to explain the costs and benefits of the rule. There are currently over 400 manufacturers of medical gloves, a vast majority of which are foreign and not covered by the Regulatory Flexibility Act. There will be little to no impact on domestic entities. Moreover, FDA does not expect any increased manufacturer costs to be directly passed on to end users because the cost increases will affect only a minority of global manufacturers and, therefore, competition will likely force these manufacturers to absorb these costs.

The estimated annualized costs equal $6.6 million using either a 3-percent annual discount rate or a 7-percent annual discount rate. Benefits of avoiding transmissions of blood-borne pathogens and unnecessary blood screens have been estimated to equal $14.8 million (using a 3-percent discount rate) or $15.1 million (using a 7-percent discount rate). The final rule is estimated to result in average annualized net benefits of $8.2 million (using a 3-percent discount rate) or $8.5 million (using a 7-percent discount rate).''

2. On page 75875, in the second column, section V of the document is corrected to read:

''V. References

The following references have been placed on display in the Division of Dockets Management 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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Dated: January 11, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–682 Filed 1–18–07; 8:45 am]

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DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 199

[DOD–2006–HA–0194; RIN 0720–AB07]

TRICARE; Certain Survivors of Deceased Active Duty Members; and Adoption Intermediaries

AGENCY: Office of the Secretary, DoD.

ACTION: Interim Final Rule.

SUMMARY: This interim final rule implements two provisions of the National Defense Authorization Act for Fiscal Year 2006 (NDAA FY06), Public Law 109–163. First, Section 715 of the NDAA FY06 extends the time frame certain dependents of Active Duty Service Members (ADSM) who die while on active duty for more than 30 days shall receive TRICARE medical benefits at active duty dependent payment rates. Second, Section 592 of the NDAA FY06 modifies the requirement for those intermediaries who provide adoption placements.

Additionally, this interim final rule makes an administrative clarification to the following two eligibility provisions: those placed in the legal custody of a member or former member; and those placed in the home of a member or former member in anticipation of adoption. This clarification makes a distinction between the two groups and specifies that for placement into legal custody by court order, the court order must be for a period of 12 consecutive months.

Public comments are invited and will be considered for possible revisions to the final rule.

DATES: This rule is effective March 20, 2007.

Comments: Written comments received at the address indicated below by March 20, 2007 will be accepted.

ADDRESSES: You may submit comments, identified by docket number and or RIN number and title, by any of the following methods:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.
- Mail: Federal Docket Management System Office, 1160 Defense Pentagon, Washington, DC 20301–1160.

Instructions: All submissions received must include the agency name and docket number or Regulatory Information Number (RIN) for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at *http://regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: Ms. Ann N. Fazzini, (303) 676–3803 for questions regarding Section 715 as it relates to the TRICARE Basic Program; and also questions regarding Section 592.

Mr. Michael Kottyan, (303) 676–3520 for questions regarding Section 715 as it relates to the Extended Health Care Option (ECHO).

Mr. John Leininger, (303) 676–3613, for questions regarding TRICARE Prime Remote.

Questions regarding payment of specific claims should be addressed to the appropriate TRICARE contractor.

SUPPLEMENTARY INFORMATION: The Department is publishing this rule as an interim final rule in order to meet statutorily required effective dates. The Department is not exercising any discretion in implementing these provisions. In accordance with Section 715(b), the effective date for Section 715 is October 7, 2001 and shall apply with respect to deaths occurring on or after that date. The Department has no discretion concerning the benefits available to surviving dependents, the effective date, nor the time periods benefits are available to surviving spouses and children respectively. The effective date for Section 592 is January 6, 2006. Prior to the NDAAFY06, a child placed in the home by a placement agency recognized by the Secretary of Defense in anticipation of the legal adoption of the person was eligible for TRICARE. Section 592 of the NDAA FY06 expands those intermediaries who perform adoption placement to include placement by any source authorized by State or local law to provide adoption placement. The Department is not exercising any discretion in defining who are intermediaries who can perform adoption placement. In accordance with Public Law 103–160, section 702(b), the effective date for placement by a court is July 1, 1994. In accordance with Public Law 103–337, section 701, the effective date for placement by a recognized adoption agency October 5, 1994. These last two changes are administrative corrections