HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/Ps): ESTABLISHMENT REGISTRATION AND LISTING; FORM FDA 3356; ELIGIBILITY DETERMINATION FOR DONORS; AND CURRENT GOOD TISSUE PRACTICE

0910-0543

SUPPORTING STATEMENT

A. Justification

1. Circumstances Making the Collection of Information Necessary

The Food and Drug Administration (FDA) is requesting an extension of Office of Management and Budget (OMB) Control No. 0910-0543 and OMB approval of the information collection provisions in 21 CFR Part 1271 including Form FDA 3356. The information collection provisions are listed below:

21 CFR Section	Category	Description
1271.10(b)(1) and (b)(2) and 1271.21(b)	Reporting	Requires domestic and foreign establishments that recover, process, store, label, package, or distribute human cells, tissues, and cellular and tissue-based products (HCT/Ps) described in § 1271.10(a), or that perform screening or testing of the cell or tissue donor to register with FDA; and submit a list of each HCT/P manufactured; and requires an annual update of the establishment registration.
1271.21(a), and 1271.25(a) and (b)	Reporting	Requires establishments to follow certain procedures for initial registration and listing of HCT/Ps; and identifies the required initial registration and HCT/P listing information.
1271.10(b)(2), 1271.21(c) (ii) and 1271.25(c)	Reporting	Requires establishments to submit HCT/P listing updates if an HCT/P has changed; and identifies the required HCT/P listing update information.
1271.26	Reporting	Requires establishments to submit an amendment if ownership or location of the establishment changes.
1271.55(a)	Disclosure	Requires certain records to accompany an HCT/P once the donor-eligibility determination has been made.
1271.60(c) and (d)(2)	Disclosure	Requires, when a product is shipped in quarantine before completion of screening and testing, the HCT/P is to be accompanied by records identifying the donor, stating that the donor-eligibility determination has not been completed; and stating that the product must not be implanted, transplanted, infused, or transferred until completion of the eligibility determination. When an HCT/P is used in cases of documented urgent medical need, the results of any completed donor screening and testing, and a list of any required screening and testing

		not yet completed also must accompany the HCT/P.
1271.155(a)	Reporting	Permits the submission of a request for FDA approval of an exemption from or alternative to from any requirement in 21 CFR Part 1271 subpart C or D.
1271.290(c)	Disclosure	Requires establishments to affix a distinct identification code to each HCT/P that it manufactures that relates the HCT/P to the donor and all records pertaining to the HCT/P.
1271.290(f)	Disclosure	Requires establishments to inform the consignee, in writing, of the product tracking requirements and the methods the establishment uses to fulfill the requirements.
1271.350(a)(1) and (a)(3)	Reporting	Requires non-reproductive HCT/P establishments to investigate and report to FDA any adverse reactions using Form FDA 3500A (form approved under OMB Control No. 0910-0291).
1271.370(b) and (c)	Disclosure	Requires establishments to include specific information either on the HCT/P label or with the HCT/P.
1271.47(a), 1271.85(b)(2), 1271.160(b)(2) and (d)(1), 1271.180(a), 1271.190(d)(1), 1271.200(b) and (c), 1271.230(a), 1271.250(a), and 1271.265(e), 1271.265(f), 1271.270(b) and (d), 1271.290(b)(1), 1271.320(a)	Recordkeeping	Requires establishment to establish and maintain procedures: (1) for all steps that are performed in determining eligibility; (2) appropriate to meet core Current Good Tissue Practice (CGTP) requirements that are performed in the manufacture of HCT/Ps; and (3) for other standard operating procedures under 21 CFR Part 1271.
1271.47(d)	Recordkeeping	Requires HCT/P establishments to record and justify any departure from a procedure relevant to preventing risks of communicable disease transmission at the time of its occurrence.
1271.50(a)	Recordkeeping	Requires documentation of donor eligibility determination by a responsible person based on the results of required donor screening.
1271.55(d)(1)	Recordkeeping	Requires records used in determining the eligibility of a donor, i.e., results and interpretations of testing for relevant communicable disease agents, the donor eligibility determination, the name and address of the

		testing laboratory or laboratories, and the name of the responsible person (defined in §1271.3(t)) who made the donor eligibility determination and the date of the determination, must be maintained.
1271.55(d)(2)	Recordkeeping	Requires if any information on the donor is not in English, the original record to be maintained and translated to English, and accompanied by a statement of authenticity from the translator.
1271.55(d)(4)	Recordkeeping	Requires HCT/P establishments to retain the records pertaining to HCT/Ps at least 10 years after the date of administration, or if the administration is not known, then at least 10 years after the date of HCT/P distribution, disposition, or expiration, whichever is latest.
1271.60(d)(3) and (d)(4) and 1271.65(b)(3)	Recordkeeping	Requires, when an HCT/P is used in cases of documented urgent need or from a donor who has been determined to be ineligible (as permitted under § 1271.65), documentation by the HCT/P establishment showing that the recipient's physician received notification that the testing and screening were not complete (in cases of urgent medical need), and upon the completion of the donor-eligibility determination, of the results of the determination.
1271.155(f)	Recordkeeping	Requires an establishment operating under the terms of an exemption or alternative to maintain documentation of FDA's grant of the exemption of approval and the date on which it began operating under the terms of the exemption or alternative.
1271.160(b)(3) and (b)(6)	Recordkeeping	Requires the quality program of an establishment that performs any step in the manufacture of HCT/Ps to document corrective actions relating to core CGTP requirements; and requires documentation of CGTP deviations.
1271.160(d)	Recordkeeping	Requires, in brief, documentation of validation of computer software if the establishment relies upon it to comply with the core CGTP requirements.
1271.190(d)(2)	Recordkeeping	Requires documentation of all cleaning and sanitation performed to prevent contamination of HCT/Ps.
1271.195(d)	Recordkeeping	Requires documentation of environmental control and monitoring activities.
1271.200(e)	Recordkeeping	Requires documentation of equipment maintenance, cleaning, sanitizing, calibration, and other activities.

1271.210(d)	Recordkeeping	Requires, in brief, documentation of the receipt, verification, and use of each supply or reagent.
1271.230(a)	Recordkeeping	Requires documentation of validation activities when the results of processing cannot be fully verified by subsequent inspection and tests.
1271.230(c)	Recordkeeping	Requires that when changes to a validated process subject to § 1271.230(a) occur, documentation of the review and evaluation of the process and revalidation, if necessary, must occur.
1271.260(d)	Recordkeeping	Requires documentation of any corrective action taken whenever proper storage conditions are not met.
1271.260(e)	Recordkeeping	Requires documentation of storage temperatures for HCT/Ps.
1271.265(c)(1)	Recordkeeping	Requires documentation that all release criteria are met before distribution of an HCT/P.
1271.265(c)(3)	Recordkeeping	Requires documentation of any departure from a procedure relevant to preventing risks of communicable disease transmission at the time of occurrence.
1271.265(e)	Recordkeeping	Requires documentation of the receipt, pre-distribution shipment, distribution, and packaging and shipping of HCT/Ps.
1271.270(a)	Recordkeeping	Requires documentation of each step in manufacturing required in Part 1271, subparts C and D.
1271.270(e)	Recordkeeping	Requires documentation of the name and address, and a list of responsibilities of any establishment that performs a manufacturing step for the establishment.
1271.290(d) and (e)	Recordkeeping	Requires documentation of a method for recording the distinct identification code and type of each HCT/P distributed to a consignee to enable tracking from the consignee to the donor and to enable tracking from the donor to the consignee or final disposition.
1271.320(b)	Recordkeeping	Requires an establishment to maintain a record of each complaint that it receives. The complaint file must contain sufficient information about each complaint for proper review and evaluation of the complaint and for determining whether the complaint is an isolated event or represents a trend.

In addition, the standard operating procedures (SOP) provisions under 21 CFR Part 1271 include the following: (1) § 1271.160(b)(2) (receiving, investigation, evaluating, and documenting information relating to core CGTP requirements, including complaints, and for sharing information with

consignees and other establishments); (2) § 1271.180(a) (to meet core CGTP requirements for all steps performed in the manufacture of HCT/Ps); (3) § 1271.190(d)(1) (facility cleaning and sanitization); (4) § 1271.200(b) (cleaning, sanitizing, and maintenance of equipment); (5) § 1271.200(c) (calibration of equipment); (6) § 1271.230(a) and (c) (validation of a process and review and evaluation of changes to a validated process); (7) § 1271.250(a) (controls for labeling HCT/Ps); (8) § 1271.265(e) (receipt, predistribution shipment, availability for distribution, and packaging and shipping of HCT/Ps); (9) § 1271.265(f) (suitable for return to inventory); (10) § 1271.270(b) and (d) (records management system); (11) § 1271.290(b)(1) (system of HCT/P tracking); and (12) § 1271.320(a) (review, evaluation, and documentation of complaints as defined in § 1271.3(aa))).

Under section 361 of the Public Health Service Act (the PHS Act) (42 U.S.C. 264), FDA may issue and enforce regulations necessary to prevent the introduction, transmission, or spread of communicable diseases between the States or possessions or from foreign countries into the States. As derivatives of the human body, all HCT/Ps pose some risk of carrying pathogens that could potentially infect recipients or handlers. FDA has issued regulations related to HCT/Ps involving establishment registration and listing using Form FDA 3356; eligibility determination for donors; and current good tissue practice (CGTP). FDA requires the use of Form FDA 3356: Establishment Registration and Listing for Human Cells, Tissues, and Cellular and Tissue-Based Products to submit the required information (§§ 1271.10, 1271.21, 1271.25, and 1271.26).

2. Purpose and Use of the Information Collection

The information FDA receives from establishments complying with registration and listing requirements is necessary to regulate the industries involved with the recovery, screening, testing, processing, storage, and distribution of HCT/Ps. The information allows FDA to efficiently and effectively handle emerging public health concerns related to HCT/Ps. The information also aids FDA to monitor the industry, to distribute educational materials, and to inform the industry about FDA requirements, guidances, and policies, and to identify entities that may be subject to FDA regulation.

Documentation of donor eligibility determination provides to the user that all of the donor's medical history and social behavior were reviewed for high risk for or clinical evidence of communicable diseases, and that all of the required testing was completed. Each distributed HCT/P must have the following accompanying documentation: (1) a distinct identification code; (2) a statement, based on the screening and testing results, that the donor is determined to be eligible or ineligible; and (3) a summary of the records used to determine eligibility. The summary of records must contain: (1) a statement that the testing was performed by a CLIA certified laboratory or by a laboratory that has met equivalent requirements as determined by the Centers for Medicare and Medicaid Services; (2) a listing and interpretation of the results of all communicable disease tests performed; (3) the name and address of the establishment determining the eligibility of the donor; and (4) in the case of an HCT/P from a donor determined to be ineligible based on screening and released for use under § 1271.65(b), a statement noting the reason for the ineligible determination.

Other reporting and recordkeeping requirements in 21 CFR Part 1271 are designed to fully disclose the screening and testing results to the user when using products from donors who are determined to be ineligible or whose eligibility has not yet been determined in an urgent medical need. The distributing establishment is also to document that the HCT/P establishment notified the physician that the screening and testing are not completed. HCT/P establishments are required to maintain records for a minimum of 10 years. Certain HCT/Ps have long storage periods and advances in medical diagnosis and therapy also have created opportunities for disease prevention or treatment many years after a recipient's exposure to a donor later determined to be at risk for communicable disease agents or diseases.

The CGTP information collection provisions provide: (1) additional measures for preventing the introduction, transmission, or spread of communicable disease; (2) step-by step consistency in the manufacturing of the product; (3) necessary information to FDA for the purpose of protecting public health and safety; (4) accountability in the manufacturing of cellular and tissue-based products; and (5) information facilitating the tracking of a product back to its original source or to a consignee or final disposition.

Without this collection of information, FDA could not monitor HCT/Ps procedures and could not fulfill its statutory responsibility to ensure that communicable diseases are not spread into or throughout the United States and its Possessions.

3. Use of Improved Information Technology and Burden Reduction

To facilitate establishment registration and listing, FDA has developed Form FDA 3356 that may be submitted electronically through a secure web server or in paper form by mail or FAX. Establishments may maintain records electronically or as original paper records, or as true copies such as photocopies, microfiche, or microfilm. Electronic recordkeeping is specifically referred to in the regulations under § 1271.270(c). Advanced methods of recordkeeping, e.g., by an electronic method, have improved the ability of HCT/P establishments to more easily maintain and retrieve records of donor eligibility determinations, and CGTP. FDA is not aware of any other improved technology to reduce the burden.

4. Efforts to identify Duplication and Use of Similar Information

Manufacturers of drug or device products that incorporate human cells or tissues register only using Form FDA 3356. To avoid duplication, 21 CFR Parts 210, 211, and 820 state that in the event of a conflict between applicable regulations in Parts 210, 211, and 820 and the regulations in part 1271, the regulation specifically applicable to the product in question must supersede the more general. No other component of FDA or other government agencies requires similar information or data to be submitted. This information is not available from any other source.

5. Impact on Small Businesses or Other Small Entities

This collection of information applies to small as well as large establishments. Although FDA must

apply the statutory and regulatory requirements equally to all enterprises, FDA does provide special help to small businesses. The Center for Biologics Evaluation and Research (CBER), Office of Communications, Outreach, and Development, Division of Manufacturer's Assistance and Training provides assistance to small businesses.

6. Consequences of Collecting the Information Less Frequency

Less frequent collection of information would not provide FDA the information needed to prevent the transmission of communicable disease by HCT/Ps through monitoring, and communication with the cell and tissue industry. The documentation of donor eligibility, the summary of records, and the information provided to physicians on the donor's eligibility when a product is used in an urgent medical need is the minimum necessary to keep the industry informed of the eligibility of each and every donor of HCT/Ps. The reporting and recordkeeping requirements of CGTP are designed to impose minimum burden on industry while preventing the introduction, transmission, or spread of communicable disease through the use of HCT/Ps.

There are no technical or legal obstacles to reducing the burden.

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

The reporting burden under 21 CFR Part 1271, subparts C and D require respondents to provide information more often than quarterly, i.e., for each individual HCT/P. This information includes an identification code number, which protects patient/donor confidential 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 July 12, 2013 (78 FR 41934). No comments were received from the public.

9. Explanation of Any Payment or Gift to Respondents

No payment or gift was 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. Inspectors may copy records as part of the inspection of a tissue establishment. This information is for internal use and may be subject to, in whole or in part, the FOIA and applicable FDA regulations.

11. Justification for Sensitive Questions

Questions of a sensitive nature, such as sexual behavior and other matters that are commonly considered private must be asked by the HCT/P establishments as part of the donor medical history evaluation. The answers to these questions help determine the eligibility of a donor. Donors that do not meet certain criteria would be determined ineligible to donate. This information is necessary to prevent the transmission of relevant communicable diseases and to protect the public health. Such information may be reviewed by FDA during an inspection.

12. Estimates of Annualized Burden Hours and Costs

12a. Annualized Hour Burden Estimate

The total annual estimated burden imposed by this collection of information is 3,938,592 hours annually.

Table 1.--Estimated Annual Reporting Burden

21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
1271.10(b)(1) and 1271.21(b)[1]	2,706	1	2,706	0.5 (30 minutes)	1,353
1271.10(b)(1) and (b)(2), 1271.21(a), and 1271.25(a) and (b)[1]	218	1	218	0.75 (45 minutes)	164
1271.10(b)(2), 1271.21(c)(ii) and 1271.25(c)[1]	3,737	1	3,737	0.5 (30 minutes)	1,869
1271.26[1]	1,222	1	1,222	0.25 (15 Minutes)	306
1271.155(a)	26	1.54	40	3	120
1271.350(a)(1) and (a)(3)	24	8.58	206	1	206
Total					4,018

[1] Using Form FDA 3356.

Table 2.--Estimated Annual Recordkeeping Burden					
21 CFR Section	No. of Record-keepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
New SOPs[1]	218	1	218	48	10,464
SOP Update[1]	2,706	1	2,706	24	64,944
1271.47(d)	1,353	1	1,353	1	1,353
1271.50(a)	2,706	33.91	91,756	5	458,780
1271.55(d)(1)	2,706	33.91	91,756	1	91,756
1271.55(d)(2)	2,706	1	2,706	1	2,706
1271.55(d)(4)	2,706	1	2,706	120	324,720
1271.60(d)(3) and (d)(4), 1271.65(b)(3)	812	1	812	2	1,624
1271.155(f)	26	1.54	40	0.25 (15 minutes)	10
1271.160(b)(3) and (b)(6)	1,694	12	20,328	1	20,328
1271.160(d)	1,694	12	20,328	1	20,328
1271.190(d)(2)	1,694	12	20,328	1	20,328
1271.195(d)	1,694	12	20,328	1	20,328
1271.200(e)	1,694	12	20,328	1	20,328
1271.210(d)	1,694	12	20,328	1	20,328
1271.230(a)	1,694	12	20,328	1	20,328
1271.230(c)	1,694	1	1,694	1	1,694
1271.260(d)	1,694	12	20,328	0.25 (15 minutes)	5,082
1271.260(e)	1,694	365	618,310	0.083 (5 minutes)	51,320
1271.265(c)(1)	1,694	1,196.49	2,026,861	0.083 (5 minutes)	168,229
1271.265(c)(3)	847	1	847	1	847
1271.265(e)	1,694	1,196.49	2,026,861	0.083 (5 minutes)	168,229
1271.270(a)	1,694	1,196.49	2,026,861	0.25 (15 minutes)	506,715
1271.270(e)	2,165	2	4,330	0.5 (30 minutes)	2,165
1271.290(d) and (e)	1,694	50.86	86,156	0.25 (15 minutes)	21,539
1271.320(b)	1,353	5	6,765	1	6,765
Total					2,031,238

[1] §§1271.47(a), 1271.85(b)(2), 1271.160(b)(2) and (d)(1), 1271.180(a), 1271.190(d)(1), 1271.200(b), 1271.200(c), 1271.230(a) and (c), 1271.250(a), 1271.265(e) and (f), 1271,270(b) and (d), 1271.290(b)(1), and 1271.320,(a) .

Table 3. – Estimated Annual Third-Party Disclosure Burden					
21 CFR Section	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Average Burden per Disclosure	Total Hours
1271.55(a)	1,965	1,103	2,167,396	0.5 (30 minutes)	1,083,698
1271.60(c) and (d)(2)	1,375	208	286,000	0.5 (30 minutes)	143,000
1271.290(c)	1,694	1,196.49	2,026,861	0.083 (5 minutes)	168,229
1271.290(f)	1,694	1	1,694	1	1,694
1271.370(b) and (c)	1,694	1,196.49	2,026,861	0.25 (15 minutes)	506,715
Total					1,903,336

Respondents to this information collection are establishments that recover, process, store, label, package or distribute any HCT/P, or perform donor screening or testing. The estimates provided below are based on the most recent available information from FDA's database system and trade organizations. The hours per response and hours per record are based on data provided by the Eastern Research Group, or FDA experience with similar recordkeeping or reporting requirements.

There are an estimated 2,706 HCT/P establishments (conventional tissue, eye tissue, peripheral blood stem cell, stem cell products from cord blood, reproductive tissue, and sperm banks), including 741 manufacturers of HCT/P products regulated under the Federal Food, Drug, and Cosmetics Act and section 351 of the PHS Act (42 U.S.C. 264), that have registered and listed with FDA. In addition, we estimate that 218 new establishments have registered with FDA (§§1271.10(b)(1) and (b)(2) and 1271.25(a) and (b)). There are an estimated 3,737 listing updates (1271.10(b)(2), 1271.21(c)(ii) and 1271.25(c)) and 1,222 location/ownership amendments (§1271.26).

Under § 1271.55(a), an estimated total of 2,167,396 HCT/Ps (which include conventional tissues, eye tissues, hematopoetic stem cells/progenitor cells, and reproductive cells and tissues), and an estimated total of 2,026,861 non-reproductive cells and tissues (total HCT/Ps minus reproductive cells and tissues) are distributed per year by an estimated 1,965 establishments (2,706 - 741 = 1,965 establishments with approved applications).

Under §1271.60(c) and (d)(2), FDA estimates that 1,375 establishments shipped an estimated 286,000 HCT/P under quarantine, and that an estimated 26 establishments requested 40 exemptions from or alternative to any requirement under 1271 subpart C or D, specifically under § 1271.155(a).

Under §§ 1271.290(c) and 1271.370(b) and (c), an estimated 1,694 non-reproductive HCT/P establishments label each of their 2,026,861 HCT/Ps with certain information. These establishments are also required to inform their consignees in writing of the requirements for tracking and of their established tracking system under § 1271.290(f).

FDA estimates 24 HCT/P establishments submitted 206 adverse reaction reports (AERs) with 167 involving a communicable disease (§ 1271.350(a)(1)).

FDA estimates that 218 new establishments will create SOPs, and that 2,706 establishments will review and revise existing SOPs annually.

FDA estimates that 1,353 HCT/P establishments (2,706 x 50% = 1,353) and 847 non-reproductive HCT/P establishments (1,694 x 50% = 847) record and justify a departure from the procedures (§ 1271.47(d) and § 1271.265(c)(3)).

Under §1271.50(a), HCT/P establishments are required to have a documented medical history interview about the donor's medical history and relevant social behavior as part of the donor's relevant medical records for each of the estimated total of 91,756 donors (which include conventional tissue donors, eye tissue donors, peripheral and cord blood stem cell donors, and reproductive cell and tissue donors), and the estimated total of 86,156 non-reproductive cells and tissue donors (total donors minus reproductive cell and tissue donors).

FDA estimates that 812 HCT/P establishments (2,706 x 30% = 812) document an urgent medical need for an HCT/P and notify the physician using the HCT/P (§ 1271.60(d)(3) and (d)(4) and 1271.65(b)(3)).

FDA also estimates that 2,165 HCT/P establishments (2,706 x 80% = 2,165) have to maintain records for an average of 2 contract establishments that perform a manufacturing process step for them (§ 1271.270(e), and 1,353 HCT/P establishments maintain an average of 5 complaint records annually (§ 1271.320(b)).

In some cases, the estimated burden may appear to be lower or higher than the burden experienced by individual establishments. The estimated burden in these charts is an estimated average burden, taking into account the range of impact each regulation may have.

12b. Annualized Cost Burden Estimate

Cost to Respondents

The estimated annual cost to respondents is $182,339,282.00.

Activity	No. of Hours	Cost per Hour	Total Cost
Reporting	4,018	$53	$212,954
Recordkeeping	2,031,238	$40	$81,249,520.00
Disclosure	1,903,336	$53	$100,876,808
Total			$182,339,282.00

The reporting/disclosure cost estimate is based on an average pay rate of $53 an hour. The average is based on the salaries of a medical director ($79/hour), a mid-level supervisor ($48/hour, responsible for completing and submitting the registration and/or listing information; creating, reviewing, or updating SOPs; or on other reporting responsibilities), and a medical technician ($32/hour). The recordkeeping cost estimate is based on an average pay rate of $40/hour of a mid-level professional and a medical technician who are involved with the documentation and maintenance of records. The estimated average hourly pay rate includes benefits but no overhead costs.

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

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

14. Annualized Cost to the Federal Government

The estimated annualized cost to FDA is $$4,582,032.

Activity	Number of Responses	Hours per Response	Cost per Hour	Total Cost
Registration and Listing	7,883	3	$42	$993,258
Exemption or Alternative Request	40	3	$67	$8,040
Establishment (non-reproductive) Inspection	847	69	$57	$3,331,251
Establishment (reproductive) Inspection	253	17	$57	$245,157
AER triage/review	206	1/2 (30 minutes)	$42	$4,326
Total				$4,582,032

The estimated cost is based on 2 FTEs (GS-7/5 and GS-13/5) who process and review the registration form, input the data, and maintain the database; and who triage and review AERs. There are approximately 1,694 non-reproductive HCT/P establishments that would be inspected on a

biennial basis (847) by a FDA Inspector at an average grade of GS-13/5. The estimated time include inspection, reviewing records and writing up a report. There are approximately 1,012 (2,706 - 1,694 = 1,012) reproductive HCT/P establishments that would be inspected for compliance with the donor eligibility requirements every 4 years (253 per year). This cost is also based on FDA regulatory review staff who process and review the requests for exemptions or alternatives. The salary estimates include benefits but no overhead costs.

15. Explanation for Program Changes or Adjustments

The previous burden estimate in 2011 was 3,871,713 hours. The slight overall increase in burden to 3,938,592 hours (66,879 hours) is mostly attributed to an increase in the number of establishments and corresponding records under §§ 1271.47, 1271.50, 1271.55, 1271.270, and 1271.320 in the recordkeeping burden chart.

A third party disclosure chart was added for following regulations previously included under the reporting burden chart: §§ 1271.55, 1271.60, 1271.290, and 1271.370. Therefore, there was a decrease under the reporting chart from 1,905,773 hours in 2011 to 4,018 (-1,901,755) hours; and a corresponding new increase of 1,903,336 hours under the disclosure chart.

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 the display of the expiration date of the OMB approval.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.