costs associated with compliance for these entities are negligible.

William Blumenthal,

General Counsel.

[FR Doc. E7–3397 Filed 2–27–07; 8:45 am]

BILLING CODE 6750–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention (CDC)

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel: Scientific, Technical and Operational Services for Epidemiology, Surveillance and Laboratory Program, Contract Solicitation Number (CSN) 2006–N–08556

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces a meeting of the aforementioned Special Emphasis Panel.

Time And Date: 12 p.m.–3 p.m., March 21, 2007 (Closed).

Place: Teleconference.

Status: The meeting will be closed to the public in accordance with provisions set forth in section 552b(c)(4) and (6), Title 5 U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Public Law 92–463.

Matters To Be Discussed: The meeting will include the review, discussion, and evaluation of the scientific merit of research applications in response to CSN 2006–N–08556, ''Scientific, Technical and Operational Services for Epidemiology, Surveillance and Laboratory Program.''

Contact Person For More Information: Christine Morrison, PhD., Designated Federal Officer, 1600 Clifton Road, Mailstop D72, Atlanta, GA 30333, telephone (404) 639–3098.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both CDC and the Agency for Toxic Substances and Disease Registry.

Elaine L. Baker,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. E7–3470 Filed 2–27–07; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N–0425]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Premarket Notification

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by March 30, 2007.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Jr., Office of the Chief Information Officer (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1472.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance:

Premarket Notification—21 CFR Part 807; Subpart E—(OMB Control Number 0910–0120)—Extension

Section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360(k)) and the implementing regulation under part 807 (21 CFR part 807, subpart E) require a person who intends to market a medical device to submit a premarket notification submission to FDA at least 90 days before proposing to begin the introduction, or delivery for introduction into interstate commerce, for commercial distribution of a device intended for human use. Based on the information provided in the notification, FDA must determine whether the new device is substantially equivalent to a legally marketed device, as defined in § 807.92(a)(3). If the device is determined to be not substantially equivalent to a legally marketed device, it must have an approved premarket approval application (PMA), Product Development Protocol or be reclassified into Class I or Class II before being marketed. The FDA makes the final decision of whether a device is equivalent or not equivalent.

The Medical Device User Fee and Modernization Act of 2002 (MDUFMA) (Public Law 107–250) added section 510(o) to the act to establish new regulatory requirements for reprocessed single-use devices (SUDs). MDUFMA was signed into law on October 26, 2002.

Section 510(o) of the act requires that FDA review the types of reprocessed SUDs subject to premarket notification requirements and identify which of these devices require the submission of validation data to ensure their substantial equivalence to predicate devices. Section 510(o) also requires that FDA review critical and semi-critical reprocessed SUDs that are currently exempt from premarket notification requirements and determine which of these devices require the submission of premarket notifications to ensure their substantial equivalence to predicate devices.

FDA has identified the reprocessed SUDs that require the submission of validation data to date. The requirement to submit validation data for certain reprocessed single-use devices has been incorporated into the premarket notification program. As with all other devices, new premarket notifications for reprocessed SUDs will be required as new manufacturers enter the market or manufacturers with cleared premarket notifications make significant changes to their device. The burden estimates in this document include the burden for submitting premarket notifications for reprocessed SUDs with the burden for all other devices. FDA may amend the lists of reprocessed SUDs that require the submission of premarket notifications with validation data as necessary.

Section 807.81 states when a premarket notification is required. A premarket notification is required to be submitted by a person who is:

- Introducing a device to the market for the first time;
- Introducing or reintroducing a device which is significantly changed or modified in design, components, method of manufacturer, or the intended use that could affect the safety and effectiveness of the device.

Section 807.87 specifies information required in a premarket notification submission.

Section 204 of the Food and Drug Administration Modernization Act

(FDAMA) amended section 514 of the act (21 U.S.C. 360d). Amended section 514 allows FDA to recognize consensus standards developed by international and national organizations for use in satisfying portions of device premarket review submissions including premarket notifications or other requirements. FDA has published and updated the list of recognized standards regularly since enactment of FDAMA and has allowed 510(k) submitters to certify conformance to recognized standards to meet the requirements of § 807.87. Certification of conformance to a recognized standard may allow a manufacturer to submit an abbreviated 510(k). FDA is now seeking approval of a form (Form FDA 3654) that will standardize certification of conformance to a recognized standard. FDA believes that use of this form will simplify the certification process for 510(k) submitters and the review process for FDA.

Form FDA 3514, a summary cover sheet form, has been created to assist respondents in categorizing 510(k) information for submission to FDA. This form also assists respondents in categorizing information for other FDA medical device programs such as PMAs, investigational device exemptions, and humanitarian device exemptions The total burden (1,000 hours) for Form FDA 3514 has been included in this information collection. Form FDA 3654 is used in the following information collections: 0910–0078, 0910–0231, and 0910–0332, but the burden is approved under this information collection (0910–0120).

Under § 807.87(h), each 510(k) submitter must include in the 510(k) either a summary of the information in the 510(k) (510(k) summary) or a statement certifying that the submitter will make available upon request the information in the 510(k) (510(k) statement). If the 510(k) submitter includes a 510(k) statement in the submission, § 807.93 requires that the official correspondent of the firm make available within 30 days of a request all information included in the submitted premarket notification on safety and effectiveness. This information will be provided to any person within 30 days of a request if the device described in the premarket notification submission is determined to be substantially equivalent. The information provided will be a duplicate of the premarket notification submission including any safety and effectiveness information, but excluding all patient identifiers and trade secret and confidential information.

In the **Federal Register** of November 3, 2006 (71 FR 64711), FDA published a 60-day notice requesting public comments on the proposed collection of information. In response to that notice, no comments were received.

The most likely respondents to this information collection will primarily be medical device manufacturers including reprocessors of single-use devices, and initial importers of devices.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	FDA Form Number	Number of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
807 Subpart E (807.81, 807.87, 807.92, & 807.93)		3,700	1	3,700	80	296,000
807.87	3514	1,956	1	1,956	0.5	978
807.90(a)(3)	3541	400	1	400	0.25	100
807.87(d) and (f)	3654	150	1	150	1	150
Totals						297,228

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

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
807.93	2,000	10	20,000	0.5	10,000

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

FDA has based these estimates on conversations with industry and trade association representatives, and from internal review of the documents listed in tables 1 and 2 of this document.

Dated: February 22, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–3444 Filed 2–27–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004D–0193]

Guidance for Industry: Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a document entitled ''Guidance for Industry: Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps),'' dated February 2007. The guidance document assists establishments with making eligibility determinations for donors of human cells, tissues, and cellular and tissue-based products. The guidance announced in this document finalizes the draft guidance, ''Guidance for Industry: Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps),'' dated May 2004. This guidance also finalizes the draft guidance, ''Guidance for Industry: Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and Variant Creutzfeldt-Jakob Disease (vCJD) by Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps),'' dated June 2002 (Docket No. 2002D–0266).

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit written comments on the guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*.

FOR FURTHER INFORMATION CONTACT: Paul E. Levine, Jr., Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a document entitled ''Guidance for Industry: Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps),'' dated February 2007. The guidance announced in this document assists HCT/P establishments with complying with the requirements under part 1271 (21 CFR part 1271), subpart C. These regulations require HCT/P establishments to perform an eligibility determination for most cell and tissue donors, based on donor testing and screening for relevant communicable disease agents and diseases. This guidance applies only to cells and tissues procured on or after the effective date of the regulations contained in part 1271, subpart C (effective date May 25, 2005). This guidance does not replace the guidance on 21 CFR part 1270, ''Guidance for Industry: Screening and Testing of Donors of Human Tissue Intended for Transplantation,'' dated July 29, 1997, which continues to apply to certain tissues recovered before May 25, 2005.

In the **Federal Register** of June 25, 2002 (67 FR 42789), FDA announced the availability of the draft guidance entitled ''Guidance for Industry: Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and Variant Creutzfeldt-Jakob Disease (vCJD) by Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps),'' dated June 2002. The draft guidance provides information intended to assist manufacturers of HCT/Ps in minimizing the risk of transmission of CJD and vCJD by HCT/P donors that have been possibly exposed to the agents of CJD and vCJD.

In the **Federal Register** of May 25, 2004 (69 FR 29835), FDA announced the availability of the draft guidance entitled ''Guidance for Industry: Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps),'' dated Ma 2004. The draft guidance provided to HCT/P establishments recommendations for the appropriate screening and testing of cell and tissue donors for relevant communicable disease agents and diseases, and recommendations for complying with the regulations for eligibility determination for donors of HCT/Ps.

FDA issued these two draft guidances to assist manufacturers in minimizing the risk of communicable disease transmission by donors of HCT/Ps. FDA received numerous comments on the two draft guidances and those comments were considered as the guidance was finalized. Based on these comments and additional data, FDA has identified West Nile Virus, Sepsis, and Vaccinia as relevant communicable disease agents or diseases (RCDAD). On the other hand, FDA has not included severe acute respiratory syndrome (SARS-CoV) as an RCDAD in this guidance because there has been no laboratory-confirmed person-to-person transmission of SARS-CoV worldwide since July 2003. In addition, the guidance recommends nucleic acid amplification testing (NAT) for human immunodeficiency virus (HIV) and hepatitis C virus (HCV) for both living and cadaveric donors. The guidance also modifies and/or clarifies the following:

- Recommendations for risk factors for vCJD;
- Physical examination of a living HCT/P donor;
- Exceptions to the requirement for determining donor eligibility and appropriate labeling;
- Screening criteria for HIV–1 group O, viral hepatitis, syphilis, *Chlamydia trachomatis* and *Neisseria gonorrhea*;
- Deferral criteria for receipt of human-derived clotting factors;
- Procedures for communicable disease testing laboratories;
- FDA's approach to identifying new RCDADs; and
- Use of gestational carriers or surrogates.

The guidance announced in this document finalizes the previously described draft guidances dated June 2002 and May 2004. The guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents FDA's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative