U.S. Food and Drug Administration
Current Good Manufacturing Practice (CGMP) and
Related Regulations for Blood and Blood Components;
and Requirements for Donation Testing,
Donor Notification, and "*Lookback*"

OMB Control No. 0910-0116

SUPPORTING STATEMENT **Part A: Justification**

1. Circumstances Making the Collection of Information Necessary

This information collection supports Food and Drug Administration (FDA, us or we) regulations. All blood and blood components introduced or delivered for introduction into interstate commerce are subject to section 351(a) of the Public Health Service Act (PHS Act) (42 U.S.C. 262(a)). Section 351(a) of the PHS Act requires that manufacturers of biological products, which include blood and blood components intended for further manufacture into products, have a license, issued upon a demonstration that the product is safe, pure, and potent and that the manufacturing establishment meets all applicable standards, including those prescribed in the FDA regulations designed to ensure the continued safety, purity, and potency of the product.

In addition, under section 361 of the PHS Act (42 U.S.C. 264), by delegation from the Secretary of Health and Human Services, FDA may make and enforce regulations necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States or possessions, or from one State or possession into any other State or possession. Section 351(j) of the PHS Act states that the Federal Food, Drug, and Cosmetic (FD&C Act) also applies to biological products. Blood and blood components for transfusion or for further manufacture into products are drugs, as that term is defined in section 201(g)(1) of the FD&C Act (21 U.S.C. 321(g)(1)). Because blood and blood components are drugs under the FD&C Act, blood and plasma establishments must comply with the substantive provisions and related regulatory scheme of the FD&C Act.

To implement these statutory provisions, regulations have been codified at 21 CFR Part 606 – *Current Good Manufacturing Practice for Blood and Blood Components*; 21 CFR Part 610 – *General Biological Products Standards*; 21 CFR Part 630 – *Requirements for Blood and Blood Components Intended For Transfusion or For Further Manufacturing Use*; and 21 CFR Part 640 – *Additional Standards for Human Blood and Blood Products*. The regulations establish quality standard requirements applicable to blood and blood products including information collection provisions. Accordingly, we request extension of OMB approval of the information collection provisions found in the applicable regulations and discussed in this supporting statement.

2. Purpose and Use of the Information Collection

The CGMP regulations for human blood and blood components (Part 606) and related regulations (Parts 610, 630, and 640) implement FDA's statutory authority to ensure the safety, purity, and potency of blood and blood components. The public health objective in testing

human blood donors for evidence of infection due to relevant transfusion-transmitted infections and in notifying donors is to prevent the transmission of relevant transfusion-transmitted infections. For example, the "lookback" requirements are intended to help ensure the continued safety of the blood supply by providing necessary information to consignees of blood and blood components and appropriate notification of recipients of transfusions that are at increased risk for transmitting HIV or HCV infection.

Consistent with the regulations, records maintained shall be made readily available for authorized inspection. FDA is authorized to inspect these records under section 704 of the FD&C Act (21 U.S.C. 374) (and its enforcement section under section 301(f) of the FD&C Act 21 U.S.C. 331(f)). We use the information to help determine compliance with regulatory requirements established to ensure the safety and efficacy of the covered products. The third-party disclosure requirements identify the various blood and blood components and important properties of the product, demonstrate that the CGMP requirements have been met, and facilitate the tracing of a product back to its original source. The reporting requirements inform FDA of certain information that may require immediate corrective action.

FDA allows the use or shipment prior to test results of human blood or blood components under two circumstances: appropriately documented medical emergency situations or for further manufacturing use as approved in writing by FDA. Use or shipment prior to test results may occur, provided the consignee is notified that test results are not available, the tests for evidence of infection due to relevant transfusion-transmitted infections are performed as soon as possible after release or shipment, and the results are provided promptly to the consignee. The regulations require an establishment to document the emergency release or shipment of blood or blood components prior to completion of testing. If the establishment ships blood or blood components for further manufacturing use prior to completion of testing, the establishment must obtain prior approval from FDA. In either instance, the establishment must complete testing as soon as possible thereafter, and must notify the consignee of test results as soon as they are available. Prior approval is necessary to help ensure that an establishment is following proper procedures in shipping potentially infectious blood and blood components for further manufacturing use. Without this information, FDA could not monitor industry procedures and discharge its statutory responsibility for protecting the nation's health.

The donor notification process is intended to prevent further donations from donors who have been deferred for positive test results for markers of certain relevant transfusion-transmitted infections as prescribed in § 610.41 or for failing to satisfy the donor eligibility criteria under §§ 630.10 and 630.15 prior to collection. Deferred donors are informed of: (1) The reason for the decision; (2) the types of donation that the donor should not donate in the future, if appropriate; (3) the results of the tests for evidence of infection due to relevant transfusion-transmitted infections that were the basis for deferral, if applicable; and (4) information concerning medical follow-up and counseling. By having this information, the deferred donor may make informed decisions as to his or her medical welfare.

3. Use of Improved Information Technology and Burden Reduction

The regulations do not prescribe specific means by which respondents must fulfill the information collection requirements. Establishments may use computers, computer discs, tapes, microfiche, or microfilm in lieu of hard copy records for the purpose of maintaining records. Computers may be used for emailing reports to FDA. Notification of consignees can be accomplished by e-mail, phone, fax, or mail. There are no technical obstacles for electronic reporting of the applicable information to FDA. FDA continues to pursue methods of applying technology to reduce burden to the respondents of its information collection.

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection. Although OMB Control No. 0910-0795 (Requirements for Blood and Blood Components Intended for Transfusion or for Further Manufacturing Use – Final Rule) was established to support amendments to the underlying regulations (RIN 0910-AG87), we have submitted a request to discontinue that collection as the information collection burden is now reflected here. Also, while GMP or quality system (QS) regulations appear in several parts of Title 21 (Food and Drugs) of the CFR, this information collection covers requirements applicable to blood and blood products as described under 21 CFR Parts 606, 630, and 640, and in this supporting statement.

5. Impact on Small Businesses or Other Small Entities

The public health protection requirements underlying the information collection apply to all respondents; however, we believe they impose no undue burden on small entities. At the same time, we assist small businesses in complying with agency requirements through our Regional Small Business Representatives and through the scientific and administrative staffs within the agency. We also provide a Small Business Guide on our website at http://www.fda.gov/ForIndustry/SmallBusinessAssistance/default.htm.

6. Consequences of Collecting the Information Less Frequently

The information collection schedule is consistent with statutory and agency requirements established to promote and protect the public health. There are no technical or legal obstacles to reducing the burden.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances for this collection of information.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

In accordance with 5 CFR 1320.8(d), FDA published a 60-day notice for public comment in the Federal Register of January 23, 2018 (83 FR 3165). One comment was received but was not responsive to the four collection of information topics solicited and was therefore not addressed.

9. Explanation of Any Payment or Gift to Respondents

No payment or gift is provided to respondents.

10. Assurance of Confidentiality Provided to Respondents

The confidentiality of information received by FDA is consistent with the Freedom of Information Act (FOIA) and FDA's published regulations of "Public Information" under 21 CFR Part 20. After an FDA investigator completes a routine inspection of a blood or blood component manufacturing establishment, the completed report with the results of the inspection becomes public information, available under the FOIA. However, certain information, such as donor and patient names, for example, is deleted from any information released by FDA under the FOIA and FDA regulations. Manufacturers of human blood and blood components are not required to reveal any proprietary information or trade secrets to achieve compliance with the provisions.

11. Justification for Sensitive Questions

Establishments as part of the donation screening process for blood collection must ask questions of a sensitive nature. These questions are used to evaluate the suitability of a donor. Donors not meeting certain criteria are deferred from donating. This information is necessary to help prevent the transmission of communicable diseases and protect public health. These records are maintained by the establishment and may be reviewed by FDA during an inspection.

12. Estimates of Annualized Burden Hours and Costs

Respondents to the information collection are licensed and unlicensed blood establishments that collect blood and blood components, including Source Plasma and Source Leukocytes, inspected by FDA, and other transfusion services inspected by Centers for Medicare and Medicaid Services (CMS). Based on information received from CBER's database systems, there are approximately 569 licensed Source Plasma establishments and approximately 1,054 licensed blood collection establishments, for an estimated total of 1,623 (569+1,054) establishments. Also, there are an estimated total of 680 unlicensed, registered blood collection establishments for an approximate total of 2,303 collection establishments (569 + 1,054 + 680 = 2,303 establishments). Of these establishments, approximately 901 perform plateletpheresis and leukopheresis. These establishments annually collect approximately 53.3 million units of Whole Blood and blood components, including Source Plasma and Source Leukocytes, and are required to follow FDA "*lookback*" procedures. In addition, there are another 4,961 establishments that fall under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) (formerly referred to as facilities approved for Medicare reimbursement) that transfuse blood and blood components.

The reporting, recordkeeping, and disclosure estimates are based on information provided by industry, CMS, and FDA experience. Based on information received from industry, FDA estimates that there are approximately 38.3 million donations of Source Plasma from

approximately 2 million donors and approximately 15 million donations of Whole Blood and apheresis Red Blood Cells, including approximately 34,500 (approximately 0.23 percent of 15 million) autologous donations, from approximately 10.9 million donors. Assuming each autologous donor makes an average of 1.1 donations, FDA estimates that there are approximately 31,364 autologous donors (34,500 autologous/1.1 average donations).

FDA estimates that approximately 0.19 percent (21,000/10,794,000) of the 72,000 donations that are donated specifically for the use of an identified recipient would be tested under the dedicated donors testing provisions in § 610.40(c)(1)(ii).

Under § 610.40(g)(2) and (h)(2)(ii)(A), Source Leukocytes, a licensed product that is used in the manufacture of interferon, which requires rapid preparation from blood, is currently shipped prior to completion of testing for evidence of infection due to relevant transfusion-transmitted infections. Shipments of Source Leukocytes are approved under a biologics license application and each shipment does not have to be reported to the Agency. Based on information from CBER's database system, FDA receives less than one application per year from manufacturers of Source Leukocytes. However, for calculation purposes, FDA is estimating one application annually.

According to CBER's database system, there are approximately 15 licensed manufacturers that ship known reactive human blood or blood components under §§ 610.40(h)(2)(ii)(C) and (D). FDA estimates that each manufacturer would ship an estimated 1 unit of human blood or blood components per month (12 per year) that would require two labels; one as reactive for the appropriate screening test under § 610.40(h)(2)(ii)(C), and the other stating the exempted use specifically approved by FDA under § 610.40(h)(2)(ii)(D).

Based on information FDA received from industry, FDA estimates that approximately 7,544 donations that test reactive by a screening test for syphilis, and are determined to be biological false positives by additional testing annually. These units would be labeled accordingly (§ 610.40(h)(2)(vi)).

Human blood or a blood component with a reactive screening test, as a component of a medical device, is an integral part of the medical device, e.g., a positive control for an in vitro diagnostic testing kit. It is usual and customary business practice for manufacturers to include on the container label a warning statement that the product was manufactured from a donation found to be reactive for the identified relevant transfusion-transmitted infection(s). In addition, on the rare occasion when a human blood or blood component with a reactive screening test is the only component available for a medical device that does not require a reactive component, then a warning statement must be affixed to the medical device. To account for this rare occasion under § 610.42(a), FDA estimates that the warning statement would be necessary no more than once a year.

FDA estimates that approximately 3,021 repeat donors will test reactive on a screening test for HIV. FDA also estimates that an average of three components was made from each donation. Under § 610.46(a)(1)(ii)(B) and (a)(3), this estimate results in 9,063 (3,021 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 9,063 (3,021 x 3) notifications to consignees of subsequent test results. FDA estimates an average of 10 minutes per notification of consignees.

FDA estimates that approximately 4,961 consignees will be required under § 610.46(b)(3) to notify transfusion recipients, their legal representatives, 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. Also under § 610.46(b)(3), FDA estimates and include the time to gather test results and records for each recipient and to accommodate multiple attempts to contact the recipient.

Furthermore, FDA estimates that approximately 6,799 repeat donors per year would test reactive for antibody to HCV. Under § 610.47(a)(1)(ii)(B) and 610.47(a)(3), collecting establishments would notify the consignee 2 times for each of the 20,397 (6,799 x 3 components) components prepared from these donations, once for quarantine purposes and again with additional HCV test results for a total of 40,794 (2 x 20,397 notifications) notifications as an annual ongoing burden. Under § 610.47(b)(3), FDA estimate that approximately 4,961 consignees would notify approximately 2,050 recipients or their physicians of record annually.

Based on industry estimates, roughly 14.3 percent of 9 million potential donors (1,287,000 donors) who come to donate annually are determined not to be eligible for donation prior to collection because of failure to satisfy eligibility criteria. It is the usual and customary business practice of approximately 1,734 (1,054+680) blood collecting establishments to notify onsite and to explain why the donor is determined not to be suitable for donating. Based on such available information, FDA estimates that two-thirds (1,156) of the 1,734 blood collecting establishments provided on site additional information and counseling to a donor determined not to be eligible for donation as usual and customary business practice. Consequently, FDA estimates that only approximately one-third, or 578 of the 1,734, blood collection establishments would need to provide, under § 630.40(a), additional information and counseling to the estimated 429,000 (one-third of approximately 1,287,000) ineligible donors.

It is estimated that another 4.5 percent of 10 million donors (450,000 donors) are deferred annually based on test results. FDA estimates that approximately 95 percent of the establishments that collect 99 percent of the blood and blood components notify donors who have reactive test results for HIV, Hepatitis B Virus (HBV), HCV, Human T-Lymphotropic Virus (HTLV), and syphilis as usual and customary business practice. Consequently, 5 percent of the 1,623 establishments (81) collecting 1 percent (4,050) of the deferred donors (405,000) would notify donors under § 630.40(a).

As part of usual and customary business practice, collecting establishments notify an autologous donor's referring physician of reactive test results obtained during the donation process required under § 630.40(d)(1). However, FDA estimates that approximately 5 percent of the 1,054 blood collection establishments (53) may not notify the referring physicians of the estimated 2 percent of 31,364 autologous donors with reactive test results (627) as their usual and customary business practice.

The recordkeeping chart reflects the estimate that approximately 95 percent of the recordkeepers, which collect 99 percent of the blood supply, have developed SOPs as part of their customary and usual business practice. Establishments may minimize burdens associated with CGMP and related regulations by using model standards developed by industries' accreditation organizations. These accreditation organizations represent almost all registered blood establishments.

Under § 606.160(b)(1)(x), FDA estimates the total annual records based on the 1,287,000 donors determined not to be eligible to donate and each of the estimated 1,692,000 (1,287,000 + 405,000) donors deferred based on reactive test results for evidence of infection because of relevant transfusion-transmitted infections. Under § 606.160(b)(1)(xi), only the 1,734 registered blood establishments collect autologous donations and, therefore, are required to notify referring physicians. FDA estimates that 4.5 percent of the 31,364 autologous donors (1,411) will be deferred under § 610.41 which in turn will lead to the notification of their referring physicians.

Under § 610.41(b), FDA estimates that there would be 25 submissions for requalification of donors. In addition, FDA estimates that there would be only 3 notifications for requalification of donors under § 630.35(b). FDA also estimates the average time for each submission.

FDA permits the shipment of untested or incompletely tested but appropriately documented human blood or blood components in rare medical emergencies and when appropriately documented (§ 610.40(g)(1)). FDA estimates the recordkeeping under § 610.40(g)(1) to be minimal with one or fewer occurrences per year. The reporting/disclosure of test results to the consignee in § 610.40(g) does not create a new burden for respondents because it is the usual and customary business practice of blood establishments.

The average burden per response (hours) and the average burden for recordkeeping (hours) are based on estimates received from industry or FDA experience with similar recordkeeping or reporting requirements.

The development of labels is a one-time burden. The container labels have been standardized and are sold commercially. The label is only customized for the firm's name and address. In addition, the instruction circular is printed by major blood banking associations, the ARC, AABB, and ABC, and are sold at minimal cost to the firms. The circulars are updated annually usually due to new industry information. Therefore no burden is imposed by FDA regarding the labeling and disclosure regulations (§§ 606.121 and 606.122) and Uniform Labeling of Blood and Blood Components using ISBT 128 (Industry Consensus Standard for the Uniform Labeling of Blood and Blood Components Using ISTB 128.

12a. Annualized Hour Burden

Based on this review, our estimate of the annual hourly burden associated with the information collection is as follows:

Table 1.--Estimated Annual Reporting Burden[1]

21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
606.170(b)[2]	81	1	81	20	1,620
610.40(g)(2)	1	1	1	1	1
610.41(b)	1,623	0.015	25	7	175
610.40(h)(2)(ii)(A)	1	1	1	1	1
630.35(b)	1,623	0.002	3	7	21
TOTAL			111		1,818

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] The reporting requirement in § 640.73, which addresses the reporting of fatal donor reactions, is included in the estimate for § 606.170(b).

Table 2.--Estimated Annual Recordkeeping Burden[1]

21 CFR Section/Activity	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
606.100(b)[2]	[5]363	1	363	24	8,712
606.100(c)	[5]363	10	3,630	1	3,630
606.110(a)[3]	[6]45	1	45	0.5 (30 min)	23
606.151(e)	[5]363	12	4,356	0.08 (5 min.)	348
606.160[4]	[5]363	1,055.096	383,000	0.75 (45 min.)	287,250
606.160(b)(1)(viii) HIV consignee notification	1,734	10.4533	18,126	0.17 (10 min.)	3,081
	4,961	3.6537	18,126	0.17 (10 min.)	3,081
606.160(b)(1)(viii) HCV consignee notification	1,734	23.5259	40,794	0.17 (10 min.)	6,935
	4,961	8.2229	40,794	0.17 (10 min.)	6,935
HIV recipient notification	4,961	0.3538	1,755	0.17 (10 min.)	298
HCV recipient notification	4,961	0.4132	2,050	0.17 (10 min.)	349
606.160(b)(1)(x)	2,303	734.6939	1,692,000	0.05 (3 min.)	84,600
606.160(b)(1)(xi)	1,734	0.8137	1,411	0.05 (3 min.)	71
606.165	[5]363	1,055.096	383,000	0.08 (5 min.)	30,640
606.170(a)	[5]363	12	4,356	1	4,356
610.40(g)(1)	2,303	1	2,303	0.5 (30 min.)	1,152
630.15(a)(1)(ii)(B)	1,734	1	1,734	1	1,734
630.20(c)	1,734	1	1,734	1	1,734
TOTAL			2,599,577		444,929

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] The recordkeeping requirements in §§ 606.171, 610.46(a) and (b), 610.47(a) and (b), 630.5(d), 630.10(c)(1) and (2), and 640.66, which address the maintenance of SOPs, are included in the estimate for § 606.100(b).
[3] The recordkeeping requirements in § 640.27(b), which address the maintenance of donor health records for the plateletpheresis, are included in the estimate for § 606.110(a).
[4] The recordkeeping requirements in §§ 606.110(a)(2); 630.5(b)(1)(i); 630.109(f)(2) and (4); 630.10(g)(2)(i); 630.15(a)(1)(ii)(A) and (B); 630.15(b)(2), (b)(7)(i) and (iii); 630.20(a) and (b); 640.21(e)(4); 640.25(b)(4) and (c)(1); 640.31(b); 640.33(b);

640.51(b); 640.53(b) and (c); 640.56(b) and (d); 630.15(b)(2); 640.65(b)(2)(i); 640.71(b)(1); 640.72; 640.73; and 640.76(a) and (b), which address the maintenance of various records are included in the estimate for § 606.160.
[5]Five percent of establishments that fall under CLIA that transfuse blood and components and FDA-registered blood establishments (0.05 × 4,961 + 2,303 = 363).
[6]Five percent of plateletpheresis and leukopheresis establishments (0.05 × 901 = 45).

Table 3.--Estimated Annual Third-Party Disclosure Burden[1]

21 CFR Section	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Average Burden per Disclosure	Total Hours
606.145(c)	4,961	0.2822	1,400	0.02	28
606.170(a)	[2]363	12	4,356	0.5 (30 min.)	2,178
610.40(c)(1)(ii)	2,303	0.0595	137	0.08 (5 min.)	11
610.40(h)(2)(ii)(C) and (h)(2)(ii)(D)	15	12	180	0.20 (12 min.)	36
610.40(h)(2)(vi)	2,303	3.28	7,554	0.08 (5 min.)	604
610.42(a)	1	1	1	1	1
610.46(a)(1)(ii)(B)	1,734	5.2266	9,063	0.17 (10 min.)	1,541
610.46(a)(3)	1,734	5.2266	9,063	0.17 (10 min.)	1,541
610.46(b)(3)	4,961	0.3538	1,755	1	1,755
610.47(a)(1)(ii)(B)	1,734	11.7630	20,397	0.17 (10 min.)	3,467
610.47(a)(3)	1,734	11.7630	20,397	0.17 (10 min.)	3,467
610.47(b)(3)	4,961	0.4132	2,050	1	2,050
630.40(a)[3]	578	742.214	429,000	0.08 (5 min.)	34,320
630.40(a)[4]	81	50	4,050	1.5	6,075
630.40(d)(1)	53	11.83	627	1	627
TOTAL			510,030		57,701

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.
[2]Five percent of establishments that fall under CLIA that transfuse blood and components and FDA-registered blood establishments (0.05 × 4,961 + 2,303 = 363).
[3]Notification of donors determined not to be eligible for donation based on failure to satisfy eligibility criteria.
[4]Notification of donors deferred based on reactive test results for evidence of infection due to relevant transfusion-transmitted infections.

12b. Annualized Cost Burden Estimate

The estimated annual cost to respondents is $33,798,083.

Activity	Total Burden Hours	Hourly Wage Rate	Total Respondent Cost
Reporting	1,818	$67	$121,806
Recordkeeping	444,930	$67	$29,810,310
Disclosure	57,701	$67	$3,865,967
Total			$33,798,083

The cost is based on a pay rate of $44/hour for a medical technologist (MT), who is responsible for recording donor, quarantine, testing, and disposition of information, notifying consignees of test results, and has the training and skills to handle various recordkeeping requirements. The cost estimate is also based on a supervisor, at a pay rate of $59/hour who is responsible for updating SOPs, recording donor information, and notifying physicians of recipients or recipients of test results, investigating, writing, and reporting a fatality, and a Medical Director (MD), at a pay rate of $97/hour, who is responsible for updating SOPs, recording donor information, and notifying physicians of recipients or recipients of test results, investigating, writing, and reporting a fatality. These salary estimates include recordkeeping, reporting, and disclosure requirements that are performed by the MT, supervisor, or MD; the cost/hour includes the average salary of the three ($67). These salary estimates include benefits but no overhead costs.

13. Estimates of Other Total Annual Cost Burden to Respondents and/or Recordkeepers/Capital Costs

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

14. Annualized Cost to the Federal Government

The estimated annualized cost to the Federal Government is $1,881,876. This estimate is based on a FDA reviewer or investigator at an average grade scale of GS-12/5 ($56/hour), who reviews the requests for approval submitted under §§ 610.40(g)(2) and 610.40(h)(2)(ii)(A), or performs biannual on-site inspections. The inspection cost includes inspection of a facility, review of facility records, and report preparation. The cost is based on 811 inspections, since the 1,623 facilities are inspected biannually. The estimated cost is also based on a GS-13/5 ($67/hour) Consumer Safety Officer who compiles, reviews, and analyzes fatality reports. In Fiscal Year 2016, FDA received 81 fatality reports. These salary estimates include benefits but no overhead costs.

Activity	Number of Respondents	Number of Hours	Cost per Hour	Total Cost
Product Release Review	2	1	$56	$112
Inspection	811	40	$56	$1,816,640
Fatality Report Review	81	12	$67	$65,124
Total				$1,881,876

15. Explanation for Program Changes or Adjustments

The information collection reflects both changes as adjustments. As noted previously, we have revised the collection to incorporate burden estimates previously accounted for under OMB Control No. 0910-0795, which was established to support rulemaking (0910-AG87) that amended the applicable regulations. At the same time, data suggests there are somewhat fewer respondents to the collection than previously estimated and we have therefore adjusted the number of respondents. Cumulatively this results in an overall decrease by 100,126 annual

responses and 5,725 burden hours. Finally, we have revised the IC list appearing at www.reginfo.gov by consolidating the previously itemized regulatory provisions. We believe this will assist the reader by more easily identifying the summary of cumulative fluctuations for the collection. At the same time, readers may still view estimated burden associated with individual provisions by referring to the agency's 60-day and 30-day notices and in the burden tables found in *Question 12: Estimates of Annualized Burden Hours and Costs* of this supporting statement.

16. Plans for Tabulation and Publication and Project Time Schedule

There are no tabulated results to publish for this information collection.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

FDA is not seeking approval to exempt display of the expiration date for OMB approval.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.