

Dated: June 8, 2010.

**Maryam I. Daneshvar,**

*Reports Clearance Officer, Centers for Disease Control and Prevention.*

[FR Doc. 2010-14158 Filed 6-11-10; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2010-N-0258]

#### **Agency Information Collection Activities; Proposed Collection; Comment Request; Submission of Petitions: Food Additive, Color Additive (Including Labeling), and Generally Recognized as Safe Affirmation; Submission of Information to a Master File in Support of Petitions; Electronic Submission Using Food and Drug Administration Form 3503**

**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 for submission of petitions, including food and color additive petitions (including labeling) and generally recognized as safe (GRAS) affirmations, submission of information to a Master File in support of petitions, and electronic submission using FDA Form 3503. This notice also notifies the public of and solicits comments on FDA's proposed changes to Form FDA 3503 and elimination of Form FDA 3504.

**DATES:** Submit either electronic or written comments on the collection of information by August 13, 2010.

**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.

#### **Submission of Petitions: Food Additive, Color Additive (Including Labeling), and GRAS Affirmation; Submission of Information to a Master File in Support of Petitions; Electronic Submission Using FDA Form 3503—21 CFR 70.25, 71.1, 170.35, 171.1, 172, 173, 179, and 180 (OMB Control Number 0910-0016)—Revision**

Section 409(a) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348(a)) provides that a food additive shall be deemed to be unsafe, unless: (1) The additive and its use, or

intended use, are in conformity with a regulation issued under section 409 of the act that describes the condition(s) under which the additive may be safely used; (2) the additive and its use, or intended use, conform to the terms of an exemption for investigational use; or (3) a food contact notification submitted under section 409(h) of the act is effective. Food additive petitions (FAPs) are submitted by individuals or companies to obtain approval of a new food additive or to amend the conditions of use permitted under an existing food additive regulation. Section 171.1 of FDA's regulations (21 CFR 171.1) specifies the information that a petitioner must submit in order to establish that the proposed use of a food additive is safe and to secure the publication of a food additive regulation describing the conditions under which the additive may be safely used. Parts 172, 173, 179, and 180 (21 CFR parts 172, 173, 179, and 180) contain labeling requirements for certain food additives to ensure their safe use.

Section 721(a) of the act (21 U.S.C. 379e(a)) provides that a color additive shall be deemed to be unsafe unless the additive and its use are in conformity with a regulation that describes the condition(s) under which the additive may safely be used, or the additive and its use conform to the terms of an exemption for investigational use issued under section 721(f) of the act. Color additive petitions (CAPs) are submitted by individuals or companies to obtain approval of a new color additive or a change in the conditions of use permitted for a color additive that is already approved. Section 71.1 of the agency's regulations (21 CFR 71.1) specifies the information that a petitioner must submit to establish the safety of a color additive and to secure the issuance of a regulation permitting its use. FDA's color additive labeling requirements in § 70.25 (21 CFR 70.25) require that color additives that are to be used in food, drugs, devices, or cosmetics be labeled with sufficient information to ensure their safe use.

FDA scientific personnel review FAPs to ensure the safety of the intended use of the additive in or on food or that may be present in food as a result of its use in articles that contact food. Likewise, FDA personnel review color additive petitions to ensure the safety of the color additive prior to its use in food, drugs, cosmetics, or medical devices.

Under section 201(s) of the act (21 U.S.C. 321(s)), a substance is GRAS if it is generally recognized among experts qualified by scientific training and experience to evaluate its safety, to be safe through either scientific procedures

or common use in food. The act historically has been interpreted to permit food manufacturers to make their own initial determination that use of a substance in food is GRAS and thereafter seek affirmation of GRAS status from FDA. FDA reviews petitions for affirmation of GRAS status that are submitted on a voluntary basis by the food industry and other interested parties under authority of sections 201, 402, 409, and 701 of the act (21 U.S.C. 342, 348, and 371). To implement the GRAS provisions of the act, FDA has set forth procedures for the GRAS affirmation petition process in § 170.35(c)(1) of its regulations (21 CFR 170.35(c)(1)). While the GRAS affirmation petition process still exists, FDA has not received a GRAS affirmation petition since the establishment of the voluntary GRAS notification program and is not expecting any during the period covered by this proposed extension of collection of information.

Currently, interested persons may transmit regulatory submissions to the

Office of Food Additive Safety in the Center for Food Safety and Applied Nutrition using Form FDA 3503 for FAP and Form FDA 3504 for CAP. FDA is revising Form FDA 3503 to better enable its use for electronic submission and to permit its use for multiple types of submissions, which eliminates the need for Form FDA 3504. Because Form FDA 3503 helps the respondent organize their submission to focus on the information needed for FDA's safety review, FDA now recommends that this form be used for FAPs and CAPs, whether submitted in electronic format or paper format. FDA estimates that the amount of time for respondents to complete the revised FDA Form 3503 will continue to be 1 hour. The revised Form FDA 3503 can be used to submit information to FDA in electronic format using the Electronic Submission Gateway portal. The revised Form FDA 3503 can be used to substitute for the "Dear Sir" section of 21 CFR 71.1(c) for a CAP and 21 CFR 171.1(c) for an FAP. The revised Form FDA 3503 provides for submitters to indicate the date of

their most recent presubmission consultation activity with FDA. The revised Form FDA 3503 can also be used to organize information within a Master File submitted in support of petitions according to the items listed on the form. Master Files can be used as repositories for information that can be referenced in multiple submissions to the agency, thus minimizing paperwork burden for food and color additive approvals. The revised Form FDA 3503 is formatted to accept submissions for both FAP and CAP, thus making Form FDA 3504 redundant for collecting CAP submissions. Therefore, FDA is eliminating Form FDA 3504.

*Description of respondents:* Respondents are businesses engaged in the manufacture or sale of food, food ingredients, color additives, or substances used in materials that come into contact with food.

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

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

21 CFR Section/ FDA Form	No. of Respond- ents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Operating & Maintenance Costs	Total Hours
<b>CAPs</b>						
70.25,71	2	1	2	1,337	\$5,600	2,674
<b>GRAS Affirmation Petitions</b>						
170.35	1 or fewer	1	1 or fewer	2,614	0	2,614
<b>FAPs</b>						
171.1	3	1	3	7,093	0	21,279
FDA Form 3503	6	1	6	1	0	6
<b>Total</b>					<b>\$5,600</b>	<b>26,573</b>

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

The estimate of burden for food additive, color additive, or GRAS affirmation petitions is based on FDA's experience and the average number of new petitions received in calendar years 2006, 2007, 2008, and 2009, and the total hours expended in preparing the petitions. In compiling these estimates, FDA consulted its records of the number of petitions received in the past four years. The figures for hours per response are based on estimates from experienced persons in the agency and in industry. Although the estimated hour burden varies with the type of petition submitted, an average petition involves analytical work and appropriate toxicological studies, as well as the

work of drafting the petition itself. The burden varies depending on the complexity of the petition, including the amount and types of data needed for scientific analysis.

Color additives are subjected to payment of fees for the petitioning process. The listing fee for a color additive petition ranges from \$1,600 to \$3,000, depending on the intended use of the color and the scope of the requested amendment. A complete schedule of fees is set forth in 21 CFR 70.19. An average of one Category A and one Category B color additive petition is expected per year. The maximum color additive petition fee for a Category A petition is \$2,600 and the maximum

color additive petition fee for a Category B petition is \$3,000. Because an average of 2 color additive petitions are expected per calendar year, the estimated total annual cost burden to petitioners for this startup cost would be less than or equal to \$5,600 (1 x \$2,600 + 1 x \$3,000 listing fees = \$5,600). There are no capital costs associated with color additive petitions.

The labeling requirements for food and color additives were designed to specify the minimum information needed for labeling in order that food and color manufacturers may comply with all applicable provisions of the act and other specific labeling acts administered by FDA. Label information

does not require any additional information gathering beyond what is already required to assure conformance with all specifications and limitations in any given food or color additive regulation. Label information does not have any specific recordkeeping requirements unique to preparing the label. Therefore, because labeling requirements under § 70.25 for a particular color additive involve information required as part of the CAP safety review process, the estimate for number of respondents is the same for § 70.25 and § 71.1, and the burden hours for labeling are included in the estimate for § 71.1. Also, because labeling requirements under parts 172, 173, 179, and 180 for particular food additives involve information required as part of the FAP safety review process under § 171.1, the burden hours for labeling are included in the estimate for § 171.1.

Dated: June 7, 2010.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2010-14155 Filed 6-11-10; 8:45 am]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Heart, Lung, and Blood Institute; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. app.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Heart, Lung, and Blood Institute Special Emphasis Panel. Ruth L. Kirschstein NRSA Institutional Research Training Grants.

*Date:* June 24, 2010.

*Time:* 1 p.m. to 5:30 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

*Contact Person:* Roy L White, PhD, Scientific Review Officer, Review Branch/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7176,

Bethesda, MD 20892-7924, 301-435-0310, [whiterl@nhlbi.nih.gov](mailto:whiterl@nhlbi.nih.gov).

*Name of Committee:* National Heart, Lung, and Blood Institute Special Emphasis Panel Comparative Effectiveness Research in Clinical Hypertension Management.

*Date:* June 24, 2010.

*Time:* 12 p.m. to 3 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892. (Telephone Conference Call).

*Contact Person:* Chang Sook Kim, PhD, Scientific Review Officer, Review Branch, DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7190, Bethesda, MD 20892, 301-435-0287, [carolko@mail.nih.gov](mailto:carolko@mail.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: June 8, 2010.

**Jennifer Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 2010-14188 Filed 6-11-10; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Small Business; Rehabilitation Sciences.

*Date:* July 9, 2010.

*Time:* 8 a.m. to 6 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Hilton Alexandria Old Town, 1767 King Street, Alexandria, VA 22314.

*Contact Person:* Jo Pelham, BA, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4102, MSC 7814, Bethesda, MD 20892, (301) 435-1786, [pelhamj@csr.nih.gov](mailto:pelhamj@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Small Business; Hematology.

*Date:* July 9, 2010.

*Time:* 8 a.m. to 5 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

*Contact Person:* Delia Tang, MD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4126, MSC 7802, Bethesda, MD 20892, 301-435-2506, [tangd@csr.nih.gov](mailto:tangd@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Fellowships: Psychopathology, Developmental Disabilities, Stress and Aging.

*Date:* July 9, 2010.

*Time:* 8 a.m. to 5 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* InterContinental Mark Hopkins, 1 Nob Hill, San Francisco, CA 94108.

*Contact Person:* Kathryn Robbins, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3182, MSC 7848, Bethesda, MD 20892, (301) 435-0913, [robbinsk@mail.nih.gov](mailto:robbinsk@mail.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; Member Conflict: BGES and NAME.

*Date:* July 9, 2010.

*Time:* 8 a.m. to 4 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892. (Virtual Meeting)

*Contact Person:* Bob Weller, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3160, MSC 7770, Bethesda, MD 20892, (301) 435-0694, [wellerr@csr.nih.gov](mailto:wellerr@csr.nih.gov).

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; ARRA: Rehabilitation Sciences.

*Date:* July 9, 2010.

*Time:* 4 p.m. to 5 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Hilton Alexandria Old Town, 1767 King Street, Alexandria, VA 22314.

*Contact Person:* Jo Pelham, BA, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4102, MSC 7814, Bethesda, MD 20892, (301) 435-1786, [pelhamj@csr.nih.gov](mailto:pelhamj@csr.nih.gov).

*Name of Committee:* AIDS and Related Research Integrated Review Group; AIDS Molecular and Cellular Biology Study Section.

*Date:* July 12, 2010.

*Time:* 8 a.m. to 5 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Bethesda North Marriott Hotel & Conference Center, 5701 Marinelli Road, Bethesda, MD 20852.

*Contact Person:* Kenneth A Roebuck, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of