

10 percent and to about \$51,900, if the HCV positive rate is 2.7 percent. We note again that these cost-effectiveness ratios hold regardless of the number of donations from repeat donors that trigger prospective "lookback."

Table 7.--Cost-Effectiveness of Recipient Notification for Prospective "Lookback"¹

	65 Percent CMS- Inspected		75 Percent CMS- Inspected	
	HCV Positive Rate			
	2.7 percent	10 percent	2.7 percent	10 percent
Costs of Testing & Lost Patient Time	\$36,956	\$41,482	\$42,642	\$47,864
"Lookback" costs	\$260,006	\$260,006	\$300,007	\$300,007
Total costs	\$296,963	\$301,488	\$342,649	\$347,871
Newly identified HCV infected recipients ²	6	21	7	24
Cost per newly identified recipient ³	\$51,897	\$14,435	\$51,897	\$14,435

¹ Numbers may not sum or multiply due to rounding.

² Recipient estimates are rounded to the nearest integer.

³ Calculated with the non-rounded number of newly identified recipients (i.e., 5.7, 20.9, 6.6, and 24.1).

5. Benefits of Retrospective "Lookback"

Because the one-time retrospective "lookback" has the potential to newly identify thousands of infected transfusion recipients, the key benefit of "lookback" is the health improvement that newly identified individuals would enjoy as a result of timely treatment. We estimate this benefit by looking first at the number of newly identified recipients chronically infected with the hepatitis C virus. Using the published Younossi model of disease progression, we then estimate the

number of quality-adjusted life years that each person could gain from interferon and ribavirin treatment of their HCV infection. Then we estimate the value that society might place on this health improvement. Next we quantify the potential costs of diagnostic testing and treatment. Finally we report the cost-effectiveness of this one-time public health initiative.

a. The number of HCV positive transfusion recipients identified by "lookback." For the analysis of the proposed rule, we estimated that about 2 percent (30 percent living x 74 percent successfully notified x 51 percent tested x 25 percent positive for HCV x 68 percent unknown infection) of the 258,125 recipient notifications¹⁰ performed under retrospective "lookback" (i.e., about 5,000 recipients) would newly identify individuals who test positive for the hepatitis C virus. As discussed previously, consignees completed at least 80 percent of the retrospective "lookback" based on multi-antigen screening by 1999. Subtracting the recipient notifications that have been completed (i.e., 80 percent), table 8 of this document shows the potential number of HCV-positive recipients that retrospective

¹⁰ "Lookback" actions for consignees include product quarantine and recipient notification. Based on their interim survey findings, CDC estimated that only about 85 percent of the components received by consignees are transfused. Based on this CDC data, consignees will perform product quarantine for about 269,100 components and perform about 258,100 recipient notifications.

"lookback" might newly identify, and the corresponding number of diagnostic tests that might be performed.

Table 8.--Estimated One-Time Number of Diagnostic Tests and Newly Identified Recipients With Retrospective "Lookback"¹

	Multi-Antigen Screening Results ²	Single-Antigen Screening Results ³	Total
HCV screening tests	2,353	17,819	20,172
Negative supplemental tests (i.e., false positive screening result) ⁴	824	6,237	7,060
Positive supplemental tests	447	5,168	5,615
Newly identified HCV-positive recipients ⁵	304	3,514	3,818

¹ Recipient estimates are rounded to the nearest integer; numbers may not sum or multiply due to rounding.

² Adjusting the number of components triggering "lookback" based on multi-antigen tests (i.e., 115,228 components) by the transfusion rate (i.e., 85 percent transfused) and the completion rate (80 percent of completed), consignees will attempt about 19,674 transfusion recipient notifications. Estimates were derived using the findings in table 3 of Ref. 3: 31 percent would be living, 78 percent would be successfully notified, 50 percent would be tested, and a 19 percent HCV positive rate.

³ Adjusting the number of components triggering "lookback" based on single-antigen tests (i.e., 188,448) by the transfusion rate (i.e., 85 percent transfused), consignees will attempt about 160,879 transfusion recipient notifications. Estimates were derived using the findings in table 2 for transfusions in 1988-1989 of Ref. 3: 30 percent would be living, 72 percent would be successfully notified, 52 percent would be tested, 29 percent HCV positive rate.

⁴ Based on 35 percent false positive rate for screening tests.

⁵ Based on CDC survey findings that 68 percent of the HCV positive recipients did not already know about their infection.

b. Number of Quality-Adjusted Life Years gained. Benefits of the retrospective "lookback" come from treating post-transfusion hepatitis C virus infections, and in doing so, delaying or reducing adverse health outcomes from illnesses that would be caused by untreated hepatitis C virus infections. We use a quality-adjusted life year as the measure of this gain in health outcomes and estimate the number of quality-adjusted life

years that newly identified infected recipients can gain from treatment of their chronic HCV infections. Adjusting for the 75 percent chronic infection rate, about 2,865 chronically infected recipients would be newly identified by retrospective "lookback" (3,818 newly identified recipients x 75 percent chronic infection rate).

As noted previously, to estimate the gain in quality-adjusted life years, we selected the Markov model of Younossi and others (Ref. 14). Their findings predict that patients receiving combination therapy with standard interferon could gain 2.8 quality-adjusted life years, compared with receiving no treatment for the infection. For this analysis, we assume that newly identified transfusion recipients are similar to the general population in terms of genotype of the hepatitis C virus (i.e., 75 percent are infected by genotype 1 HCV) and suitability for treatment (33 percent of HCV positive individuals would receive drug therapy). Accounting for these factors, an estimated 945 individuals (2,864 patients x 33 percent treated) would gain 2,640 quality-adjusted life years (2.79 quality-adjusted life years/patient x 945 patients).

c. The societal value of "lookback". The preferred measure of the value of the benefit of retrospective "lookback" is the average willingness to pay to reduce the probability of adverse health outcomes from untreated post-transfusion HCV

infections. Such measures are not readily available for most illnesses, including those caused by hepatitis C virus infection. In the absence of the direct measures recommended in the literature (Ref. 18), we assign a monetary value to a quality-adjusted life year as a proxy for willingness to pay. We recognize, however, that there is no unique, accepted societal monetary value for a quality-adjusted life year gained, and some economists are skeptical that this measure of public health improvement is even sufficiently consistent with consumer preferences to permit systematic estimates of its monetary value. To reflect the uncertainty about the value of a quality-adjusted life year, FDA uses a range of dollar amounts.

As a lower bound, FDA uses \$100,000 per quality-adjusted life year, an amount similar to that used by Cutler and Richardson (Ref. 19). We derive other values for a quality-adjusted life year from estimates of the value of a statistical life. A number of empirical studies indicate a societal willingness to pay from \$1.6 million to \$11.6 million to avoid a statistical death. Although there is not necessarily a direct link between the willingness to pay to reduce the probability of a particular illness (or set of symptoms) and the willingness to pay to reduce the probability of death, the value of a statistical life--the sum of individual willingness to pay to avoid small risks of premature death that together add up to one

expected life saved--bounds the value of a quality-adjusted life year, which is used in this analysis as a proxy for the sum of individual willingness to pay to avoid small risks of being undiagnosed as HCV positive and suffering additional morbidity impacts.

Current estimates of the value of a statistical life run from \$1 million to \$11 million (Ref. 20). In recent regulatory analyses, we have used values of \$5 million and \$6.5 million, which fall within that range. Because the Younossi model was developed with a 3 percent discount rate, we use this discount rate to estimate the value of a statistical life year. Annualizing \$6.5 million over 35 years at 3 percent implies a value of \$300,000 for an additional statistical life year and to develop an upper bound, annualizing \$10 million over 35 years at 3 percent discount rates implies a value of \$465,000 for an additional statistical life year.¹¹ We therefore calculate estimated benefits from this final rule with three possible values of a quality-adjusted life year: \$100,000, \$300,000 and \$465,000. This range of values is consistent with a reasonable interpretation of studies of willingness to pay to reduce mortality risks (Ref. 20).

¹¹ We could, however, generate these same two values with many different combinations of values of a statistical life, discount rates, and years.

At \$100,000 per quality-adjusted life year gained, the retrospective "lookback" would yield one-time benefits to society of \$264 million (2,640 quality-adjusted life years x \$100,000 per quality-adjusted life year). At \$300,000 per quality-adjusted life year gained, the retrospective "lookback" would yield one-time benefits to society of \$792 million (2,640 quality-adjusted life years x \$300,000 per quality-adjusted life year). At \$465,000 per quality-adjusted life year gained, the retrospective "lookback" would yield one-time benefits to society of \$1,228 million (2,640 quality-adjusted life years x \$465,000 per quality-adjusted life year).

d. Testing costs of retrospective "lookback." Table 9 of this document summarizes the potential diagnostic testing costs associated with retrospective "lookback." Diagnostic costs are based on the number of newly identified recipients with a hepatitis C virus infection, the related testing frequencies, and the unit costs for diagnostic tests and lost time for patients. As noted previously, we selected the Markov model of Younossi and others for our analysis (Ref. 14). Because Younossi's simulation begins after a patient has received a liver biopsy and uses HCV genotype to determine the duration of therapy, we also estimate these costs. All recipients infected with the hepatitis C virus would receive genotyping, however, only those infected with the genotype 1 virus (i.e., 75 percent)

would undergo a liver biopsy. We exclude all treatment costs from this analysis because Younossi and others found negative incremental treatment costs (i.e., a lifetime cost savings over the no treatment option) (Ref. 14).

Table 9.--Total Costs of Diagnostic Testing and Lost Patient Time of Retrospective "Lookback"¹

Type Diagnostic Tests	Cost of Diagnostic Tests ² (\$ mil)
HCV screening tests ³	1.4
Negative supplemental tests (i.e., false positive screening result) ³	0.9
Positive supplemental tests ³	1.1
Hepatitis C virus genotype tests ⁴	1.5
Liver biopsy ⁵	2.6
Total	7.5

¹ Numbers may not sum or multiply due to rounding.

² Unit costs for diagnostic tests are from table 4 of this document.

³ Number of diagnostic tests are from table 8 of this document.

⁴ We assume that seventy-five percent of the recipients with positive supplemental tests are chronically infected with the hepatitis C virus and have HCV genotype testing.

⁵ The prevalence rate for hepatitis C virus genotype 1 is approximately 75 percent; ninety-five percent of recipients infected with genotype 1 have a needle biopsy, and 5 percent of recipients infected with genotype 1 have a wedge biopsy.

e. Cost-effectiveness of retrospective "lookback." The cost-effectiveness of retrospective "lookback" can be expressed as the cost per newly identified transfusion recipient or as the cost per quality-adjusted life year gained. Compliance with the retrospective "lookback" will cost about \$61.8 million (see table 3 of this document). Accounting for these compliance

costs and the screening and supplemental test costs in table 9 of this document, the one-time retrospective "lookback" will cost about \$17,100 per newly identified HCV positive person (((\$1.4 million screening tests + \$0.9 million negative supplemental tests + \$1.1 million positive supplemental tests + \$61.8 million compliance costs) / 3,818 recipients).

Including all testing costs, the retrospective "lookback" provisions of the final rule would cost approximately \$69.4 million (\$61.8 million "lookback" costs + \$7.5 million total testing costs) with a cost-effectiveness of \$26,300 per quality-adjusted life year gained (\$69.4 million/2,640 quality-adjusted life years). Younossi's article reports an incremental treatment cost savings, but we do not have sufficient information to include these savings in the cost per quality-adjusted life year (Ref. 14) and therefore ignore all treatment costs in our analysis. To the extent that we exclude these cost savings, the cost-effectiveness ratio is overstated.

6. Summary of Benefits and Costs of the Final Rule

Recent public reviews of blood supply issues have recognized the importance of ensuring safety. Although the current risk of transfusion-transmitted HCV infection is already very low (i.e., less than 1:1.6 million), one-time retrospective "lookback" has the potential to newly identify thousands of infected transfusion recipients. In contrast, because we

anticipate that prospective "lookback" will occur infrequently, in most years, between 0 and 5 newly identified recipients might seek treatment and benefit from a gain in quality-adjusted life years. The size of this gain is so small, however, that it is captured in the rounding for the retrospective "lookback" analysis. Therefore, we exclude these gains from this analysis of the final rule and quantify only the benefits of gains in quality-adjusted life years from the retrospective "lookback." The final rule can be expected to gain a one-time total of 2,640 quality-adjusted life years with an estimated discounted value that ranges from \$264 million to \$1,228 million. As presented in table 10, over 10 years the annualized net benefits of all provisions of the final rule, including direct and diagnostic costs for both retrospective "lookback" and prospective "lookback," will range from about \$20.6 million (\$31.0 million annualized benefits - \$10.3 million annualized costs) to \$133.6 million (\$143.9 million annualized benefits - \$10.3 million annualized costs). For all provisions of the final rule, the present value of all costs equals \$87.6 million and is the sum of (1) The one-time "lookback" costs (\$65.9 million) and one-time diagnostic costs (\$7.5 million) for the retrospective "lookback", and (2) the present value of the annual direct and diagnostic costs for the prospective "lookback" over 10 years at a 3 percent discount rate (\$13.8 million in direct costs + \$0.4

million in diagnostic costs). The cost-effectiveness of the entire final rule equals \$33,200 per quality-adjusted life year (\$87.6 million / 2,640 quality-adjusted life years) as shown in table 10.

Table 10.--Summary of Net Benefits and Cost Per QALY¹

Annualized Costs ² :			
Prospective and Retrospective "Lookback"	\$9.4		
Testing and Lost Patient Time	\$0.9		
Total Annualized Costs	\$10.3		
Annualized Benefits ³ :	Low value of QALY	Medium value of QALY	High value of QALY
Value of QALYs gained	\$31.0	\$92.9	\$143.9
Total Annualized Net Benefits	\$20.6	\$82.5	\$133.6
Cost-Effectiveness:			
Present Value of Total Costs ⁴	\$87.6		
Number of QALYs gained ⁵	2,640		
Cost per QALY (\$)	\$33,200		

¹ Some numbers are rounded. Unless noted, all dollar amounts are \$ million. Costs and benefits annualized over 10 years at 3 percent discount rate.

² Includes costs to comply with all provisions of the final rule, all costs associated with the gain in QALYs from the retrospective "lookback," and the costs of screening and confirmatory tests to newly identify HCV positive recipients with prospective "lookback."

³ Includes only quantifiable benefits of retrospective "lookback." QALYs are valued at \$100,000, \$300,000 and \$465,000.

⁴ Includes one-time costs and the present value of annual costs over 10 years at 3 percent.

⁵ Because so few individuals would be newly identified from prospective "lookback," the summary benefits equal the gains through retrospective "lookback." Note that prospective effects, should they exist, unambiguously increase benefits but the size of this gain would be so small that it is captured in the rounding for the retrospective "lookback" analysis.

7. Alternatives Considered for HCV "Lookback"

FDA finds that the targeted "lookback" approach is the most effective alternative when evaluated in terms of ethical, cost,

and effectiveness criteria. The following provides a discussion of the baseline for the analysis and the alternatives that have been considered.

a. Baseline: No regulatory action. FDA has already issued an industry guidance concerning HCV "lookback." Because FDA can only recommend a process and timeframe with a guidance, with no means of enforcing it, some establishments might decide not to perform "lookback" or to adopt a more extended timeframe to perform the "lookback" based on the review of historical testing records to spread the costs of this effort. Such delay, however, would increase each recipient's risk of serious disease complications.

b. Alternative: Use of general "lookback." General "lookback" is an alternative approach that has the potential to reach all patients who received transfusions during the period covered by "lookback." The cost and ultimate effectiveness of general "lookback" would vary depending on the program structure and the risk message. Because general "lookback" would not be based on identification of at-risk donations, the risk message would communicate the average risk of HCV infection from a blood transfusion. To be effective, the risk message should reach those recipients who would have been contacted by targeted "lookback" and motivate them to seek testing, but not to unnecessarily alarm and burden the majority of recipients who

would never be contacted by targeted "lookback" and who face an extremely low risk of being infected by HCV from a transfusion. Compared with targeted "lookback," general "lookback" programs shift costs from blood collection establishments and consignees to: (1) The entity conducting the general "lookback" program; and (2) recipients, health-care providers and payers.

No nationwide general "lookback" campaign has been conducted in the United States, although some limited programs have been initiated. For example, a CDC Web site offers educational materials about hepatitis C (www.cdc.gov/hepatitis). In 1999, CDC pilot-tested an HCV general "lookback" with public service announcement posters in the public transit systems of two cities, and also distributed an audio- and videotaped general "lookback" message by the surgeon general to radio and television stations in 2000. The effectiveness of these programs is unknown.

In the United States, few articles have been published on the outcomes of general "lookback" programs. Although several general and targeted "lookback" programs have been conducted in Canada, there has been no standardization of outcomes or cost estimates in that country. The authors of an article reviewing general "lookback" programs in Canada concluded that without standardized data, it is impossible to compare the cost-effectiveness of Canadian targeted and general "lookback"

programs (Ref. 21). Moreover, it is uncertain whether the Canadian experience would be comparable to what would happen in the United States. Nevertheless, in Canada, general "lookback" programs missed some recipients that were identified by targeted "lookback." For example, a Canadian hospital had completed a general letter "lookback" for HCV when the Canadian Red Cross Society began targeted "lookback" in 1995. By April of 1998, at least 13 new seropositive recipients had been identified by targeted "lookback" who were missed by general "lookback" (Ref. 22). As a result, targeted "lookback" raised the number of HCV-positive recipients tested at that hospital by at least 9 percent over general "lookback."

In 2000, the Alaska Native Medical Center - a hospital providing services to Alaska Natives - began a general "lookback" program to contact adults and children who had received transfusions between January 1980 and July 1992 (Ref. 23). Patients identified by the record review were sent letters notifying them of their transfusion history and encouraged them to seek testing for HCV infection. In a study of that program, the study's authors estimate that the entire program cost \$129,000, a total that includes \$56 for each patient notification. They note that a similar program in a private sector health care setting would cost substantially more than their results suggest.

Another general "lookback" program conducted in Alaska notified patients who had received transfusions in a neonatal intensive care unit between January 1975 and July 1992. These patients may have been unaware of the previous transfusion event. As a regional referral center located in Anchorage, the neonatal intensive care unit provided care for patients from the Alaska Native Medical Center (i.e., integrated health-care setting) and for patients of private sector health-care providers.

Results of general "lookback" varied significantly between the two health-care settings, with a higher percentage of patients identified and screened in the integrated health care setting than in the private sector setting (Ref. 24). As shown in table 11 of this document, 63 percent of the patients in the integrated health-care setting sought testing for hepatitis C virus infection, compared with 17 percent of the patients in the private sector health-care setting. This difference illustrates the uncertainty about the yield of a general "lookback" program in the United States. Characteristics of each health-care setting might explain some of the differences in yields between health-care settings. For example, patient records in the integrated health-care setting contain the results of hepatitis C tests. In contrast, private sector patients had to report the

results of their hepatitis C tests on an anonymous questionnaire.

With the results of the two Alaskan programs we provide a rough estimate of the potential costs and outcomes of a nationwide general "lookback" program for patients who received transfusions between 1988 and mid-1992 (i.e., a similar timeframe to the retrospective targeted "lookback" based on single-antigen tests). Published data suggests that about 15.2 million patients received red blood cell or whole blood transfusions during this period (Refs. 25, 26, and 27). We apply the transitional probabilities from the two Alaskan "lookback" programs, shown in table 11 of this document, to the total number of patients transfused, to estimate the number of patients that might be identified at each stage of the general "lookback" program. With this information, we estimate a type of general "lookback" program similar to the recipient notification programs conducted in Canada and calculate an estimate of the total potential "lookback" and diagnostic costs.

Table 11. Yields of Three "Lookback" Programs ¹

Percentage of Patients from the Prior Stage of "Lookback" (number of patients)	Published Results of General "Lookback" Programs		Targeted "Lookback" ⁴
	Integrated Health Care Setting ²	Private Sector Health Care Setting ³	
Transfused	100% (3,169)	100% (1,396)	100% (160,879)
Sent notice	38% (1,213)	27% (374)	21% (34,267)
Notified who were screened	63% (764)	17% (64)	52% (17,819)
Screened who tested HCV+	2%	2%	29%

	(19)	(1)	(5,168)
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¹ Numbers may not sum or multiply due to rounding.

² Based on the results from Ref. 23.

³ Based on the results from Ref. 24.

⁴ Based on the CDC interim survey results for transfusions from 1988 to 1989 (Ref. 3).

Comparing the yield of a nationwide general "lookback" program in a private sector health care setting to the yield of a nationwide general "lookback" program in an integrated health care setting gives us a range of potential outcomes for a general "lookback" program for recipients who received transfusions between 1988 and mid-1992. It should be noted that the Alaskan programs include some recipients who received blood transfusions prior to 1988, before blood donations were routinely screened for HCV. In addition, applying the transitional probabilities from the Alaskan programs to recipients transfused between 1988 and mid-1992, when the risk of transfusion-related HCV infection was falling, overestimates the potential yield of general "lookback."

A general "lookback" program with recipient notification requires far more resources than targeted "lookback." As shown in Table 12 of this document our analysis suggests that a general transfusion recipient notification program could cost more than \$500 million and newly identify between 3,600 and 30,000 recipients of transfusions who are infected with the hepatitis C virus and who choose to receive treatment. However,

these results should be interpreted with caution. CDC estimated that about 300,000 people might have been infected by blood transfusions in the 20 years prior to donor screening for HCV (Ref. 3). Our analysis suggests that general "lookback" might newly identify from 1.2 percent to 10 percent of those people who were infected with HCV from a blood transfusion even though we only include transfusion recipients between 1988 and mid-1992. However, in the United States, about 3.9 million people are infected with the hepatitis C virus (Ref. 28). Because general "lookback" contacts more persons than targeted "lookback," the program might identify persons who were infected with the hepatitis C virus by other routes than transfusions. Thus, general "lookback" is likely to generate benefits not directly related to at-risk transfusions.

"Lookback" programs can take many forms and target different at-risk populations. General "lookback" activities, such as those tested by CDC, can play an important role in efforts to reach the population at risk due to parental drug use or other risk behaviors not involving blood transfusion (Ref. 3). We have considered an Alaskan-type general "lookback" here as a potential alternative to a targeted "lookback." If further evidence or analysis shows that the yield of the Alaskan-type program is representative of the potential yield of a nationwide general "lookback" program, then a general "lookback" program

might be a cost-effective public health initiative to complement a targeted "lookback" and notify a subset of transfusion recipients who might be missed by the targeted "lookback" (e.g. patients who received transfusions before blood donations were screened for HCV; patients who were transfused as infants but who are unaware of the transfusion event and who respond only after receiving the second "lookback" notification).

To understand the potential yield of a general "lookback" that complements targeted "lookback," we use the numbers shown in table 12 to adjust our estimate of the total costs and number of quality-adjusted life years gained. This approach assumes that the targeted "lookback" program is completed before the general "lookback" program begins. We also assume that all of the infected persons identified by the targeted "lookback" would be included within the set of infected persons identified by general "lookback" programs. To adjust the yields, we subtract the diagnostic costs and quality-adjusted life years gained from targeted "lookback" from the diagnostic costs and quality-adjusted life years gained from general "lookback." The adjusted total costs for a general recipient notification "lookback" that complements the targeted "lookback" range from \$487.3 million (= \$494.1 million - \$6.8 million) to \$735.1 million (= \$741.9 million - \$6.8 million), and the adjusted gain in quality-adjusted life years range from 7,567 quality-adjusted life years

(= 9,992 quality-adjusted life years - 2,425 quality-adjusted life years) to 81,205 quality-adjusted life years (= 83,630 quality-adjusted life years - 2,425 quality-adjusted life years). Thus, the potential cost per quality-adjusted life year for a general "lookback" program that complements targeted "lookback" range from \$9,050 to \$64,400. We therefore conclude that the targeted "lookback" analyzed here is the preferred alternative for this final rule, but an Alaskan-type general "lookback" could be a cost-effective HCV policy.

c. Final: Use of targeted "lookback." The "lookback" provisions of the final rule can be characterized as a targeted "lookback" program, meaning that the notification of infection risk is limited to, or targeted at, individuals identified as recipients of blood from donors subsequently found to be infected with HCV. Targeted "lookback" requires that the transfusion service be aware that the donor subsequently tested positive, donor and product disposition records be available to link blood components with the identified donors, and the physician or transfusion service know the recipient's current whereabouts. Blood consignees would locate recipient records for all transfused units from an affected donor, and send out notifications to the most recent address. Ideally, the recipient will still be alive and be able to receive testing and treatment, if appropriate.

Despite the difficulties of implementing targeted "lookback," FDA concludes that this alternative remains the most reliable means of reaching people at increased risk of HCV infection from a transfusion. However, in response to comments on the proposed rule, some of the more prescriptive language was moved from the codified section to the accompanying guidance for industry. Therefore, the final rule lists the objective actions required of industry, and the timeframe in which they must be taken to give individual establishments the flexibility to accomplish these actions in the most cost effective manner.

d. Limited comparison of regulatory alternatives. The purpose of this final rule is to contact recipients who received transfusions of blood or blood components that were at risk of transmitting the hepatitis C virus. Table 12 of this document presents a comparison of the retrospective targeted "lookback" based on single-antigen tests and possible general "lookback" programs for recipients of transfusions between 1988 and mid-1992. The two general "lookback" estimates illustrate the uncertainty of general "lookback" and the likelihood that this program would identify people who were infected by other routes than transfusion events. The cost-effectiveness of the targeted "lookback" program falls in between the cost-effectiveness of the two general programs. The estimated effectiveness of targeted "lookback" is less uncertain than the estimated

effectiveness of general "lookback", and is therefore more likely to achieve the goals of this final rule.

Table 12. Comparison of the Targeted "Lookback" Program Based on Single-Antigen Screening Tests and Two General "Lookback" Programs for Recipients Who Received Transfusions Between 1988 and mid-1992 ¹

	Targeted "Lookback" for donations screened with single antigen test	Estimate of a Nationwide General "Lookback" Program for Recipients Transfused Between 1988 and mid-1992	
		Private sector health care setting	Integrated health care setting
Number of patients transfused	160,879	15.2 million	15.2 million
Number of "lookback" notifications	34,267	4,058,811	5,798,974
Number of screening tests	17,819	694,556	3,652,446
Number of supplemental tests	11,405	10,852	181,666
Number of HCV+ patients	5,168	10,852	90,833
Number of HCV+ patients treated	869	3,581	29,975
"Lookback" costs (\$ mil)	\$55.9 ²	\$426.2 ³	\$324.7 ⁴
Diagnostic costs ⁵ (\$ mil)	\$6.8	\$67.9	\$417.2
Total costs (\$ mil)	\$62.7	\$494.1	\$741.9
Number of QALYs gained	2,425	9,992	83,630
Cost per QALY gained (\$)	\$25,862 ⁶	\$49,449	\$8,871
<i>Incremental cost per QALY gained between targeted and the upper and lower bounds of general "lookback"</i>	--	\$57,011	\$8,364

¹ Unless noted, all dollar amounts are \$ million.

² "Lookback" costs of \$113 for blood collection establishments and \$184 for transfusion establishments.

³ "Lookback" costs of \$105 based on Ref. 24.

⁴ "Lookback" costs of \$56 based on Ref. 23.

⁵ Unit costs for diagnostic tests are shown in table 4 of this document.

⁶ For this example, we report the cost-effectiveness of the retrospective "lookback" based on single-antigen tests. This differs from the cost-effectiveness of the entire retrospective "lookback" reported in section 6.e. of this document.

C. Impact on Small Entities

No comments were received on the initial regulatory flexibility analysis or the agency's request for specific information essential to estimate the final rule's impact on small entities. Because information on the affected industries is limited, the agency cannot predict the extent of the economic impact of the final rule on small entities and, therefore, performed a final regulatory flexibility analysis.

The final rule will help ensure the continued safety of the blood supply and will help ensure that consignees and recipients who received blood and blood components at increased risk of transmitting HCV are informed. Affected entities include commercial plasma centers, community and hospital blood banks, and hospital transfusion services that collect or receive blood and blood components. For the regulatory flexibility analysis affected firms are considered small if they are: (1) A for-profit firm with annual receipts or revenue less than the current Small Business Administration (SBA) industry size standards; (2) an independently owned and operated, not-for-profit enterprise which is not dominant in its field; or (3) operated by a small governmental jurisdiction with a population of less than 50,000 individuals. Aggregate information about hospitals and blood banks are available under SIC (Standard Industrial Classification) group 80 for health services.

However, the North American Industry Classification System (NAICS) reports information at the blood and organ banks level. Similarly, more detailed general medical and surgical hospital information is available with NAICS than with the SIC system. To estimate the economic impact of the final rule on these different types of small entities, the costs per firm shown in table 13 of this document are expressed as a percentage of average annual revenue in tables 14, 15, and 16 of this document.

Table 13.--Estimated Per Firm Regulatory Costs by Type of Small Entity¹

Type of Small Entity	Share of "Lookback" Costs	Annual Costs ²	One-Time Costs ³	Total Annualized Costs	
				3 percent	7 percent
Plasma collection	N/A	--	\$1,350	\$160	\$190
Blood collection	0.04%	--	\$10,210	\$1,200	\$1,450
For-profit hospital	0.02%	\$1,410	\$7,370	\$2,270	\$2,460
Not-for-profit hospital	0.02%	\$1,410	\$7,060	\$2,240	\$2,420
Government hospital	0.00%	\$1,370	\$1,420	\$1,540	\$1,570

¹ Numbers may not add due to rounding.

² Although 80 percent of hospitals already retain records for 10 years, this analysis assumes small hospitals are not in compliance with this provision of the final rule. Blood collection establishments currently comply with these provisions of the final rule.

³ Includes one-time cost for SOPs and historical "lookback" actions.

In the United States, most plasma establishments are owned by large, for-profit companies, whereas almost all blood collection establishments are not-for-profit organizations. The SBA size standards in effect since December 6, 2005, define as small any blood and organ bank (NAICS 621991) with an annual income of less than \$9 million. Although the 1997 Economic

Census lists 449 blood and organ banks (including plasma collection establishments) owned by 173 for-profit firms and 721 blood and organ banks owned by 300 not-for-profit firms (NAICS 621991), this data has limited use because it includes organ banks, excludes any blood collection establishment operating as part of a hospital, and uses different receipt sizes than the SBA.

FDA estimates the final rule will affect 60 commercial plasma collection establishments and 981 blood collection establishments. The FDA registry of blood establishments does not provide an indication of the size of the registered entities. However, previously the agency estimated that 37 small plasma establishments collect approximately 8 percent of the plasma and 906 small blood banks collect 35 percent of the donated blood (66 FR 31146 at 31159).

Each affected establishment will incur the one-time cost to revise SOPs. Blood and plasma collection establishments have had procedures in place for HIV "lookback" for years. Thus, no additional skills are required because each establishment has existing personnel experienced in preparation of SOPs and the establishment would update existing SOPs by including HCV into the "lookback" procedures. Using 1997 Economic Census data on for-profit firms included in NAICS 621991, table 14 of this document illustrates that the annualized costs of the SOPs will

be less than 0.5 percent of average receipts for all small plasma entities, illustrating that the average impact of the final rule will not be significant for small plasma entities.

Table 14.--One-Time and Annualized Costs of the Final Rule on For-Profit Plasma Centers Operating All Year¹

Receipts Size of Firm ¹	Number of Firms ¹	Receipts ¹ (\$1,000)	Average Receipt per Firm ¹ (\$1,000)	Per Firm One-Time Costs as Percent of Average Receipts ²	Per Firm Annualized Costs as Percent of Average Receipts ²	
					3 percent	7 percent
< \$100,000	28	1,714	61.2	2.2%	0.3%	0.3%
\$100,000 to \$249,999	21	3,257	155.1	0.9%	0.1%	0.1%
\$250,000 to \$499,999	16	5,737	358.6	0.4%	0.0%	0.1%
\$500,000 to \$999,999	30	21,626	720.9	0.2%	0.0%	0.0%
\$1,000,000 to \$2,499,999	37	56,837	1,536.1	0.1%	0.0%	0.0%
\$2,500,000 to \$4,999,999	16	55,677	3,479.8	0.0%	0.0%	0.0%
\$5,000,000 to \$9,999,999	5	37,124	7,424.8	0.0%	0.0%	0.0%
\$10,000,000 +	20	804,559	NA	NA		NA
Total	173	986,531				

¹ Source: U.S. Department of Commerce, Economics and Statistics Administration, U.S. Census Bureau, "1997 Economic Census, Health Care and Social Assistance, Subject Series: Establishment and Firm Size," EC97S62S-SZ, October 2000, table 4a, NAICS 621991 (blood and organ banks).

² Per firm costs from table 13 of this document.

In addition to the cost of revising SOPs, the one-time costs of the retrospective "lookback" will be proportional to the volume of blood collected by blood establishments. Therefore, small entities collecting few donations will incur the lowest "lookback" costs. Because 906 small entities collect about 35 percent of the blood, the proportion of "lookback" costs for each entity will be small. For example, if blood donations are distributed evenly among small blood collection establishments, each small organization would incur only 0.04 percent (0.04 percent = 35 percent / 906) of the "lookback" costs and collect approximately 5,400 donations each year (5,408

donations / establishment = 14 million donations x 35 percent / 906 establishments). Using \$96 as the price for a unit of red blood cells, small blood collection establishments average a minimum annual revenue of approximately \$520,000 (Ref. 29).

Table 15 of this document summarizes the one-time and annualized costs of the final rule as a percentage of this minimum average revenue for small blood collection organizations.

Table 15.--One-Time and Annualized Costs of the Final Rule on Not-For-Profit Blood Collection Organizations

Number of Small Organizations	Average Annual Revenue ¹	Per Firm One-Time Costs as Percent of Average Revenue ²	Per Firm Annualized Costs as Percent of Average Revenue ²	
			3 percent	7 percent
906	\$519,200	2.0%	0.2%	0.3%

¹ 5,370 units x \$96/unit of red blood cells = \$515,520. A unit of whole blood can be separated into non-red blood cell components that yield additional revenues in excess of \$135.

² Per firm costs from table 13 of this document.

An estimated 4,980 hospitals perform transfusion services in the United States. The SBA defines as small any general medical and surgical hospital (NAICS 622110) with annual receipts less than \$31.5 million. Similar to blood banks, the census uses receipt sizes that differ from those of the SBA. Therefore, in this analysis, for-profit hospitals with annual receipts less than \$25 million are treated as small businesses. Furthermore, not-for-profit, non-government hospitals that have no more than one establishment are treated as small organizations. Similarly, the number of government hospitals

(NAICS 6221101) classified as single-unit firms, or firms with one establishment, provides an estimate of the number of small government hospitals. This approach most likely overestimates the number of hospitals operated by small government jurisdictions, because many urban county hospitals (i.e., with populations greater than 50,000) may have only one establishment.

In contrast to blood banks, the 1997 Economic Census reports data separately on 774 for-profit hospitals (NAICS 622110), 1,571 government hospitals (NAICS 6221101), and 3,076 non-government, not-for-profit hospitals (NAICS 6221102). Each hospital transfusion service will incur the cost of preparing SOPs and 20 percent will spend more to retain records an additional 5 years. Hospitals have experience preparing SOPs and have already been performing an historical "lookback" under an agency guidance to industry. Thus compliance with the final rule requires no new skills.

Similar to blood banks, "lookback" costs are proportional to transfusion volume. Unlike blood banks, however, data from several sources provides sufficient information to distribute transfusion volume to different types of small entities. National statistics from the Healthcare Cost and Utilization Project (HCUP) on in-hospital blood transfusions in 1997 (i.e., clinical classifications software procedure category 222) give a

reasonable estimate of the volume of blood transfused by hospitals categorized by ownership (i.e., government; private, not-for-profit; and private, for-profit) (Ref. 8). Furthermore, HCUP provides data on the number of transfusions by ownership category and bed size. In 1997, HCUP defined bed size category based on location and teaching status of the hospital. Thus small bed size refers to the following: (1) 1 to 49 beds for rural hospitals; (2) 1 to 99 beds for urban, non-teaching hospitals; and (3) 1 to 299 beds for urban, teaching hospitals. However, most teaching hospitals are affiliated with public or private, not-for-profit colleges or universities which would be considered organizations. Using the HCUP definition, small for-profit hospitals are assumed to have no more than 99 beds. Data from a 1998 American Hospital Association (AHA) survey on hospitals in the United States shows that hospitals with less than 100 beds had average revenues of \$27.7 million or less (Ref. 7). The HCUP data on the number of transfusions given in small, for-profit hospitals is used, therefore, to estimate the share of total transfusion for small businesses. In contrast, small not-for-profit or government hospitals may not necessarily be classified as small based on HCUP bed size. Thus for these small entities, revenue shares calculated from the 1997 Economic Census data serve as proxies for transfusion volume.

Table 16 of this document shows the average one-time and annual costs incurred by small hospitals as a percentage of annual receipts or revenue. In all cases, one-time costs are less than one percent of average revenue or receipts and annualized costs are less than 0.2 percent of average revenue or receipts. Therefore, the final rule does not have a significant economic impact on these small entities.

Table 16.--Hospital Industry One-Time and Annual Costs as a Percentage of Average Annual Revenue by Size and Type of Firm^{1,2}

Receipt Size of Firm	Number of Firms	Receipts (\$1,000)	Average Receipt Per Firm (\$1,000)	Per Firm One-Time Costs as Percent of Average Receipts	Per Firm Annualized Costs as Percent of Average Receipts	
					3 percent	7 percent
For-Profit Hospitals Operating All Year: ³						
\$0 to \$999,999	0					
\$1,000,000 to \$2,499,999	6	9,737	1,622.8	0.5%	0.1%	0.2%
\$2,500,000 to \$4,999,999	21	73,777	3,513.2	0.2%	0.1%	0.1%
\$5,000,000 to \$9,999,999	43	316,631	7,363.5	0.1%	0.0%	0.0%
\$10,000,000 to \$24,999,999	38	630,189	16,583.9	0.0%	0.0%	0.0%
\$25,000,000 +	66	NA	NA			NA
Total	174	33,782,805				
Size Category (share of total revenue)	Number of Firms	Revenue (\$1,000)	Average Revenue Per Firm (\$1,000)	Per Firm One-Time Costs as Percent of Average Revenue	Per Firm Annualized Costs as Percent of Average Revenue	
					3 percent	7 percent
Not-For-Profit Hospitals Operating All Year: ⁴						
Single-unit firm (14%)	918	44,832,121	48,836.7	0.0%	0.0%	0.0%
One establishment (23%)	813	74,651,556	91,822.3	0.0%	0.0%	0.0%
Total	2,034	242,896,322				
Government Hospitals Operating All Year: ⁵						
Single-unit firm (7%)	994	23,175,491	23,315.4	0.0%	0.0%	0.0%
One establishment (14%)	515	43,739,763	84,931.6	0.0%	0.0%	0.0%
Total	1,537	77,024,061				

¹ Source: U.S. Department of Commerce, Economics and Statistics Administration, U.S. Census Bureau, "1997 Economic Census, Health Care and Social Assistance, Subject Series: Establishment and Firm Size," EC97S62S-SZ, October 2000.

² Per firm costs from table 13 of this document.

³ 1997 Economic Census, table 4a, NAICS 622110. Based on 1997 HCUP data, small private for-profit hospitals account for approximately 2 percent of the annual transfusion volume (1.8% = 23,182 / 1,296,723).

⁴ 1997 Economic Census, table 3b, NAICS 6221102. HCUP data shows private, not-for-profit hospitals account for 71% of all transfusions (=924,730 / 1,296,723). According to 1997 Economic Census data, hospitals with less than two establishments account for 37% of total revenues for all private, not-for-profit hospitals. Therefore small, private, not-for-profit hospitals will incur about 27% (27% = 71% x 37%) of the consignee "lookback" costs. Costs as a percent of revenue less than 0.05 percent are rounded to 0.0 percent.

⁵ 1997 Economic Census, table 3b, NAICS 6221101, HCUP data shows government hospitals account for 15% of all transfusions (= 193,679 / 1,296,723). According to 1997 Economic Census data, government hospitals with less than two establishments account for 21% of total revenues for all government hospitals. Therefore, small government hospitals will incur about 3% (3% = 15% x 21%) of the consignee "lookback" costs. Costs as a percent of revenue less than 0.05 percent are rounded to 0.0 percent.

As described earlier, FDA has considered several alternatives, and considers that a targeted "lookback" will be

the most effective approach to inform recipients of HCV-infected blood products. Because "lookback" costs are proportional to blood collection or transfusion volume, the smallest entities will incur the lowest costs. Furthermore, the agency allows for flexibility in an establishment's individual approach to compliance by moving the prescriptive language of the proposed rule to an industry guidance document and specifying only the objective actions required by an establishment in the final rule. This will enable each entity to develop procedures that are most appropriate and cost-effective given the particular situation and the resources available. In addition, the agency has specified a limited time frame for notification to provide a clear endpoint to facilitate efforts related to the historical "lookback." The agency concludes that this final rule will ensure the safety of the blood supply and meet public health goals in the least intrusive and most cost-effective way. Therefore, the agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities.

V. The Paperwork Reduction Act of 1995

This final rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501-3520). A description of these provisions,

with an estimate of the annual reporting and recordkeeping burden, follows. Included in the estimate is the time for reviewing the instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

Title: Current Good Manufacturing Practices for Blood and Blood Components; Notification of Consignees and Transfusion Recipients Receiving Blood and Blood Components at Increased Risk of Transmitting Hepatitis C Virus Infection ("Lookback").

Description: This final rule requires collecting establishments and consignees to prepare and follow written procedures when a donor who tests reactive for evidence of HIV or HCV infection either on a repeat donation or after a review of historical testing records (recordkeeping burden in § 606.100(b)(19)). Such collections may be at increased risk of transmitting HIV or HCV infection. We are requiring collecting establishments to review testing records, to quarantine prior in-date blood and blood components from such a donor, to perform further testing on the donor, and to notify consignees of prior in-date blood and blood components from such a donor for quarantine purposes (reporting burden in §§ 610.46(a)(1)(ii)(B), 610.47(a)(1)(ii)(B), and 610.48(b)(3)(ii) and (b)(3)(iii)) and to notify consignees of further testing results (reporting burden in §§ 610.46(a)(3), 610.47(a)(3), and 610.48(b)(4)). We

also are requiring consignees to notify transfusion recipients, the recipients' physicians of record, or the recipients' legal representatives that the recipient received blood and blood components at increased risk of transmitting HIV or HCV (reporting burden in §§ 610.46(b)(3), 610.47(b)(3), and 610.48(c)(3)). Records of these actions must be kept (recordkeeping burden in § 606.160(b)(1)(viii)). We also are extending record retention under § 606.160(d) from 5 to 10 years.

Description of Respondents: Collecting establishments (business and not-for-profit) and consignees of collecting establishments, including hospitals, transfusion services, and physicians.

As required by section 3506(c)(2)(B) of the PRA, we provided an opportunity for public comment on the information collection requirements of the HCV "lookback" proposed rule (65 FR 69378). In accordance with the PRA, OMB reserved approval of the information collection burden in the proposed rule, stating it will make an assessment in light of public comments received on the proposed rule. No comments on the information collection requirements were submitted to OMB or the docket.

The total reporting and recordkeeping burden for the first year is estimated to be 495,309.5 hours. However, of this total approximately 456,280 hours would be expended on a one-time

basis for establishing the written procedures and doing the one-time retrospective review of historical HCV testing records. Therefore, 39,029.5 hours is estimated as the ongoing annual burden related to these regulations. The total ongoing annual burden for collecting establishments under §§ 610.46(a)(1)(ii)(B), 610.46(a)(3), 610.46(b)(3), and 606.160(b)(1)(viii) for HIV "lookback" is estimated to be 12,763 hours. The total ongoing annual burden for collecting establishments under §§ 610.47(a)(1)(ii)(B), 610.47(a)(3), 610.47(b)(3), and 606.160(b)(1)(viii) for HCV "lookback" is estimated to be 26,266.5 hours.

Based on information retrieved from FDA's registration database and as discussed in section IV of this document, there are approximately 1,041 FDA registered establishments (60 licensed plasma establishments and 981 registered collecting establishments) in the United States that collect approximately 27 million donations annually: 13 million donations of Source Plasma and 14 million donations of Whole Blood, including approximately 695,000 autologous units. As calculated in section IV of this document, there are approximately 11.2 million donations of Whole Blood from repeat donors per year. As previously discussed in section IV.A.3.b of this document, the Source Plasma industry will only be minimally affected by these requirements. Therefore, we are only estimating burden

for Source Plasma collecting establishments in regards to § 606.100(b)(19). The following reporting and recordkeeping estimates are based on information provided by industry and FDA experience.

A. Annual Reporting Burden

1. HIV Reporting Burden

In table 17 of this document, we estimate that approximately 3,500 repeat donors will test reactive on a screening test for HIV. We estimate that an average of three components were made from each donation. Under § 610.46(a)(1)(ii)(B) and 610.46(a)(3), this estimate results in 10,500 (3,500 x 3) notifications of the HIV screening test results to consignees by collecting establishments for the purpose of quarantining affected blood and blood components, and another 10,500 (3,500 x 3) notifications to consignees of subsequent test results. We estimate an average of 10 minutes per notification of consignees. The estimate for consignee notifications in the final rule is higher than the estimate in the proposed rule because we based our calculations in the final rule on the number of components at risk of transmitting HCV infection rather than the number of reactive donors. We also have increased the number of components per donation from two to three.

In addition, we estimate that § 610.46(b)(3) will require 4,980 consignees to notify transfusion recipients or physicians of record an average of 0.35 times per year resulting in a total number of 1,755 (585 confirmed positive repeat donors x 3) notifications. In the proposed rule, we estimated 0.5 hours as the average time for a reasonable attempt to notify recipients by consignees. However, under § 610.46(b)(3), we are increasing the estimate to 1 hour to accommodate the time to gather test results and the recipient's records and to accommodate multiple attempts to contact the recipient.

2. HCV Reporting Burden

We estimate that approximately 7,800 repeat donors per year would test reactive for antibody to HCV (780 repeat donors confirmed HCV positive / 0.1 rate for repeat donors confirmed HCV positive / repeat donors with reactive tests = 7,800 repeat donors with reactive tests). Under §§ 610.47(a)(1)(ii)(B) and 610.47(a)(3), collecting establishments would notify the consignee two times for each of the 23,400 (7,800 x 3 components) components prepared from these donations, once for quarantine purposes and again with additional HCV test results for a total of 46,800 notifications as an annual ongoing burden. Under § 610.47(b)(3), we estimate that approximately 4,980 consignees would notify approximately 2,050 recipients (calculated in section IV.A.4.b.i of this document) or their

physicians of record annually. The estimated average 1 hour to complete notification is based on the criteria discussed in the previous section on HIV Reporting Burden.

B. Estimated One-Time Reporting Burden

Based on estimates from CDC, we expect that for the one-time retrospective review of historical testing records, as many as approximately 212,000 blood components (calculated in section IV.A.4.b.ii of this document) would be at increased risk for transmitting HCV. For each of these products, under §§ 610.48(b)(3)(ii) and (b)(3)(iii), and 610.48(b)(4) collecting establishments would notify consignees to quarantine these products and report additional HCV test results to consignees, and, under § 610.48(c)(3), consignees would notify transfusion recipients or recipients' physicians of record. CDC estimated that there could be approximately 212,000 transfusion recipients that would be notified after a one-time retrospective review of historical test results for HCV screening. The numbers in the "Hours per Response" column of table 18 of this document are the same as the burden for table 7 of this document.

C. Estimated Annual and One-Time Recordkeeping Burden

In the recordkeeping tables (tables 19 and 20 of this document), the numbers in the "Hours per Record" column are based on our estimate of the time to complete one record. We also estimate that each documentation of consignee and recipient

notification takes approximately 5 minutes. In table 20 of this document, we estimate that it will take collecting establishments approximately 40 hours to establish the written procedures required under § 606.100(b)(19) and consignees approximately 16 hours to establish written procedures under § 606.100(b)(19). In table 19 of this document, the estimate for annual recordkeeping is based on the estimate that it takes approximately 10 minutes to document and maintain the records to relate the donor with the unit number of each previous donation for both the collecting establishment and the consignee. The time required for recordkeeping under § 606.160(b)(1)(viii) is estimated to be approximately 10 minutes for each HIV or HCV reactive donation record and approximately 10 minutes per transfusion recipient record required under §§ 610.46(b)(3), 610.47(b)(3), and 610.48(c)(3).

Because the final rule will not affect current industry practice of retaining "lookback" records for 10 years, no burden is calculated for § 606.160(d). We estimate the burden for this collection of information as follows:

Table 17.--Estimated Annual Reporting Burden¹

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
610.46(a)(1)(ii)(B)	981	10.7	10,500	0.17	1,785
610.46(a)(3)	981	10.7	10,500	0.17	1,785
610.46(b)(3)	4,980	0.35	1,755	1.0	1,755
610.47(a)(1)(ii)(B)	981	23.85	23,400	0.17	3,978
610.47(a)(3)	981	23.85	23,400	0.17	3,978
610.47(b)(3)	4,980	0.41	42,050	1.0	2,050
Total					15,331

¹ There are no capital or operating and maintenance costs associated with this collection of information.

Table 18.--Estimated One-Time Reporting Burden¹

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
610.48(b)(3)(ii) and (b)(3)(iii)	981	216.1	212,000	0.17	36,040
610.48(b)(4)	981	216.1	212,000	0.17	36,040
610.48(c)(3)	4,980	42.57	212,000	1.0	212,000
Total					284,080

¹ There are no capital or operating and maintenance costs associated with this collection of information.

Table 19.--Estimated Annual Recordkeeping Burden¹

21 CFR Section	No. of Recordkeepers	Annual Frequency of Recordkeeping	Total Annual Records	Hours per Record	Total Hours
606.160(b)(1)(viii)					
HIV consignee notification	981	21.4	21,000	.17	3,570
	4,980	4.2	21,000	.17	3,570
HCV consignee notification	981	47.71	46,800	.17	7,956
	4,980	9.4	46,800	.17	7,956
HIV recipient notification	4,980	0.35	1,755	.17	298
HCV recipient notification	4,980	0.41	2,050	.17	348.5
Total					23,698.5

¹ There are no capital or operating and maintenance costs associated with this collection of information.

Table 20.--Estimated One-Time Recordkeeping Burden¹

21 CFR Section	No. of Recordkeepers	Annual Frequency of Recordkeeping	Total Annual Records	Hours per Record	Total Hours
606.100(b)(19)	1,041	1	1,041	40	41,640
606.100(b)(19)	4,980	1	4,980	16	79,680
606.160(b)(1)(viii)	1,041	203.65	212,000	.08	16,960
606.160(b)(1)(viii)	4,980	42.57	212,000	.08	16,960
610.48(c)(3)	4,980	42.57	212,000	.08	16,960
Total					172,200

¹ There are no capital or operating and maintenance costs associated with this collection of information.

The information collection provisions of this final rule have been submitted to OMB for review.

Before the final rule becomes effective, we will publish a notice in the FEDERAL REGISTER announcing OMB's decision to approve, modify, or disapprove the information collection provisions in this final rule. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number.

VI. Environmental Impact

The agency has determined under 21 CFR 25.30(j) 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.

VII. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency has concluded that the rule does not contain policies that have federalism

implications as defined in the Executive Order and, consequently, a federalism summary impact statement is not required.

VIII. References

The following references have been placed on display in the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, 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 we are not responsible for subsequent changes to the Web sites after this document publishes in the FEDERAL REGISTER.)

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Lists of Subjects

21 CFR Part 606

Blood, Labeling, Laboratories, Reporting and recordkeeping requirements.

21 CFR Part 610

Biologics, Labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act, and the Public Health Service Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 606 and 610 are amended as follows:

PART 606--CURRENT GOOD MANUFACTURING PRACTICE FOR BLOOD AND BLOOD COMPONENTS

1. The authority citation for 21 CFR part 606 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 355, 360, 360j, 371, 374; 42 U.S.C. 216, 262, 263a, 264.

2. Section 606.100 is amended by revising paragraph

(b) (19) to read as follows:

§ 606.100 Standard operating procedures.

* * * * *

(b) * * *

(19) Procedures under §§ 610.46, 610.47, and 610.48 of this chapter:

(i) To identify previously donated blood and blood components from a donor who later tests reactive for evidence of human immunodeficiency virus (HIV) infection or hepatitis C virus (HCV) infection when tested under § 610.40 of this chapter, or when a blood establishment is made aware of other reliable test results or information indicating evidence of HIV or HCV infection;

(ii) To quarantine in-date blood and blood components previously donated by such a donor that are intended for use in another person or further manufacture into injectable products, except pooled components intended solely for further manufacturing into products that are manufactured using validated viral clearance procedures;

(iii) To notify consignees to quarantine in-date blood and blood components previously donated by such a donor intended for use in another person or for further manufacture into injectable products, except pooled components intended solely for further

manufacturing into products that are manufactured using validated viral clearance procedures;

(iv) To determine the suitability for release, destruction, or relabeling of quarantined in-date blood and blood components;

(v) To notify consignees of the results of the HIV or HCV testing performed on the donors of such blood and blood components;

(vi) To notify the transfusion recipient, the recipient's physician of record, or the recipient's legal representative that the recipient received blood or blood components at increased risk of transmitting HIV or HCV, respectively.

* * * * *

3. Section 606.160 is amended by revising paragraph (b) (1) (viii) and the second sentence of paragraph (d) to read as follows:

§ 606.160 Records.

* * * * *

(b) * * *

(1) * * *

(viii) Records concerning the following activities performed under §§ 610.46, 610.47, and 610.48 of this chapter: Quarantine; consignee notification; testing; notification of a transfusion recipient, the recipient's physician of record, or the recipient's legal representative; and disposition.

* * * * *

(d) * * * You must retain individual product records no less than 10 years after the records of processing are completed or 6 months after the latest expiration date for the individual product, whichever is the later date. * * *

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PART 610--GENERAL BIOLOGICAL PRODUCTS STANDARDS

4. The authority citation for 21 CFR part 610 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 360, 360c, 360d, 360h, 360i, 371, 372, 374, 381; 42 U.S.C. 216, 262, 263, 263a, 264.

5. Section 610.41 is amended by adding paragraph (c) to read as follows:

§ 610.41 Donor deferral.

* * * * *

(c) You must comply with the requirements under §§ 610.46 and 610.47 when a donor tests reactive by a screening test for HIV or HCV required under § 610.40(a) and (b), or when you are aware of other reliable test results or information indicating evidence of HIV or HCV infection.

6. Section 610.46 is revised to read as follows:

§ 610.46 Human immunodeficiency virus (HIV) "lookback"
requirements.

(a) If you are an establishment that collects Whole Blood or blood components, including Source Plasma and Source Leukocytes, you must establish, maintain, and follow an appropriate system for the following actions:

(1) Within 3 calendar days after a donor tests reactive for evidence of human immunodeficiency virus (HIV) infection when tested under § 610.40(a) and (b) or when you are made aware of other reliable test results or information indicating evidence of HIV infection, you must review all records required under § 606.160(d) of this chapter, to identify blood and blood components previously donated by such a donor. For those identified blood and blood components collected:

(i) Twelve months and less before the donor's most recent nonreactive screening tests, or

(ii) Twelve months and less before the donor's reactive direct viral detection test, e.g., nucleic acid test or HIV p24 antigen test, and nonreactive antibody screening test, whichever is the lesser period, you must:

(A) Quarantine all previously collected in-date blood and blood components identified under paragraph (a)(1) of this section if intended for use in another person or for further manufacture into injectable products, except pooled blood

components intended solely for further manufacturing into products that are manufactured using validated viral clearance procedures; and

(B) Notify consignees to quarantine all previously collected in-date blood and blood components identified under paragraph (a) (1) of this section if intended for use in another person or for further manufacture into injectable products, except pooled blood components intended solely for further manufacturing into products that are manufactured using validated viral clearance procedures;

(2) You must perform a supplemental (additional, more specific) test for HIV as required under § 610.40(e) of this chapter on the reactive donation.

(3) You must notify consignees of the supplemental (additional, more specific) test results for HIV, or the results of the reactive screening test if there is no available supplemental test that is approved for such use by FDA, or if under an investigational new drug application (IND) or investigational device exemption (IDE), is exempted for such use by FDA, within 45 calendar days after the donor tests reactive for evidence of HIV infection under § 610.40(a) and (b) of this chapter. Notification of consignees must include the test results for blood and blood components identified under paragraph (a) (1) of this section that were previously collected

from donors who later test reactive for evidence of HIV infection.

(4) You must release from quarantine, destroy, or relabel quarantined in-date blood and blood components, consistent with the results of the supplemental (additional, more specific) test performed under paragraph (a)(2) of this section or the results of the reactive screening test if there is no available supplemental test that is approved for such use by FDA, or if under an IND or IDE, exempted for such use by FDA.

(b) If you are a consignee of Whole Blood or blood components, including Source Plasma and Source Leukocytes, you must establish, maintain, and follow an appropriate system for the following actions:

(1) You must quarantine all previously collected in-date blood and blood components identified under paragraph (a)(1) of this section, except pooled blood components intended solely for further manufacturing into products that are manufactured using validated viral clearance procedures, when notified by the collecting establishment.

(2) You must release from quarantine, destroy, or relabel quarantined in-date blood and blood components consistent with the results of the supplemental (additional, more specific) test performed under paragraph (a)(2) of this section, or the results of the reactive screening test if there is no available

supplemental test that is approved for such use by FDA, or if under an IND or IDE, is exempted for such use by FDA.

(3) When the supplemental (additional, more specific) test for HIV is positive or when the screening test is reactive and there is no available supplemental test that is approved for such use by FDA, or if under an IND or IDE is exempted for such use by FDA, you must notify transfusion recipients of previous collections of blood and blood components at increased risk of transmitting HIV infection, or the recipient's physician of record, of the need for recipient HIV testing and counseling. You must notify the recipient's physician of record or a legal representative or relative if the recipient is a minor, deceased, adjudged incompetent by a State court, or, if the recipient is competent but State law permits a legal representative or relative to receive information on behalf of the recipient. You must make reasonable attempts to perform the notification within 12 weeks after receiving the supplemental (additional, more specific) test results for evidence of HIV infection from the collecting establishment, or after receiving the donor's reactive screening test result for HIV if there is no available supplemental test that is approved for such use by FDA, or if under an IND or IDE is exempted for such use by FDA.

(c) Actions under this section do not constitute a recall as defined in § 7.3 of this chapter.

7. Section 610.47 is revised to read as follows:

§ 610.47 Hepatitis C virus (HCV) "lookback" requirements.

(a) If you are an establishment that collects Whole Blood or blood components, including Source Plasma and Source Leukocytes, you must establish, maintain, and follow an appropriate system for the following actions:

(1) Within 3 calendar days after a donor tests reactive for evidence of hepatitis C virus (HCV) infection when tested under § 610.40(a) and (b) of this chapter or when you are made aware of other reliable test results or information indicating evidence of HCV infection, you must review all records required under § 606.160(d) of this chapter, to identify blood and blood components previously donated by such a donor. For those identified blood and blood components collected:

(i) Twelve months and less before the donor's most recent nonreactive screening tests, or

(ii) Twelve months and less before the donor's reactive direct viral detection test, e.g., nucleic acid test and nonreactive antibody screening test, whichever is the lesser period, you must:

(A) Quarantine all previously collected in-date blood and blood components identified under paragraph (a)(1) of this section if intended for use in another person or for further manufacture into injectable products, except pooled blood

components intended solely for further manufacturing into products that are manufactured using validated viral clearance procedures; and

(B) Notify consignees to quarantine all previously collected in-date blood and blood components identified under paragraph

(a) (1) of this section if intended for use in another person or for further manufacture into injectable products, except pooled blood components intended solely for further manufacturing into products that are manufactured using validated viral clearance procedures;

(2) You must perform a supplemental (additional, more specific) test for HCV as required under § 610.40(e) on the reactive donation.

(3) You must notify consignees of the supplemental (additional, more specific) test results for HCV, or the results of the reactive screening test if there is no available supplemental test that is approved for such use by FDA, or if under an investigational new drug application (IND) or investigational device exemption (IDE), is exempted for such use by FDA, within 45 calendar days after the donor tests reactive for evidence of HCV infection under § 610.40(a) and (b).

Notification of consignees must include the test results for blood and blood components identified under paragraph (a) (1) of

this section that were previously collected from donors who later test reactive for evidence of HCV infection.

(4) You must release from quarantine, destroy, or relabel quarantined in-date blood and blood components consistent with the results of the supplemental (additional, more specific) test performed under paragraph (a) (2) of this section, or the results of the reactive screening test if there is no available supplemental test that is approved for such use by FDA, or if under an IND or IDE, exempted for such use by FDA.

(b) If you are a consignee of Whole Blood or blood components, including Source Plasma or Source Leukocytes, you must establish, maintain, and follow an appropriate system for the following actions:

(1) You must quarantine all previously collected in-date blood and blood components identified under paragraph (a) (1) of this section, except pooled blood components intended solely for further manufacturing into products that are manufactured using validated viral clearance procedures, when notified by the collecting establishment.

(2) You must release from quarantine, destroy, or relabel quarantined in-date blood and blood components, consistent with the results of the supplemental (additional, more specific) test performed under paragraph (a) (2) of this section, or the results of the reactive screening test if there is no available

supplemental test that is approved for such use by FDA, or if under an IND or IDE, is exempted for such use by FDA.

(3) When the supplemental (additional, more specific) test for HCV is positive or when the screening test is reactive and there is no available supplemental test that is approved for such use by FDA, or if under an IND or IDE, is exempted for such use by FDA, you must notify transfusion recipients of previous collections of blood and blood components at increased risk of transmitting HCV infection, or the recipient's physician of record, of the need for recipient HCV testing and counseling. You must notify the recipient's physician of record or a legal representative or relative if the recipient is a minor, adjudged incompetent by a State court, or if the recipient is competent but State law permits a legal representative or relative to receive information on behalf of the recipient. You must make reasonable attempts to perform the notification within 12 weeks after receiving the supplemental (additional, more specific) test results for evidence of HCV infection from the collecting establishment, or after receiving the donor's reactive screening test result for HCV if there is no available supplemental test that is approved for such use by FDA, or if under an IND or IDE, is exempted for such use by FDA.

(c) Actions under this section do not constitute a recall as defined in § 7.3 of this chapter.

8. Section 610.48 is added to subpart E to read as follows:

§ 610.48 Hepatitis C virus (HCV) "lookback" requirements based on review of historical testing records.

(a) Establishments that collect Whole Blood or blood components, including Source Plasma and Source Leukocytes, must complete the following actions by [insert date 545 days after date of publication in the FEDERAL REGISTER].

(b) If you are an establishment that collects Whole Blood or blood components, including Source Plasma and Source Leukocytes, you must establish, maintain, and follow an appropriate system for the following actions:

(1) You must:

(i) Review all records of donor testing for hepatitis C virus (HCV) performed before [insert date 180 days after date of publication in the FEDERAL REGISTER]. The review must include records dating back indefinitely for computerized electronic records, and to January 1, 1988, for all other records. Record review, quarantine, testing, notification, and disposition performed before [insert date 180 days after date of publication in the FEDERAL REGISTER] that otherwise satisfy the requirements under § 610.47, are exempt from this section.

(ii) Identify donors who tested reactive for evidence of HCV infection. Donors who tested reactive by a screening test and negative by an appropriate supplemental (additional, more

specific) test under § 610.40(e) for evidence of HCV infection on the same donation are not subject to further action.

(iii) Identify the blood and blood components previously collected from such donors:

(A) Twelve months and less before the donor's most recent nonreactive screening tests, or

(B) Twelve months and less before the donor's reactive direct viral detection test, e.g., nucleic acid test and nonreactive antibody screening test, whichever is the lesser period.

(2) If you did not perform a supplemental (additional, more specific) test at the time of the reactive donation, you may perform a supplemental test or a licensed screening test with known greater sensitivity than the test of record using either a frozen sample from the same reactive donation or a fresh sample from the same donor, if obtainable. If neither is available, proceed with paragraphs (b) (3), (b) (4), and (b) (5) of this section.

(3) You must, within 3 calendar days after identifying the blood and blood components previously collected from donors who tested reactive for evidence of HCV infection:

(i) Quarantine all previously collected in-date blood and blood components identified under paragraph (b) (1) (iii) of this section if intended for use in another person or for further

manufacture into injectable products, except pooled components solely intended for further manufacturing into products that are manufactured using validated viral clearance procedures.

(ii) Notify consignees to quarantine all previously collected in-date blood and blood components identified under paragraph (b)(1)(iii) of this section if intended for use in another person or for further manufacture into injectable products, except pooled blood components intended solely for further manufacturing into products that are manufactured using validated viral clearance procedures; and

(iii) Notify consignees of the donor's test results, including the results of a supplemental (additional, more specific) test or a licensed screening test with known greater sensitivity than the test of record, if available at that time.

(4) You must notify consignees of the results of the supplemental (additional, more specific) test or the licensed screening test with known greater sensitivity than the test of record for HCV, if performed, within 45 calendar days of completing the further testing. Notification of consignees must include the test results for blood and blood components identified under paragraph (b)(1)(iii) of this section that were previously collected from a donor who later tests reactive for evidence of HCV infection.

(5) You must release from quarantine, destroy, or relabel quarantined in-date blood and blood components consistent with the results of the further testing performed under paragraph (b) (2) of this section or the results of the reactive screening test if there is no available supplemental test that is approved for such use by FDA, or if under an investigational new drug application (IND) or investigational device exemption (IDE), is exempted for such use by FDA.

(c) If you are a consignee of Whole Blood or blood components, including Source Plasma and Source Leukocytes, you must establish, maintain, and follow an appropriate system for the following actions, which you must complete within 1 year of the date of notification by the collecting establishment:

(1) You must quarantine all previously collected in-date blood and blood components identified under paragraph (b) (1) (iii) of this section, except pooled blood components solely intended for further manufacturing into products that are manufactured using validated viral clearance procedures, when notified by the collecting establishment.

(2) You must release from quarantine, destroy, or relabel quarantined in-date blood and blood components, consistent with the results of the further testing performed under paragraph (b) (2) of this section, or the results of the reactive screening test if there is no available supplemental test that is approved

for such use by FDA, or if under an IND or IDE is exempted for such use by FDA.

(3) When the supplemental (additional, more specific) test for HCV is positive; or the supplemental test is indeterminate, but the supplemental test is known to be less sensitive than the screening test; or the screening test is reactive and there is no available supplemental test that is approved for such use by FDA, or if under an IND or IDE, is exempted for such use by FDA; or if supplemental testing is not performed, you must make reasonable attempts to notify transfusion recipients of previous collections of blood and blood components at increased risk of transmitting HCV infection, or the recipient's physician of record, of the need for recipient HCV testing and counseling. You must notify the recipient's physician of record or a legal representative or relative if the recipient is a minor, adjudged incompetent by a State court, or if the recipient is competent but State law permits a legal representative or relative to receive information on behalf of the recipient.

(d) Actions under this section do not constitute a recall as defined in § 7.3 of this chapter.

(e) This section will expire on [insert date 8 years after date of publication in the FEDERAL REGISTER].

Date: 7/5/07
July 5, 2007.



Jeffrey Shuren,
Assistant Commissioner for Policy.

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