the Personal Responsibility and Work Opportunity Reconciliation Act of 1996. It consists of disaggregated and aggregated demographic and program information that will be used to determine participation rates and other statutorily required indicators for the Temporary Assistance for Needy Families (TANF) program. OMB previously approved this data collection under emergency procedures through January 31, 1998. We are now requesting an extension through September 30, 1998, in order to maintain the continuity of data collection pending OMB approval of the data collection instruments published in the NPRM dated November 20, 1997.

Respondents: States and Territories.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Emergency TANF Data Report	54	4	451	97,416

Estimated Total Annual Burden Hours: 97,416.

Additional Information

Copies of the proposed collection may be obtained by writing to The Administration for Children and Families, Office of Information Services, Division of Information Resource Management Services, 370 L'Enfant Promenade, S.W., Washington, D.C. 20447, Attn: ACF Reports Clearance Officer.

OMB Comment

OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register.** Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, 725 17th Street, N.W., Washington, D.C. 20503, Attn: Ms. Laura Oliven.

Dated: January 7, 1998.

Bob Sargis,

Acting Reports Clearance Officer.

[FR Doc. 98–1251 Filed 1–16–98; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–0497]

Request for Proposed Standards for Unrelated Allogeneic Peripheral and Placental/Umbilical Cord Blood Hematopoietic Stem/Progenitor Cell Products; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is requesting submission of comments proposing product standards intended to ensure the safety and effectiveness of minimally manipulated hematopoietic stem/progenitor cells derived from peripheral and cord blood for unrelated allogeneic use.[1] The comments should include supporting clinical and nonclinical laboratory data and other relevant information. This information will aid FDA in developing product standards for hematopoietic stem/progenitor cell products intended for allogeneic use in recipients unrelated to the donor (hereinafter referred to as unrelated allogeneic), including manufacturing controls and product specifications. FDA is also announcing its intention to phase-in implementation of investigational new drug application (IND) and license application requirements for minimally manipulated[2] unrelated allogeneic hematopoietic stem/progenitor cell products 3 years after the date of issuance of this notice to permit the development of licensing standards for those products where possible. This action is taken in response to the agency's ''Proposed Approach to Regulation of Cellular and Tissue-based Products,'' which fullfills the objectives of the administration's ''Reinventing the Regulation of Human Tissue'' initiated to streamline regulatory requirements to ease the burden on regulated industry, while providing adequate protection to the public health.

[1] The term *unrelated allogeneic use* means the implantation, infusion, or transfer of a human cellular or tissue-based product from one person to another who is not a parent, sibling, or a child of the donor.

[2] The term *minimally manipulated* means processing of cells and nonstructural tissues that does not alter the biological characteristics and thus, potentially, the function or integrity of the cells or tissues.

DATES: Submit requested standards and supporting clinical and nonclinical laboratory data by January 20, 2000.

ADDRESSES: Submit proposed product standards and supporting data to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Paula S. McKeever, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

A. Use of Peripheral and Cord Blood Stem/Progenitor Cells for Hematopoietic Reconstitution

The field of hematologic transplantation has changed substantially during the last two decades. Improved understanding of the diverse aspects of human hematologic precursors has facilitated their experimental manipulation. Our knowledge of their localization in humans during both fetal and postnatal development, growth regulation, differentiation, homing, and of phenotypic and functional characteristics has facilitated the development of new methods of transplantation. Traditional bone marrow transplantation, involving the extraction of bone marrow by aspiration from bone cavities with further processing by density centrifugation, is increasingly being supplanted by novel approaches that include use of hematopoietic stem/progenitor cells and biotechnologic procedures to purify and expand hematopoietic stem/progenitor cells. Human cord blood, which is enriched with pluripotent hematopoietic stem/progenitor cells, and peripheral blood, which can be enriched in hematopoietic stem/progenitor cells by a variety of

interventions, have emerged as sources of hematopoietic cells alternative to bone marrow aspirates for bone marrow reconstitution.

B. Stem/Progenitor Cell Workshops

FDA held a public workshop to discuss procedures for preparation and storage of cord blood stem/progenitor cells on December 13, 1995 (60 FR 58088, November 24, 1995). The workshop was jointly sponsored by FDA and the National Heart, Lung, and Blood Institute (NHLBI), National Institutes of Health. The purpose of the workshop was to identify and discuss steps for collection, processing, and storage of cord blood stem/progenitor cells for transplantation and to identify what additional post transplantation scientific data are needed in this area. A draft document, discussing an appropriate regulatory approach for placental/umbilical cord blood stem/progenitor cell products for transplantation, was made available at the workshop, and a notice of availability for comment was published in the **Federal Register** of February 26, 1996 (61 FR 7087). In response to requests to extend the comment period, a notice extending the comment period by 90 days was published in the **Federal Register** of May 28, 1996 (61 FR 26473).

In the **Federal Register** of February 8, 1996 (61 FR 4786), FDA announced a public workshop, jointly sponsored by FDA and NHLBI to be held on February 22 and 23, 1996, to discuss procedures for the preparation, processing, and characterization of human peripheral blood stem/progenitor cells. The purpose of the workshop was to identify and discuss the methods for the collection, processing, and storage of peripheral blood stem/progenitor cells for transplantation and to identify areas in need of further research. A draft document was made available at the workshop describing FDA's proposed regulatory approach for human peripheral blood stem/progenitor cell products for transplantation.

Based, in part, on information presented at these meetings, FDA recognized a need to reconsider whether the concepts and procedures used to regulate traditional biological products were appropriate for regulation of peripheral and cord blood hematopoietic stem/progenitor cells and other cellular and tissue-based products which are a result of new technologies. After consultation with representatives of the involved public, FDA proposed a new regulatory framework for cellular and tissue-based products, including hematopoietic stem/progenitor cells, in February 1997, entitled ''Reinventing the Regulation of Human Tissue,'' and ''Proposed Approach to Regulation of Cellular and Tissue-based Products.'' On March 4, 1997, the agency announced a public meeting, to be held on March 17, 1997, to solicit information and views from the interested public on the agency's proposed regulatory approach for such products, and the agency requested that written comments be submitted to the docket (62 FR 9721).

C. New Regulatory Approach for Human Cellular and Tissue-Based Products

The proposed framework provides a tiered approach to human cellular and tissue-based product[3] regulation. The regulation focuses on three general areas: (1) Preventing use of contaminated tissues with the potential for transmitting infectious diseases; (2) preventing improper handling or processing that might contaminate or damage tissues, or produce cellular or tissue-based products of inadequate quality; and (3) ensuring that clinical safety and effectiveness are demonstrated for most tissues that are highly processed, are used for other than their homologous use,[4] are combined with nontissue components, or have a systemic effect.

Under the tiered approach, FDA intends to impose Federal requirements only to the extent necessary to protect the public health, with minimal regulation for some products and with increasing degrees of oversight as the potential risk increases. For example, tissues transplanted from one person to another for their normal structural or reproductive functions and without undergoing extensive processing will be subject to requirements for infectious disease screening and testing, and to requirements for good processing and handling procedures, but will not need FDA marketing approval before distribution and use. Thus, FDA expects that most processors of reproductive tissue, tissue products currently regulated under 21 CFR part 1270, and other minimally manipulated products will not be required to seek FDA premarket approval of their products nor to submit detailed clinical information about their products to FDA. The agency intends to regulate as biological drugs or devices those tissues that are processed extensively, combined with nontissue components, promoted or labeled for use other than homologous use, or (with limited exceptions) that have systemic effect on the body. Minimally manipulated hematopoietic stem/progenitor cells derived from peripheral and cord blood, for unrelated allogeneic use, would therefore be regulated as biological drugs under the Public Health Service Act and the Federal Food, Drug, and Cosmetic Act. FDA does not intend to request clinical data to demonstrate safety and effectiveness for cellular and tissue-based products with systemic effect that are for autologous use[5] or family-related allogeneic use[6] or for reproductive tissues for reproductive use providing such products are minimally manipulated, for homologous use, and not combined with a nontissue component. FDA intends to require that establishments manufacturing such minimally manipulated hematopoietic stem/progenitor cell products for hematopoietic reconstitution register and list their products with FDA, comply with good tissue practice regulations, and ensure that all labeling and promotional materials are clear, accurate, balanced, and nonmisleading.

D. Application of the Proposed Regulatory Approach to Hematopoietic Stem/Progenitor Cell Products

For unrelated allogeneic hematopoietic stem/progenitor cells intended for hematopoietic reconstitution, provided they are not more than minimally manipulated (i.e., processing does not alter the biological characteristics of the cells), the agency believes that it may be possible to develop product standards and establishment and processing controls based on existing clinical trial data or data developed in the near future demonstrating the safety and efficacy of the cells. If adequate information can be developed, the agency intends to issue guidance for establishment controls, processing controls, and product standards in accordance with the agency's ''Good Guidance Practices,'' issued in the **Federal Register** of February 27, 1997 (62 FR 8961). FDA intends to propose that, in lieu of individual applications containing clinical data, licensure may be granted

[3] The term *human cellular and tissue-based product* means a product containing human cells or tissues or any cell or tissue-based component of such a product.

[4] The term *homologous use* means the use of a cellular or tissue-based product for a normal function that is analogous to that of the cells or tissues being replaced or supplemented.

[5] The term *autologous use* means the implantation, transplantation, infusion, or transfer of a human cellular or tissue-based product back into the individual from whom the cells or tissue comprising such product were removed.

[6] The term *family-related allogeneic use* means the implantation, transplantation, infusion, or transfer of a human cellular or tissue-based product into a first-degree blood relative of the individual from whom cells or tissue comprising such product were removed.

for products certified as meeting issued standards. To allow sufficient time for data and standards to be developed, the agency will phase-in IND and license application requirements for minimally manipulated unrelated allogeneic hematopoietic stem/progenitor cell products for hematopoietic reconstitution 3 years following the date of issuance of this **Federal Register** notice. FDA is inviting product providers, professional groups, and other interested persons to submit to the agency proposed standards and supporting data designed to ensure the safety and effectiveness of minimally manipulated hematopoietic stem/progenitor cell products for hematopoietic reconstitution. Proposed standards should be supported by adequate data and other relevant information. In order to permit development of useful standards within the phase-in period for enforcement of premarket application requirements, FDA suggests that interested parties work together to achieve consensus on uniform standards before submission to FDA. FDA will evaluate the information submitted. If the agency determines that the submissions support the development of standards, FDA intends to issue such standards through the agency's guidance documents procedures. If FDA determines that adequate establishment and processing controls and product standards are not available, the agency intends to enforce IND and license application requirements at the close of the 3 year period. FDA reminds affected parties that cells that have been more than minimally manipulated (e.g., expanded, activated, genetically modified or otherwise have their biological characteristics altered) or combined with nontissue components continue to require IND's and licensing approval, and are not subject to a phase-in period for enforcement of these requirements.

II. Request for Product Standards with Supporting Clinical and Nonclinical Data

A. Purpose

FDA is inviting product providers, professional groups, and other interested persons to submit to the agency proposed product standards with supporting clinical and nonclinical laboratory data, and other relevant information, designed to ensure the safety and effectiveness of minimally manipulated hematopoietic stem/progenitor cells derived from peripheral and placental/umbilical cord blood for unrelated allogeneic hematopoietic reconstitution. Submitted data may be specific for a patient subset, e.g., pediatric patients, and should identify the patient subset, if applicable.

FDA is requesting that proposed establishment controls include standards for personnel, facilities, quality management, standard operating procedures, staff training and competence, and process validation. Establishment controls should also include standards for recordkeeping regarding donors, processing, quarantine, storage, labeling, distribution, tracking, handling of errors and accidents, deviations from standard operating procedures, suspected adverse reactions, and quality control processes.

FDA is requesting that proposed processing controls include standards for donor selection, informed consent, donor testing and screening, histocompatibility testing, collection procedures, product testing, volume reduction methods, cryopreservation, storage conditions in liquid and frozen state, storage monitoring, transportation within and between facilities, temperature limits, packaging, and thawing procedures. The processing controls should include standards for testing for product contamination, product viability, composition, and functionality, and include when and how such testing is to be performed.

FDA is requesting that proposed product standards include the criteria for acceptance of a unit of hematopoietic stem/progenitor cells derived from peripheral or placental/umbilical cord blood. Criteria should include volume of the product, viable cell number (specified as nucleated or mononuclear cells), storage temperature limits, microbial or other contamination limits, and any other appropriate characteristics of the product, e.g., CD34 positive cell enumeration. For peripheral blood hematopoietic stem/progenitor cell products, information regarding the treatment regimens of the donors with mobilizing agents should also be provided including the type of mobilizing agent, duration of mobilization, and the number of apheresis collections.

The agency is suggesting that evidence of hematopoietic stem/progenitor cell engraftment for these products be consistently expressed as the time, expressed as number of days from the day of hematopoietic stem/progenitor cell infusion to the day that a neutrophil count of equal to or greater than 500 cells/μL is obtained, and the time, expressed as number of days from the day of hematopoietic stem/progenitor cell infusion to the first of 3 consecutive days in which the transfusion-independent platelet count of equal to or greater than 20,000 platelets/μL is demonstrated in the recipient. Information relevant to sustained platelet engraftment, such as the number of days from the day of hematopoietic stem/progenitor cell infusion to the day in which a transfusion-independent platelet count of equal to or greater than 50,000 platelets/μL is observed, should also be provided. Data provided should include the extent of HLA (human leukocyte antigen) disparity, the nucleated cell dose/kg body weight of the recipient, the weight, age, and underlying disease of the recipient, the extent and severity of Graft-Versus-Host Disease, the criteria utilized for evidence for allogeneic cell engraftment, and any other important information regarding the safety and efficacy of the infused product, e.g., incidence of infection. In addition, a description of the methods used for data evaluation, including statistical techniques, should be included.

B. Review and Consolidation of Submitted Information by FDA

FDA will review and assess the information submitted, and evaluate it as to its application in issuing hematopoietic stem/progenitor cell product standards. FDA may find it necessary to present any or all of the aspects of the standards and/or data for public discussion. Any public meeting held by FDA will be announced to the public prior to the date of the meeting. Subsequent to receiving sufficient standards with supporting data, FDA intends to adopt appropriate standards as guidance and announce their availability in the **Federal Register**.

III. Submissions

Interested persons may, on or before January 20, 2000 submit to the Dockets Management Branch (address above) written proposed standards and supporting clinical and nonclinical laboratory data. Two copies of standards and data should be submitted, except that individuals may submit one copy. Standards and data should be identified with the docket number found in brackets in the heading of this document. All information submitted will be placed on public display and will be subject to public disclosure. Any information that is not intended to be made public must be deleted before submission to the Dockets Management Branch. Trade secrets and confidential commercial information, as well as information that could be used to identify individual patients or others whose privacy should be maintained, should be deleted before being submitted. All comments proposing

standards with supporting data will be available for public examination in the Dockets Management Branch (address above) between 9 a.m. and 4 p..m., Monday through Friday.

Dated: January 8, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–1171 Filed 1–16–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Ophthalmic Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Ophthalmic Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA regulatory issues.

Date and Time: The meeting will be held on February 12 and 13, 1998, 8 a.m. to 5 p.m.

Location: Parklawn Bldg., conference rooms D and E, 5600 Fishers Lane, Rockville, MD.

Contact Person: Sara M. Thornton, Center for Devices and Radiological Health (HFZ–460), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2053, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12396, or the world wide web at http://www.fda.gov. Please call the Information Line for up-to-date information on this meeting.

Agenda: On February 12, 1998, the committee will discuss specific questions related to the development of contact lens extended wear clinical testing guidance for 7-day extended wear, prolonged extended wear beyond 7 days, and overnight use of contact lenses for orthokeratology. On February 13, 1998, the committee will discuss, make recommendations, and vote on a premarket approval application (PMA) for a broad beam excimer laser for the correction of myopia with astigmatism using laser in-situ keratomileusis. The committee will also discuss, make recommendations, and vote on a PMA for a scanning excimer laser for the correction of myopia with astigmatism using photorefractive keratectomy.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by February 6, 1998. Oral presentations from the public will be scheduled between approximately 8:30 a.m. and 9:30 a.m. on February 12 and 13, 1998. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before February 2, 1998, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: January 12, 1998.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 98–1170 Filed 1–16–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 93N–0195]

Agency Information Collection Activities; Announcement of OMB Approval

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Procedures for the Safe Processing and Importing of Fish and Fishery Products'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA).

FOR FURTHER INFORMATION CONTACT: Margaret R. Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of October 31, 1997 (62 FR 58973), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under section 3507 of the PRA (44 U.S.C. 3507). 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 control number. OMB has now approved the information collection and has assigned OMB control number 0910–0354. The approval expires on December 31, 2000.

Dated: January 8, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–1167 Filed 1–16–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–0040]

Agency Information Collection Activities; Announcement of OMB Approval

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Survey of Food Safety Practices of Food Processing Firms'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA).

FOR FURTHER INFORMATION CONTACT: Margaret R. Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of August 7, 1997 (62 FR 42559), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under section 3507 of the PRA (44 U.S.C. 3507). 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 control number. OMB has now approved the information collection and has assigned OMB control number 0910–0355. The approval expires on November 30, 2000.

Dated: January 9, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–1168 Filed 1–16–98; 8:45 am]

BILLING CODE 4160–01–F