

# SUPPORTING STATEMENT FOR

Establishment Registration and Listing for Manufacturers of Human Cellular and Tissue-Based Products

**OMB No. 0910-0372**

## A Justification

### 1. Circumstances that Make Collection of Information Necessary

The Food and Drug Administration (FDA) is requesting OMB approval of the information collection requirements contained in proposed rule 21 CFR 1271 (Attachment A). The proposed rule also includes conforming amendments for 21 CFR Parts 207 and 807 (Attachment B). The information collections for which approval is requested are:

21 CFR 1271.10	Reporting	All owners and operators of establishments that manufacture human cellular and tissue-based products are required to register and list each human cellular and tissue-based product manufactured.
21 CFR 1271.21	Reporting	Owners and operators of establishments are required to register within 5 days after beginning operations and shall update registration annually and their product lists biannually.
21 CFR 1271.22	Reporting	Registration and listing shall be submitted on FDA 3356 (Attachment C). Copies of the form obtained from CBER via mail, FAX, or on the Internet.
21 CFR 1271.26	Reporting	Changes to ownership or location of an establishment shall be submitted to FDA within 5 days of such changes.
21 CFR 207.20	Reporting	Owners and operators of establishments or persons engaged in the recovery, screening, testing, processing, storage, or distribution of human cellular or tissue-based products, as defined in proposed 1271.3(e), shall register and list those products following the procedures set out in subpart B of proposed part 1271.
21 CFR 807.20	Reporting	Owners and operators of establishments or persons engaged in the recovery, screening, testing, processing, storage, or distribution of human cellular or tissue-based products, as defined in proposed

1271.3(e), shall register and list those products following the procedures set out in subpart B of proposed part 1271.

FDA has never had a single, unified system for the regulation of human cellular and tissue-based products. Products that consist of, or that incorporate, human cells or tissues pose the public health risk of transmitting diseases to persons who, handle, receive, or come in close contact to recipients of these products. FDA has determined that case-by case evaluation of human cellular and tissue-based products is inadequate and has, therefore, proposed a system by which establishments will register and list the products they produce. The registration and listing scheme would enable FDA to characterize the state of the human cellular and tissue-based product industry. Characterization of the industry would enable FDA to identify public health concerns and permit the agency to communicate warnings, guidances and other information directly to specific industry segments. The information would also enable FDA to conduct inspections in a more efficient manner.

FDA is promulgating the proposed regulations solely under the authority of section 361 of the PHS Act (Attachment D). Under that section, the Food and Drug Administration may make and enforce regulations necessary to prevent the introduction, transmission, or spread of communicable diseases between the States or from foreign countries into the States.

## **2. Purpose and Use of the Information**

The registration of manufacturers of human cellular and tissue-based products and the listing of the products manufactured by each establishment would provide basic information about the industry and its products, such as the name, location and products produced. This information would enable the agency to communicate with the human cell and tissue industry and effectively distribute educational material and information regarding FDA policies, guidances, and requirements, monitor the industry, and conduct inspections. The information will also help FDA identify new public health risks and react swiftly to by alerting members of the industry.

The proposed registration regulations would lay the foundation for a regulatory program that would be an important tool in preventing the transmission of communicable diseases. Additional regulations would be promulgated later that would require such measures as the maintenance of "good tissue practices" and various tests for communicable diseases. Without the information collected through establishment registration and product listing, FDA could not effectively prevent the transmission of communicable disease or monitor compliance with the future regulations.

## **3. Use of Information Technology and Burden Reduction**

FDA proposes to make the form for registration and listing available electronically and through direct mailing. In the future, the agency intends to accept electronic submissions of completed forms by manufacturers. When the agency has developed sufficient validation procedures for electronic submissions, manufacturers may be able to register and list electronically. FDA is not aware of any other improved technology to reduce the burden.

#### **4. Efforts to Identify Duplication and Use of Similar Information**

The agency has carefully created the establishment registration and product listing scheme to avoid unnecessary duplication of information collection to target only human cellular and tissue-based products that are not currently regulated by the agency. To avoid duplication of registration and listing, drug and device products only will register under the Drug Registration and Listing System or the Medical Device Establishment Registration. Drug or device products that incorporate human cells or tissues will register only under the proposed regulation. This will avoid duplicate registration and listing under both the proposed regulation and the existing regulations for the registration and listing of drug and device products, 21 CFR 207 and 807, respectively.

#### **5. Impact on Small Business and Other Entities**

FDA believes that its duty requires the equal application of the regulations to all enterprises. While FDA does not believe it can apply different standards with respect to statutory requirements, FDA does provide special help to small businesses. The Center for Biologics Evaluation and Research, Office of Communications, Training, and Manufacturers Assistance provides assistance to small businesses subject to FDA's regulatory requirements. FDA determined that of the approximately 680 entities estimated to be affected by the proposed rule, a majority would be considered "small" under criteria established by the Small Business Administration.

#### **6. Consequences if Data were Collected Less Frequently**

Less frequent collection of information or other methods of reducing the frequency of information would not provide the information needed to prevent the transmission of communicable disease by human cellular and tissue-based products through monitoring and communication with the cell and tissue industry. There are no technical or legal obstacles to reducing the burden.

#### **7. Special Circumstances Relating to the Guideline of 5 CFR 1320.5**

There are no special circumstances for the collection of the information requirements.

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

A 30 day notice requesting comments from the public on the information collection provisions will be provided in the proposed rule published in the **Federal Register**.

#### **9. Explanation of Any Payment or Gifts to Respondents**

No payment or gift was provided to respondents.

#### 10. Assurance of Confidentiality Provided to Respondents

The confidentiality of information received by FDA under the proposed rule would be consistent with the Freedom of Information Act and the agency's regulations under 21 CFR Part 20.

Manufacturers registering and listing their products with the agency would not be required to reveal any proprietary information or trade secrets to achieve compliance with the proposed rule.

#### 11. Justification for Sensitive Questions

No questions of a sensitive nature would be asked by FDA of the registering and listing manufacturers.

#### 12. Estimate of Hour Burden Including Annualized Hourly Costs

The estimated annual burden for this information collection is 1119 hours.

##### Estimated Annual Reporting Burden

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response (ave.)
Part 1271	680	2	1360	0.75
207.20	1	2	2	0.75
807.20	65	2	130	0.75
<b>TOTAL</b>	<b>746</b>		<b>1492</b>	

Since exact number of entities that would be required to begin registration and listing under part 1271 is difficult to ascertain, the agency has developed estimates of the number of entities that would be affected by using information obtained from various trade organizations related to the human cellular and tissue-based industry. The agency included in its analysis the 65 manufacturers of human cellular and tissue-based device products that are registered with the agency under 21 CFR 807. The Musculoskeletal Transplant Foundation, lists approximately 25 tissue and organ recovery members, which it estimates to be about one third of the tissue and organ procurement organizations in the U.S. The National Bone Marrow Donor Program, which includes establishments that recover peripheral blood stem cells, lists approximately 101 donor centers and 114 collection centers in the U.S. The American Association of Tissue Banks (AATB) lists

approximately 60 tissue banks. The Eye Bank Association of America represents about 112 eye banks, which it estimates is about 95% of the U.S. eye banks. The American Society for Reproductive Medicine has a membership of approximately 7200 physicians, researchers and other health care professionals, of which perhaps only 120 would be subject to the registration and listing requirements. In addition, it is estimated that there are about 90 semen depositories in commercial operation. The total number of entities that would be subject to the proposed rule is approximately 680.

#### Cost to Respondents

The estimated annual cost to respondents is \$42,522.00.

Activity	No. of Hours	Cost per Hour	Total Cost
Reporting	1119	\$38.00	\$42,522.00

FDA estimates that it should require an average of 1 hour of staff time per registrant because the format of the proposed form and the information requested on it are similar to the information collection conducted under 21 CFR Part 607 C Establishment Registration and Product Listing for Manufacturers of Human Blood and Blood Products. The blood product registration form (FDA Form 2830) (Attachment E) is similar in length, type of information requested, and complexity to the proposed Form FDA 3356. The proposed rule would require an update of the product list which is estimated to require about 0.5 hour of staff time. Thus, registration and listing is anticipated to require about 1.5 hours of staff time per annum. The estimated 1.5 hours of staff time has been averaged over the two required dates to yield an average time of 0.75 hours per each registration and listing submission. At an estimated \$38.00/hour value of staff time for the owner or operator of the establishment who would perform the registration and listing, most registrants are expected to incur an annual cost of approximately \$57.00 to comply with the requirements of the proposed rule. The salary estimates include benefits but no overhead costs.

#### 13. Estimate of Other Total Annual Cost Burden to Respondents of Recordkeepers

There are no capital costs and start-up, and operation, maintenance and purchase costs associated with the information collection.

#### 14. Annulized Cost to the Federal Government

The total estimated first year cost to the Federal Government is \$157,916.00. This figure is based on the combined costs of: (1) \$51,750.00 for an information technology development contract; (2) \$15,000.00 for the salary for one temporary employee who would accession the registration and listing data; \$74,956 for one GS-14 Consumer Safety Officer to serve as the program manager; \$8500.00 for the pro rata time a Commissioned Officer Level 6 to serve as the Information Technology Management Officer (calculated as 0.1 of the full time position), and \$7710.00 for the pro rata time of a GS-14 Consumer Safety Officer to serve as the Information Technology Management Data Base Manager (calculated as 0.1 of the full time position). The total estimated annualized cost to the Federal Government for subsequent years would be \$106,166.00 because

the information technology development contract would not be a recurring expense. The salary estimates include benefits but no overhead costs.

**15. Explanation of Program Changes or Adjustments**

Changes in burdens is not applicable as this is the first submission for the proposed rule.

**16. Plans for Tabulation and Publication and Program Time Schedule**

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

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

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

**18. Exception to the Certification for Paperwork Reduction Act Submission**

There are no exceptions to Item 19 of OMB Form 83-I

**SECTION B - Collection of Information Employing Statistical Methods**

The collection of data does not employ statistical methods.

[Information Collection Requests](#)

[GUIDELINES TO OBTAIN OMB APPROVAL FOR COLLECTIONS OF INFORMATION REQUIREMENTS](#)