

(CHMI). Demonstration programs have been funded through Child Support Enforcement waivers authorized under section 1115 of the Social Security Act to support healthy marriage, improve child well-being and increase the financial security of children. The objective of the evaluation is to: (1) Assess the implementation of community interventions designed to provide marriage education by examining the way the projects operate and by examining child support outcomes among low-income families in the community; and (2) evaluate the community impacts of these interventions on marital stability and satisfaction, child well-being and child support outcomes among low-income families.

The purpose of this information collection is to continue to collect

implementation data under the protocols previously approved by the Office of Management and Budget (OMB), OMB Approval No. 0970-0283. Primary data for the implementation evaluation will come from observations, interviews, focus groups and records. One-on-one and small group interviews with project staff and marriage education service providers in the community will provide a detailed understanding of the administration and operation of the demonstrations. Focus group discussions will provide insights into participants' perspectives on marriage education and their experiences with the CHMI interventions.

In addition to the implementation information collected under this request, an impact evaluation will be integrated with the implementation

study and will assess the effects of healthy marriage initiatives by comparing family and child well-being outcomes in the CHMI communities with similar outcomes in comparison communities that are well matched to the project sites. Data from the implementation studies will provide the basis for the instrumental variable models of CHMI impacts to help determine direct or indirect exposure to marriage-related services. Baseline data collected under the impact evaluation has been approved by OMB (see OMB Approval No. 0970-0322).

Respondents: Lead Project Staff, Service Provider Organization Staff, Key Community, Civic Stakeholders, and Program Participants.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Average number of responses per respondent	Average burden hours per response	Total burden hours
Administrative interviews	200	2	1	400
Small group interviews	25	1	1.6	40

Estimated Total Annual Burden Hours: 440.

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. E-mail address: OPREInfoCollection@acf.hhs.gov. All requests should be identified by the title of the information collection.

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, *Fax:* 202-395-6974, *Attn:* Desk Officer for ACF.

Dated: June 9, 2008.

Brendan C. Kelly,

OPRE Reports Clearance Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2008-N-0170]

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

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 July 21, 2008.

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, or e-mailed to baguilar@omb.eop.gov. All comments

should be identified with the OMB control number 0910-0330. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Jonna Capezuto, Office of the Chief Information Officer (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4659.

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 for a New Dietary Ingredient—(OMB Control Number 0910-0330)—Extension

Section 413(a) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 350b(a)) provides that at least 75 days before the introduction or delivery for introduction into interstate commerce of a dietary supplement that contains a new dietary ingredient, a manufacturer or distributor of dietary supplements or of a new dietary ingredient is to submit to FDA (as delegate for the Secretary of Health and Human Services) information upon which the manufacturer or distributor has based its conclusion that a dietary supplement containing a new dietary

ingredient will reasonably be expected to be safe. Part 190 (21 CFR part 190) implements these statutory provisions. Section 190.6(a) requires each manufacturer or distributor of a dietary supplement containing a new dietary ingredient, or of a new dietary ingredient, to submit to the Office of Nutrition, Labeling, and Dietary Supplements notification of the basis for their conclusion that said supplement or ingredient will reasonably be expected to be safe. Section 190.6(b) requires that the notification include the following:

(1) The complete name and address of the manufacturer or distributor, (2) the name of the new dietary ingredient, (3) a description of the dietary supplements that contain the new dietary ingredient, and (4) the history of use or other evidence of safety establishing that the dietary ingredient will reasonably be expected to be safe.

The notification requirements described previously are designed to enable FDA to monitor the introduction into the food supply of new dietary ingredients and dietary supplements

that contain new dietary ingredients, in order to protect consumers from unsafe dietary supplements. FDA uses the information collected under these regulations to help ensure that a manufacturer or distributor of a dietary supplement containing a new dietary ingredient is in full compliance with the act.

In the **Federal Register** of March 26, 2008 (73 FR 16020), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
190.6	71	1	71	20	1,420

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

The agency believes that there will be minimal burden on the industry to generate data to meet the requirements of the premarket notification program because the agency is requesting only that information that the manufacturer or distributor should already have developed to satisfy itself that a dietary supplement containing a new dietary ingredient is in full compliance with the act. However, the agency estimates that extracting and summarizing the relevant information from the company's files and presenting it in a format that will meet the requirements of section 413 of the act will require a burden of approximately 20 hours of work per submission.

The estimated number of premarket notifications and hours per response is an average based on the agency's experience with notifications received during the last 3 years (i.e., 2005, 2006, and 2007), and information from firms that have submitted recent premarket notifications.

Dated: June 13, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8-13818 Filed 6-18-08; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice

is hereby given of the following meeting.

The meeting 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, The Biochemistry and Molecular Biology of Pathogens.

Date: June 20, 2008.

Time: 11 a.m. to 2 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: Rolf Menzel, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3196, MSC 7808, Bethesda, MD 20892, 301-435-0952, menzelro@csr.nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: June 10, 2008.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E8-13509 Filed 6-18-08; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Center for Scientific Review Special Emphasis Panel, July 21, 2008, 12 p.m. to July 21, 2008, 1:30 p.m., National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD, 20892 which was published in the **Federal Register** on June 9, 2008, 73 FR 32589-32590.

The meeting will be held July 29, 2008, 2 p.m. to 3:30 p.m. The meeting location remains the same. The meeting is closed to the public.

Dated: June 10, 2008.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E8-13510 Filed 6-18-08; 8:45 am]

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