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