consistency appeals. The correct cross reference is §§ 930.121 and 122. Sections 930.121 and 122 are the two grounds available on which to base an appeal. With this technical correction, § 930.125(b) requires the notice of appeal to: (1) Explain why the project is consistent with the objectives or purposes of the CZMA (§ 930.121), and/or is otherwise necessary in the interest of national security (§ 930.122), outlining appellant's arguments for each element contained within §§ 930.121 and/or 930.122 (with the understanding that appellant will amplify upon these arguments in briefs); and (2) identify any procedural arguments pursuant to § 930.129(b).

Rule Change 2: § 930.127(d)(1) and § 930.127(i)(2). Both of these sections require the appellant to submit four copies of briefs, supporting materials and, in the case of appeals of energy projects under § 930.127(i)(2), the consolidated record maintained by the lead Federal permitting agency. NOAA has determined that one hard copy and one electronic copy are sufficient to process appeals to the Secretary. This technical change will also reduce paperwork burdens on appellants.

Miscellaneous Rulemaking Requirements

Executive Order 12372: Intergovernmental Review

This program is subject to Executive Order 12372.

Executive Order 12866: Regulatory Planning and Review

This final rule has been determined to be not significant for the purposes of Executive Order 12866.

Executive Order 13211

Executive Order 13211 requires that agencies prepare and submit a ''Statement of Energy Effects'' to the Office of Management and Budget for certain actions. This action will not result in any adverse effect upon the supply, distribution, or use of energy. Rather, this rule makes technical corrections and changes that will clarify existing requirements and will reduce paperwork burdens on appellants.

Administrative Procedure Act

Pursuant to 5 U.S.C. 553(b)(B), the Assistant Administrator for Ocean Services, NOAA finds good cause to waive prior notice and an opportunity for public comment on this action, as notice and comment are unnecessary. This Final Rule makes only minor technical amendments that will correct mistakes and provide clarification to the public. The first change will correct an internal cross-reference in order to provide correct information regarding the processing of appeals. The second change will reduce unnecessary paperwork submissions by states and appellants. Neither change affects the substance of the Secretarial appeal process. For this same reason, NOAA finds good cause to waive the 30-day delay in the effective date of this action under 5 U.S.C. 553(d)(3).

Regulatory Flexibility Act

Because prior notice and opportunity for public comment are not required for this rule by 5 U.S.C. 553, or any other law, the analytical requirements of the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.*, are not applicable.

Paperwork Reduction Act

This rule contains no additional collection-of-information requirements subject to review and approval by OMB under the Paperwork Reduction Act (PRA).

National Environmental Policy Act

NOAA has concluded that this regulatory action does not have the potential to pose significant impacts on the quality of the human environment. Further, NOAA has concluded that this rule will not result in any changes to the human environment. As defined in sections 5.05 and 6.03c3(i) of NAO 216–6, this action is of limited scope, of a technical and procedural nature and any environmental effects are too speculative or conjectural to lend themselves to meaningful analysis. Thus, this rule is categorically excluded from further review pursuant to NEPA.

List of Subjects in 15 CFR Part 930

Administrative practice and procedure, Coastal zone, Reporting and recordkeeping requirements.

■ Accordingly, 15 CFR part 930 is amended by making the following technical corrections:

PART 930—FEDERAL CONSISTENCY WITH APPROVED COASTAL MANAGEMENT PROGRAMS

■ 1. The authority citation continues to read as follows:

Authority: 16 U.S.C. 1451 *et seq.*

§ 930.125 [Corrected]

■ 2. Section 930.125 is corrected in the first sentence of paragraph (b) by removing the term ''§ 923.121'' and adding in its place the phrase ''§§ 930.121 and/or 930.122.''

§ 930.127 [Corrected]

■ 3. Section 930.127 is corrected in the first sentence of paragraph (d)(1) and in the first sentence of paragraph (i)(2) by removing the word ''four'' and adding in its place the word ''two.''

Dated: December 14, 2006.

William Corso,

Deputy Assistant Administrator for Ocean Services and Coastal Zone Management.

[FR Doc. E6–21615 Filed 12–18–06; 8:45 am]

BILLING CODE 3510–08–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

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule to improve the barrier quality of medical gloves marketed in the United States. 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).

DATES: This rule is effective December 19, 2008.

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:

I. Background

Since 1990, FDA has tested patient examination and surgeons' gloves for barrier integrity in accordance with the sampling plans, test method, and AQLs contained in § 800.20 (21 CFR 800.20). The FDA test method was adopted by the consensus standards organizations, ISO and ASTM, who incorporated this method in ISO 10282, ISO 11193, ASTM D3577, and ASTM D 3578. Subsequently, ISO and ASTM lowered

the AQLs in their consensus standards to be more stringent than the criteria in the FDA test method. In the **Federal Register** dated March 31, 2003 (68 FR 15404), FDA published a proposed rule to amend the FDA test method and harmonize the acceptance criteria with those in the consensus standards. We provided a period of 90 days for comments from interested parties. We received comments from several parties, which we summarize and discuss below, and we have revised the final rule in response to the comments as appropriate.

(Comment 1) FDA received several comments expressing concern that the proposal to lower the AQLs in the FDA rule to match those in the ASTM standard does not truly harmonize with ASTM because ASTM applies the AQLs only to pinhole defects, whereas FDA applies the AQLs to both pinhole and visual defects.

Historically, FDA has always considered visual defects that affect barrier integrity as failures during glove testing. The visual analysis of gloves while conducting water leak testing was specifically included in the original FDA test method published in December 1990 and codified at § 800.20. Our experience with laboratory analyses of medical gloves indicates that visual defects are relatively rare. However, due to public health concerns, FDA cannot ignore visual defects when they are observed. FDA will continue to consider visual defects affecting barrier integrity as failures. FDA does not agree that including these defects in the analysis will affect harmonization with currently recognized consensus standards for the vast majority of samples.

FDA has, however, included language in the rule clarifying that only visual defects that are likely to affect the barrier integrity should be counted as failures and has described the main types of visual defects that are likely to affect barrier integrity. FDA understands the concerns of manufacturers that the lower AQLs could result in more sample failures, especially if FDA analysts count visual defects that do not affect barrier integrity. Therefore, FDA intends to provide guidance to analysts on how to identify visual defects that affect barrier integrity.

(Comment 2) One comment disagreed with the FDA statement ''Because the standards organization updated their standards to reflect the improvement in manufacturing technology, the consensus standards currently have lower AQLs for medical gloves than FDA's regulations'' on the grounds that the consensus standards' AQLs do not count visual defects. The commenter proposed that FDA reword this statement.

Until now, the AQLs in the consensus standards have been tighter than those in the FDA test method, even when visual defects are considered. As noted previously, visual defects are rarely observed. Even when they are found, they may not increase the total number of failures in an analysis because the tears and holes detected by means of a visual examination would most likely leak if subjected to water leak testing and count as failures. Other visually defective gloves, such as adhering gloves, which often tear when pulled apart, might also leak if subjected to water leak testing.

(Comment 3) FDA received a number of comments expressing concern that the phrase ''other defects visible upon initial examination that may affect the barrier integrity'' is subject to interpretation. Some comments recommended a list of specific criteria for identifying visually defective gloves. Other comments suggested adding the word ''obvious'' before ''defects.''

FDA understands these concerns and has revised the rule to include more examples of specific visual defects that should be considered as failures. However, FDA realizes that it cannot predict all possible defects that may be encountered. Therefore, the phrase immediately following the list of specifically identified visual defects has been revised to read, ''or other visual defects that are likely to affect the barrier integrity.'' FDA disagrees that adding ''obvious'' before ''defects'' would clarify the type of defects that should be counted or reduce the risk of subjective interpretation.

(Comment 4) FDA received several comments requesting us to revise the test procedure and acceptance criteria to have two sets of samples per lot, one set for testing for pinhole defects and the second set for testing or determining visual defects. The comments suggested that visual defects should have less stringent AQLs than pinhole defects. Also, one comment stated that the test certificates glove manufacturers routinely issue generally categorize pinholes and visual defects separately.

FDA disagrees with these comments. FDA is aware that glove manufacturers routinely inspect their gloves for visual cosmetic defects that may affect the acceptability of the gloves to buyers. Since these defects are related to the cosmetic appearance of gloves rather than safety, they are visually inspected at a lower AQL than pinhole defects. In contrast, FDA analysis of medical gloves is intended to ensure that gloves are safe and effective for their intended use, barrier protection. The FDA test method includes only those visual defects, such as tears, embedded foreign objects, etc., that are likely to affect the barrier integrity of the glove. As previously stated, FDA has historically considered visual defects that affect the barrier integrity as failures during glove testing and has always included them in the total count of defective gloves. Sampling and counting visual defects that affect barrier integrity separately from gloves that leak during the water leak test would change established FDA sampling procedures and could allow more total defects in glove lots than were allowed under the previous AQLs. This would not be consistent with the purpose of this rulemaking to improve the quality of gloves on the U.S. market. Also, because visual defects that affect barrier integrity are much less common than cosmetic visual defects, they would probably not be present in the majority of samples. Routinely taking two sets of samples when one sample is expected to have no defects would be an inefficient use of resources for the FDA. The increased time required for two analyses could also result in delaying entry of imported products.

(Comment 5) Three comments noted that the ASTM standards for patient examination and surgeons' gloves specify the use of single normal sampling plans rather than the multiple normal sampling plans used by FDA.

FDA understands that ASTM uses single normal sampling. However, the same ISO document that ASTM references for its single sampling plans (ISO 2859, ''Sampling Procedures for Inspection by Attributes'') also provides multiple sampling plans that establish the acceptability or non-acceptability of the lot with equivalent statistical confidence, but generally using a much smaller total sample size. In view of the volume of gloves that FDA must test each year, we cannot justify the additional expense that would accompany the use of the single sampling plans. Since the sampling plans are statistically very similar, we consider the revised test method and acceptance criteria to be harmonized with the ASTM standard.

(Comment 6) Another comment stated that it was unlikely that manufacturers could supply medical gloves that meet the new AQLs without any price increase. The comment further stated that tightening the AQLs would cause manufacturers to test to even tighter in-house specifications, which could lead to significant ''downgrading'' of some lots of gloves.

It is FDA's understanding, based on representations made in 510(k)

submissions and interactions with glove manufacturers, that the glove industry is already manufacturing gloves that meet the 1.5 and 2.5 AQLs for surgeons' and patient examination gloves, respectively. FDA recognizes that some manufacturers may decide to withhold from the market or ''downgrade'' some glove lots in order to reduce the risk of failing the FDA test. However, our analysis, described in section III.E of this document, indicates that the actual number of lots that would have to be withheld in order to maintain the current failure risk level is a small percentage of the total number of gloves manufactured and, consequently, will have a minimal impact on the industry.

(Comment 7) We received several comments that pointed out that an AQL value should not reference a percentage because it is technically a number without a unit. The comments suggested that we remove the reference to percent.

FDA agrees with this comment. The AQL values in the final rule do not refer to percent.

(Comment 8) One comment requested that the effective date of this rule be delayed until the year 2010.

FDA disagrees with this comment. ASTM lowered its AQLs for surgeons' and patient examination gloves in 1998. FDA believes that manufacturers have had sufficient time to adapt their manufacturing process to conform to these standards and that, in fact, the vast majority of currently manufactured gloves already meet the new AQLs.

(Comment 9) One comment suggested the use of normal sampling plans in ISO 2859 for reconditioned lots instead of the tightened sampling plans proposed by FDA. This comment maintained that the normal inspection plans were the optimal plans for glove lots and that these same sampling plans should also be used for reconditioned lots for both technical and economic reasons.

FDA disagrees with this comment. When testing reconditioned lots, FDA needs greater assurance that the gloves are safe and effective because there has already been an initial failure and an appearance of adulteration. It is important, therefore, that the tightened sampling plans be used to test reconditioned lots.

(Comment 10) One comment advised that the sampling plan for Surgeons' Gloves at 1.5 AQL Normal Sampling and a lot size of 1,201 to 3,200 does not provide for lot acceptance for the first 32 gloves sampled.

FDA agrees and has revised the chart.

(Comment 11) One comment asked why the tables for both the Surgeons' and Patients Examination Gloves were changed from the original rule to list increasing quantities of gloves from top to bottom rather than from bottom to top.

This change was made to harmonize with the tables in the ISO–2859 sampling plans.

(Comment 12) One comment noted that the leak test materials and set up described in § 800.20 are an example of what might be used in small scale testing environments, but that the use of these materials and set up in high volume test environments is not realistic. Another comment pointed out that many manufacturers use opaque cylinders rather than clear plastic cylinders, as described in paragraph § 800.20(b)(2)(i). A suggestion was made to note that the materials and set up described in § 800.20(b)(2) and (b)(3)(ii) are only examples.

FDA agrees that the materials and set up described in the referenced section are only examples and may not be realistic for high volume test settings and, therefore, has changed the wording in § 800.20(b)(2) *Leak test materials*, to ''FDA considers the following to be the minimal materials required for this test.'' FDA will continue to use clear cylinders to remain harmonized with the ASTM consensus standard D5151 for detection of holes in medical gloves.

(Comment 13) One comment recommended that FDA define the elongation and tensile strength required for medical grade gloves.

This comment is beyond the scope of this rule. This rule describes a barrier test method applicable to gloves of all materials and not a physical properties test method that will necessarily vary for differing materials.

(Comment 14) A suggestion was made to increase the water leak test duration to 3 minutes from the current 2 minutes because there are some gloves that begin to leak shortly after the 2 minute mark, usually at 2 minutes and 30 seconds.

Changes to this rule are intended to harmonize with the current consensus standards. Harmonization would not be accomplished if FDA were to increase its water leak test duration to 3 minutes. Moreover, there are no reliable data justifying the increase.

(Comment 15) One comment suggested that § 800.20(b)(2)(iv) should be moved to the preamble because it is a guidance.

It is important that FDA's test method for analyzing gloves be presented in a coherent manner that thoroughly describes the method in a way that is understandable. FDA believes that deleting § 800.20(b)(2)(iv) from the codified language would make the test method more difficult to understand and, therefore, disagrees that it should be moved to the preamble.

(Comment 16) A suggestion was made to move ''Record the number of defective gloves'' from (b)(3)(iii)(B) to a new paragraph (b)(3)(iii)(C). The rationale for this suggestion was that the data are generated in both (b)(3)(iii)(A) and (b)(3)(iii)(B), and not in just (b)(3)(iii)(B). Therefore, it appeared that the recording requirement should be in a separate paragraph.

FDA agrees and has removed ''Record the number of defective gloves'' from section (b)(3) (iii)(B) and added a new section ''(b)(3)(iii)(C), Record the number of defective gloves.''

(Comment 17) Another comment stated that the preamble should discuss the relationship between Import Alert 80–04 and § 800.20.

This rule describes FDA's analytical test method for determining whether individual gloves are defective and acceptance criteria for determining whether lots of medical gloves are adulterated. It applies equally to medical gloves offered for import and medical gloves already in domestic distribution. While the results of analysis could cause a firm to be placed on Import Alert 80–04, this rule is not intended to describe or modify FDA's current guidance to FDA field personnel regarding ''Surveillance and Detention Without Physical Examination of Surgeon's and or Patient Examination Gloves,'' which is contained in Import Alert 80–04.

(Comment 18) One comment suggested that we add the following or equivalent language to (d)(2)(ii) ''*Adulteration levels and acceptance criteria for reconditioned gloves*'': ''FDA considers the reconditioned lot of medical gloves tested by an independent laboratory under tightened sampling to meet the AQLs which will provide additional assurance to the consumers. If the retest result has been determined to be acceptable, the initial analysis of the failed lot before reconditioning shall be nullified.''

FDA disagrees with this comment. When a collection of gloves that has been seized or refused entry based on a violative sample is ''reconditioned,'' some of the problematic sizes or lots of the gloves may have been removed (segregated) from the reconditioned sample. When this occurs, and the reconditioned sample passes the test under the tightened sampling plan, FDA will consider the remaining/reconditioned lots in the collection of gloves to be acceptable, as described in § 800.20. However, FDA believes that, in the situation described previously, FDA

cannot ignore the initial failure which is part of the firm's historical record.

(Comment 19) Several comments mentioned that the rule would result in increased costs to consumers of gloves. These comments asserted that manufacturing and production changes at manufacturing sites would entail significant costs that would ultimately be passed on to consumers in the form of price increases.

FDA disagrees with these comments. As stated in section III of this document, most lots of imported gloves already meet the lower AQLs. This implies that significant changes in the manufacturing processes will not be necessary. In addition, there is no universal economic presumption that costs are passed on to consumers in order to maintain a constant profit margin to manufacturers. Market conditions will dictate the specific degree to which regulatory costs are borne by various economic sectors, i.e., manufacturers, distributors, purchasers, payers, or consumers. Because of the competitive nature of this industry and the relatively small proportion of gloves affected by this rule, FDA believes that these costs are not likely to be directly passed on in the form of price increases.

II. 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.

III. Analysis of Impacts

A. Introduction

FDA has examined the final rule under Executive Order 12866, the Regulatory Flexibility Act (5 U.S.C. 601–602), 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). FDA has determined that this final rule is not a significant regulatory action under the Executive order.

If a rule has a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize the 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 issuing a final rule that includes any Federal mandate that may result in the expenditure of State, local and tribal governments, in the aggregate, or the private sector of $100 million or more (adjusted annually for inflation) in any one year. The current threshold after adjustment for inflation is $118 million, using the most current (2004) implicit price deflator for the Gross National Product. The agency does not expect this final rule to result in a 1-year expenditure that would meet or exceed this amount.

The information in the following sections sets forth the bases for the above 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) (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 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. 2). 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 (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 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.

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 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 have stated that ''most'' of the occupational transmissions are due to percutaneous injuries (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 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 (Ref. 3). Over 2.7 million patients have reported chronic conditions. 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. 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 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 39.2 billion medical gloves were imported into the United States during 2004 (Ref. 6). 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 Chinese manufacturers supply approximately 30 percent (Ref. 7). 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. 8), 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 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 the period. 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. 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 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. 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 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

[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.

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

Year	Costs for Quality Control	Costs for Sampling	Total Costs
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. 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, 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 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 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 seven 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. 9 and 10). 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 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

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

Year	Reduction in Blood-Borne Pathogen Transmission	Reduction in Unnecessary Blood Screens
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) are divided by the present values of the expected reductions to arrive at the cost per avoided event. This is shown in Table 4.

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 (Refs. 11, 12, and 13). 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 (Refs. 14, 15, and 16), 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 willingness to pay 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 (Refs. 16 and 17). 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].

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.

[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.

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 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 had a future life expectancy of 41.1 years (Ref. 14)). 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 willingness to pay 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 (ref. 17a) 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).

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 $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 (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 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 willingness to pay 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 willingness to pay 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 (Ref. 18) has determined cost-effectiveness estimates (excluding pain and suffering) of $2.1 million per avoided case of HIV.

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 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 (Ref. 5) 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.

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 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. 20). 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 (Ref. 16) and have outcomes similar to physiological morbidity. 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 (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 $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).

IV. Paperwork Reduction Act of 1995

This final rule contains no collections of information that are subject to review by OMB under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520). The information collection described in this rule regarding testing to establish the reconditioning of adulterated gloves is exempted from the requirements of the PRA under 5 CFR 1320.4(a)(2) and (c): The rule describes testing to be conducted on specific lots of adulterated gloves ''during the conduct of an administrative action, investigation, or audit involving the agency against specific individuals'' (1320.4(a)(2)) and ''after a case file or equivalent is opened with respect to a particular party'' (1320.4(c)).

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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List of Subjects in 21 CFR Part 800

Administrative practice and procedure, Medical devices, Opthalmic 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, 21 CFR part 800 is 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 visual defects will be conducted by a visual examination and by a water leak test 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 include 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. Other defects include tears, embedded foreign objects, extrusions of glove material on the exterior or interior surface of the glove, gloves that are fused together so that individual glove separation is impossible, gloves that adhere to each other and tear when separated, or other visual defects that are likely to affect the barrier integrity.

(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.* FDA considers the following to be the minimum materials required for this test :

(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);

(v) Timer capable of measuring two minute intervals.

(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, although 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 (deg)C to 30 (deg)C) into the open end of the fill tube. The water should 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 the water is added to the glove. Use only minimum manipulation of the fingers to check for leaks.

(C) 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

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

Lot Size	Sample	Sample Size	Number Examined	Number Defective	
				Accept	Reject
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	—	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
	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	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

ACCEPT/REJECT CRITERIA AT 2.5 AQL FOR PATIENT EXAMINATION GLOVES—Continued

Lot Size	Sample	Sample Size	Number Examined	Number Defective	
				Accept	Reject
	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 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 Defective	
			Accept	Reject
8 to 50	Single sample	8	0	1
51 to 280	Single sample	32	1	2

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

Lot Size	Sample	Sample Size	Number Defective	
			Accept	Reject
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: December 12, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9303]

RIN 1545–BF84

Corporate Reorganizations; Distributions Under Sections 368(a)(1)(D) and 354(b)(1)(B)

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final and temporary regulations.

SUMMARY: This document contains temporary regulations under section 368 of the Internal Revenue Code of 1986 (Code). The temporary regulations provide guidance regarding the qualification of certain transactions as reorganizations described in section 368(a)(1)(D) where no stock and/or securities of the acquiring corporation is issued and distributed in the transaction. These regulations affect corporations engaging in such transactions and their shareholders. The text of the temporary regulations also serves as the text of the proposed regulations set forth in the notice of proposed rulemaking on this subject in the Proposed Rules section in this issue of the **Federal Register**.

DATES: *Effective Date:* These regulations are effective on December 19, 2006.

Applicability Date: For dates of applicability, see § 1.368–2T(l)(4)(i).

FOR FURTHER INFORMATION CONTACT: Bruce A. Decker at (202) 622–7550 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

The IRS and Treasury Department have received requests for immediate guidance regarding whether certain acquisitive transactions can qualify as reorganizations described in section 368(a)(1)(D) where no stock of the transferee corporation is issued and distributed in the transaction. Currently, the IRS and Treasury Department are undertaking a broad study of issues related to acquisitive section 368(a)(1)(D) reorganizations. In the interest of efficient tax administration, the IRS and Treasury Department are issuing these temporary regulations to provide the requested certainty for taxpayers regarding these acquisitive transactions pending the broader study of issues. Although these rules also are being proposed in the Proposed Rules section in this issue of the **Federal Register**, the IRS and Treasury Department contemplate that the proposed rules may change upon completion of this broader study and the comments received.

The Code provides general nonrecognition treatment for reorganizations specifically described in section 368(a). Section 368(a)(1)(D) describes as a reorganization a transfer by a corporation (transferor corporation) of all or a part of its assets to another corporation (transferee corporation) if, immediately after the transfer, the transferor corporation or one or more of its shareholders (including persons who were shareholders immediately before the transfer), or any combination thereof, is in control of the transferee corporation; but only if stock or securities of the controlled corporation are distributed in pursuance of a plan of reorganization in a transaction that qualifies under section 354, 355, or 356.

Section 354(a)(1) provides that no gain or loss shall be recognized if stock or securities in a corporation a party to a reorganization are, in pursuance of the plan of reorganization, exchanged solely for stock or securities in such corporation or in another corporation a party to the reorganization. Section 354(b)(1)(B) provides that section 354(a)(1) shall not apply to an exchange in pursuance of a plan of reorganization described in section 368(a)(1)(D) unless the transferee corporation acquires substantially all of the assets of the transferor corporation, and the stock, securities, and other properties received by such transferor corporation, as well as the other properties of such transferor corporation, are distributed in pursuance of the plan of reorganization.

Further, section 356 provides that if section 354 or 355 would apply to an exchange but for the fact that the property received in the exchange consists not only of property permitted by section 354 or 355 without the recognition of gain or loss but also of other property or money, then the gain, if any, to the recipient shall be recognized, but not in excess of the amount of money and fair market value of such other property. Accordingly, in the case of an acquisitive transaction, there can only be a distribution to which section 354 or 356 applies where the target shareholder(s) receive at least some property permitted to be received by section 354.

Notwithstanding the requirement in section 368(a)(1)(D) that ''stock or securities of the corporation to which the assets are transferred are distributed in a transaction which qualifies under section 354, 355, or 356'', the IRS and the courts have not required the actual issuance and distribution of stock and/or securities of the transferee corporation in circumstances where the same person or persons own all the stock of the transferor corporation and the transferee corporation. In such circumstances, the IRS and the courts have viewed an issuance of stock to be