

(2) *Specialists*. This cohort includes office-based practitioners in rheumatology with at least 3 years of experience and who engage in patient care at least 50 percent of the time.

Cohorts will be identified and recruited to represent a reasonable range of age, gender, and ethnicity.

Within each cohort, 20 practitioners will be interviewed by trained interviewers in one-on-one in-depth telephone interviews. A sample size of 40 (approximately 20 primary care providers and 20 rheumatologists) is sufficiently large for the qualitative findings to capture a wide depth and range of people's thinking. The

interviews will take approximately 45 minutes. The health care provider interviews will be used to create a mental model of physician decisionmaking factors with respect to drug product effectiveness.

Potential physician participants will be randomly identified through a purchased list based on the American Medical Association's (AMA) Physician Masterfile. This list tracks all physicians, M.D. (doctor of medicine) and DO (doctor of osteopathic medicine), practicing in the United States, not only members of the AMA.

FDA intends this collection to be used as formative research. As with our focus

group research (OMB control number 0910-0360), the results of this formative research will provide direction toward potential areas of focus. Further research is necessary, and planned, to test concepts obtained from these results. This research will be useful in designing survey questions for the next phases of this research project (which will be submitted for approval at a later date).

In the **Federal Register** of November 24, 2008 (73 FR 71006), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

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

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours Per Response	Total Hours
21 U.S.C. 393(b)(2)(c) Questionnaire, Pretesting	4	1	4	.75	3
21 U.S.C. 393(b)(2)(c) Questionnaire, Study	40	1	40	.75	30
Total					33

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

Dated: March 27, 2009.

**Jeffrey Shuren,**

*Associate Commissioner for Policy and Planning.*

[FR Doc. E9-7471 Filed 4-2-09; 8:45 am]

BILLING CODE 4160-01-S

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2008-N-0653]

#### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Filing Objections and Requests for a Hearing on a Regulation or Order

**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 May 4, 2009.

**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 [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910-0184. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Jonna Capezzuto, Office of Information Management (HFA-710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-796-3794.

**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.

#### Filing Objections and Requests for a Hearing on a Regulation or Order—(OMB Control Number 0910-0184)—Extension

The regulations in 21 CFR 12.22, issued under section 701(e)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 371(e)(2)), set forth the instructions for filing objections and requests for a hearing on a regulation or

order under § 12.20(d) (21 CFR 12.20(d)). Objections and requests must be submitted within the time specified in § 12.20(e). Each objection, for which a hearing has been requested, must be separately numbered and specify the provision of the regulation or the proposed order. In addition, each objection must include a detailed description and analysis of the factual information and any other document, with some exceptions, supporting the objection. Failure to include this information constitutes a waiver of the right to a hearing on that objection. FDA uses the description and analysis to determine whether a hearing request is justified. The description and analysis may be used only for the purpose of determining whether a hearing has been justified under 21 CFR 12.24 and do not limit the evidence that may be presented if a hearing is granted.

Respondents to this information collection are those parties that may be adversely affected by an order or regulation.

In the **Federal Register** of January 14, 2009 (74 FR 2080), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

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

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

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
12.22	5	1	5	20	100

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

The burden estimate for this collection of information is based on past filings. Agency personnel, responsible for processing the filing of objections and requests for a public hearing on a specific regulation or order, estimate approximately five requests are received by the agency annually, with each requiring approximately 20 hours of preparation time.

Dated: March 27, 2009.

**Jeffrey Shuren,**

*Associate Commissioner for Policy and Planning.*

[FR Doc. E9-7472 Filed 4-2-09; 8:45 am]

**BILLING CODE 4160-01-S**

2009, 5 p.m., National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 which was published in the **Federal Register** on February 17, 2009, 74 FR 7452.

This meeting is being amended to reschedule the meeting to April 13-14, 2009 from 8 a.m. to 5 p.m. The meeting is closed to the public.

Dated: March 24, 2009.

**Jennifer Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. E9-7263 Filed 4-2-09; 8:45 am]

**BILLING CODE 4140-01-M**

Career Development Awards for Scientists and Clinicians; 93.272, Alcohol National Research Service Awards for Research Training; 93.273, Alcohol Research Programs; 93.891, Alcohol Research Center Grants, National Institutes of Health, HHS)

Dated: March 25, 2009.

**Jennifer Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. E9-7319 Filed 4-2-09; 8:45 am]

**BILLING CODE 4140-01-M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Notice of a Conference Call of a Working Group of the NIH Blue Ribbon Panel

The purpose of this notice is to inform the public about a conference call of the NIH Blue Ribbon Panel to Advise on the Risk Assessment of the National Emerging Infectious Diseases Laboratories at Boston University Medical Center. This meeting is the first in a series of public meetings to review and discuss the ongoing supplementary risk assessment study.

The conference call will be held on Tuesday, April 7, 2009 from approximately 11 a.m. to 1 p.m. The toll-free number to participate in the call is 1-800-779-2616. Indicate to the conference operator that your participant passcode is "NIH."

The panel will review earlier National Research Council (NRC) recommendations regarding a supplementary risk assessment study, Blue Ribbon Panel recommendations regarding various aspects of the risk assessment study, and a new Statement of Task for the NRC.

Public comment will begin at approximately 12:45 p.m. In the event that time does not allow for all those interested to present oral comments, anyone may file written comments by sending them to the address below. Comments should include the name, address, telephone number and when applicable, the business or professional affiliation of the commenter.

A draft agenda and slides for the meeting may be obtained by connecting to <http://nihblueribbonpanel-bumc->

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Cancer Institute; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the President's Cancer Panel, March 23, 2009, 12:30 p.m. to March 23, 2009, 3 p.m., National Institutes of Health, 6116 Executive Boulevard, Rockville, MD 20852 which was published in the **Federal Register** on March 19, 2009, 74 FR 11741.

This meeting is being amended to reschedule the meeting to Tuesday, March 31, 2009, 10 a.m. to 12:30 p.m. as a telephone conference. The meeting is closed to the public.

Dated: March 25, 2009.

**Jennifer Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. E9-7318 Filed 4-2-09; 8:45 am]

**BILLING CODE 4140-01-M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Center for Complementary & Alternative Medicine; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Center for Complementary and Alternative Medicine Special Emphasis Panel, March 24, 2009, 8 a.m. to March 25,

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute on Alcohol Abuse and Alcoholism; Notice of Closed Meeting

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 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:* National Institute on Alcohol Abuse and Alcoholism, Special Emphasis Panel. AA3 Deferred Applications.

*Date:* April 22, 2009.

*Time:* 2 p.m. to 4 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* NIH/NIAAA, 5635 Fishers Lane, Bethesda, MD 20892 (Telephone Conference Call).

*Contact Person:* Katrina L Foster, PhD, Scientific Review Officer, National Inst on Alcohol Abuse & Alcoholism, National Institutes of Health, 5635 Fishers Lane, Rm. 2019, Rockville, MD 20852, 301-443-4032. [katrina@mail.nih.gov](mailto:katrina@mail.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.271, Alcohol Research