

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

#### Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Pregnancy Risk Assessment Monitoring System (PRAMS), DP11-001 Panel E, Initial Review

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 the aforementioned meeting:

*Time and Date:* 10 a.m.–5 p.m., March 8, 2011 (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 initial review, discussion, and evaluation of “Pregnancy Risk Assessment Monitoring System (PRAMS), DP11-001 Panel E.”

*Contact Person for More Information:* Donald Blackman, Ph.D., Scientific Review Officer, CDC, National Center for Chronic Disease Prevention and Health Promotion, Office of the Director, Extramural Research Program Office, 4770 Buford Highway, NE., Mailstop K-92, Atlanta, GA 30341, Telephone: (770) 488-3023, e-mail: [DBY7@cdc.gov](mailto:DBY7@cdc.gov).

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 the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: December 2, 2010.

**Elaine L. Baker,**

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

[FR Doc. 2010-31147 Filed 12-10-10; 8:45 am]

**BILLING CODE 4163-18-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

#### Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Pregnancy Risk Assessment Monitoring System (PRAMS), DP11-001 Panel F, Initial Review

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 the aforementioned meeting:

*Time and Date:* 9 a.m.–6 p.m., March 4, 2011 (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 initial review, discussion, and evaluation of “Pregnancy Risk Assessment Monitoring System (PRAMS), DP11-001 Panel F.”

*Contact Person for More Information:* Donald Blackman, PhD, Scientific Review Officer, CDC, National Center for Chronic Disease Prevention and Health Promotion, Office of the Director, Extramural Research Program Office, 4770 Buford Highway, NE., Mailstop K-92, Atlanta, GA 30341, Telephone: (770) 488-3023, e-mail: [DBY7@cdc.gov](mailto:DBY7@cdc.gov).

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 the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: December 2, 2010.

**Elaine L. Baker,**

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

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**BILLING CODE 4163-18-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

#### Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Pregnancy Risk Assessment Monitoring System (PRAMS), DP11-001 Panel D, Initial Review

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 the aforementioned meeting:

*Time and Date:* 11 a.m.–3 p.m., February 25, 2011 (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 initial review, discussion, and evaluation of “Pregnancy Risk Assessment

Monitoring System (PRAMS), DP11-001 Panel D.”

*Contact Person for More Information:* Donald Blackman, Ph.D., Scientific Review Officer, CDC, National Center for Chronic Disease Prevention and Health Promotion, Office of the Director, Extramural Research Program Office, 4770 Buford Highway, NE., Mailstop K-92, Atlanta, GA 30341, Telephone: (770) 488-3023, e-mail: [DBY7@cdc.gov](mailto:DBY7@cdc.gov).

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 the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: December 2, 2010.

**Elaine L. Baker,**

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

[FR Doc. 2010-31143 Filed 12-10-10; 8:45 am]

**BILLING CODE 4163-18-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2010-N-0622]

#### Agency Information Collection Activities; Proposed Collection; Comment Request; Color Additive Certification Requests and Recordkeeping

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection provisions of FDA's regulations governing batch certification of color additives manufactured for use in foods, drugs, cosmetics or medical devices in the United States.

**DATES:** Submit either electronic or written comments on the collection of information by February 11, 2011.

**ADDRESSES:** Submit electronic comments on the collection of information to <http://>

www.regulations.gov. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Denver Presley, Jr., Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-3793.

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

**Color Additive Certification Requests and Recordkeeping—21 CFR Part 80 (OMB Control Number 0910-0216)—Extension**

FDA has regulatory oversight for color additives used in foods, drugs, cosmetics, and medical devices. Section 721(a) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 379e(a)) provides that a color additive shall be deemed to be unsafe unless it meets the requirements of a listing regulation, including any requirement for batch certification, and is used in accordance with the regulation. FDA lists color additives that have been shown to be safe for their intended uses in title 21 of the Code of Federal Regulations (CFR). FDA requires batch certification for all color additives listed in 21 CFR part 74 and for all color additives provisionally listed in 21 CFR part 82. Color additives listed in 21 CFR part 73 are exempted from certification.

The requirements for color additive certification are described in part 80 (21 CFR part 80). In the certification procedure, a representative sample of a new batch of color additive, accompanied by a "request for certification" that provides information about the batch, must be submitted to FDA's Office of Cosmetics and Colors. FDA personnel perform chemical and other analyses of the representative sample and, providing the sample satisfies all certification requirements, issue a certification lot number for the batch. FDA charges a fee for certification based on the batch weight and requires manufacturers to keep records of the batch pending and after certification.

Under § 80.21, a request for certification must include: Name of color additive, manufacturer's batch number and weight in pounds, name and address of manufacturer, storage conditions, statement of use(s), certification fee, and signature of person requesting certification. Under § 80.22, a request for certification must include a sample of the batch of color additive that is the subject of the request. The sample must be labeled to show: Name of color additive, manufacturer's batch number and quantity, and name and address of person requesting certification. Under § 80.39, the person to whom a certificate is issued must keep complete records showing the

disposal of all of the color additive covered by the certificate. Such records are to be made available upon request to any accredited representative of FDA until at least 2 years after disposal of all of the color additive.

The purpose for collecting this information is to help FDA assure that only safe color additives will be used in foods, drugs, cosmetics, and medical devices sold in the United States. The required information is unique to the batch of color additive that is the subject of a request for certification. The manufacturer's batch number is used for temporarily identifying a batch of color additive until FDA issues a certification lot number and for identifying a certified batch during inspections. The manufacturer's batch number also aids in tracing the disposal of a certified batch or a batch that has been denied certification for noncompliance with the color additive regulations. The manufacturer's batch weight is used for assessing the certification fee. The batch weight also is used to account for the disposal of a batch of certified or certification-denied color additive. The batch weight can be used in a recall to determine whether all unused color additive in the batch has been recalled. The manufacturer's name and address and the name and address of the person requesting certification are used to contact the person responsible should a question arise concerning compliance with the color additive regulations. Information on storage conditions pending certification is used to evaluate whether a batch of certified color additive is inadvertently or intentionally altered in a manner that would make the sample submitted for certification analysis unrepresentative of the batch. FDA checks storage information during inspections. Information on intended uses for a batch of color additive is used to assure that a batch of certified color additive will be used in accordance with the requirements of its listing regulation. The statement of the fee on a certification request is used for accounting purposes so that a person requesting certification can be notified promptly of any discrepancies.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

21 CFR Section	Number of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
80.21 .....	32	185	5,920	0.17	1,006

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>—Continued

21 CFR Section	Number of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
80.22 .....	32	185	5,920	0.05	296
Total .....					1,302

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN<sup>1</sup>

21 CFR Section	Number of recordkeepers	Annual frequency of recordkeeping	Total annual records	Hours per record	Total hours
80.39 .....	32	185	5,920	0.25	1,480
Total .....					1,480

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA bases its estimate on its review of the certification requests received over the past 3 fiscal years (FY). The annual burden estimate for this information collection is 2,782 hours. The estimated reporting burden for this information collection is 1,302 hours and the estimated recordkeeping burden for this information collection is 1,480 hours. From FY 2008 to FY 2010, FDA processed an average of 5,932 responses (requests for certification of batches of color additives) per year. There were 32 different respondents, corresponding to an average of approximately 185 responses from each respondent per year. Using information from industry personnel, FDA estimates that an average of 0.22 hour per response is required for reporting (preparing certification requests and accompanying samples) and an average of 0.25 hour per response is required for recordkeeping.

FDA's Web-based color certification information system allows certifiers to request color certification online, follow their submissions through the process, and obtain information on account status. The system sends back the certification results electronically, allowing certifiers to sell their certified color before receiving hard copy certificates. Any delays in the system result only from shipment of color additive samples to FDA's Office of Cosmetics and Colors for analysis. FDA has estimated a reduction in the hour burden for reporting from use of the Web-based system.

Dated: December 8, 2010.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2010-31195 Filed 12-10-10; 8:45 am]

**BILLING CODE 4160-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2010-N-0389]

#### Medical Device User Fee Program; Meetings on Reauthorization; Request for Notification of Patient and Consumer Advocacy Group Intention to Participate

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; request for notification of participation.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing this notice to request that patient and consumer advocacy groups notify FDA of their intent to participate in periodic consultation meetings on reauthorization of the Medical Device User Fee Amendments of 2007 (MDUFA) (the Food and Drug Administration Amendments Act of 2007). The statutory authority for MDUFA expires September 30, 2012. At that time, new legislation will be required for FDA to continue collecting user fees for the medical device program. The Federal Food, Drug, and Cosmetic Act (the FD&C Act) requires that FDA consult with a range of stakeholders in developing recommendations for the next MDUFA program. The FD&C Act also requires that FDA hold continued discussions with representatives of patient and consumer advocacy groups at least monthly during FDA's negotiations with the regulated industry. The purpose of this request for notification is to ensure continuity and progress in these discussions by establishing consistent

patient and consumer advocacy group representation.

**DATES:** Submit notification of intention to participate by January 6, 2011. The first patient and consumer advocacy group meeting will be held on January 13, 2011, from 9 a.m. to 11 a.m. Meetings will continue at least monthly during reauthorization negotiations with the regulated industry.

**ADDRESSES:** Submit notification of intention to participate in monthly patient and consumer advocacy group meetings by e-mail to [MDUFAReauthorization@fda.hhs.gov](mailto:MDUFAReauthorization@fda.hhs.gov). The first meeting will be held at the Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, rm. 1503 B and C, Silver Spring, MD 20993-0002.

**FOR FURTHER INFORMATION CONTACT:** Cindy Garris, Food and Drug Administration, Center for Devices and Radiological Health 10903 New Hampshire Ave., Bldg. 66, rm. 4610, Silver Spring, MD 20993-0002, 301-796-5861, FAX: 301-847-8149.

#### SUPPLEMENTARY INFORMATION:

##### I. Introduction

The authority for MDUFA (Pub. L. 110-85) expires September 30, 2012. Without new legislation to reauthorize the program, FDA will no longer be able to collect user fees to fund the medical device program. Section 738A(b)(1) (21 U.S.C. 379j-1(b)(1)) of the FD&C Act requires that FDA consult with a range of groups in developing recommendations for the next MDUFA program, including scientific and academic experts, health care professionals, and representatives from patient and consumer advocacy groups. FDA initiated this process of consultation on September 14, 2010, by