the Dietary Supplement and Nonprescription Drug Consumer Protection Act: Questions and Answers.'' The estimates for one-time reporting are based on FDA's knowledge of nonprescription drug product labeling in the United States, whether or not marketed under an approved application.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN [1]

	No. of Respondents	Frequency per Response	Total Responses	Hours per Response	Total Hours
Domestic address or telephone number labeling requirement (21 U.S.C. 502(x)) and recommendation to clarify its purpose	200	500	100,000	4	400,000

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

As indicated in Table 1 of this document, we estimate that approximately 200 manufacturers will revise approximately 100,000 labels to add a full domestic address and a domestic telephone number, and should they choose to adopt the guidance's recommendation, to add a statement identifying the purpose of the domestic address or telephone number. FDA believes that designing the label change should not take longer than 4 hours per label. Automated printing of the labels should only require a few seconds per label. This estimate accounts for the possibility that every manufacturer will make label revision, which is unlikely. Because the majority of over-the-counter drug product labels currently have a domestic telephone number that satisfies the requirement, we believe many manufacturers will opt not to adopt the guidance's recommendation to add a statement identifying the purpose of the address or telephone number, significantly reducing the number of total responses. However, assuming that all labels are revised, estimate a one-time reporting burden for this information collection of 400,000 hours.

In the **Federal Register** of January 2, 2008 (73 FR 196), FDA published a notice of availability for the original draft guidance that also gave notice of the proposed collections of information in the draft guidance, included an analysis and burden estimate for those proposed collections of information, and provided 60 days for public comment under the PRA. FDA did not revise the PRA burden analysis and estimate when it issued the revised draft guidance in December 2008 because the revisions did not affect them.

FDA received one comment on the proposed collections of information, stating that the time involved in revising labels would be significantly longer than the typical timeframe to implement labeling changes because the volume of labels required to be revised at one time might exceed manufacturers' labeling revision capacity. Several comments requested that FDA extend the date of its enforcement discretion. In response to comments, in December 2008, FDA published a notice of availability of the revised draft guidance for industry. The revised draft guidance was identical to the first draft guidance, with the exception that, in the revised draft guidance, FDA stated its intention to exercise enforcement discretion until January 1, 2010. As a result, any label revision made as a result of this guidance would likely be made contemporaneously with other scheduled label revisions, minimizing the burden to industry.

Dated: February 17, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–3917 Filed 2–23–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0664]

Clinical Trial Design for Hospital-Acquired Pneumonia and Ventilator-Associated Pneumonia; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public workshop, cosponsored with the Infectious Diseases Society of America (IDSA), the American College of Chest Physicians (ACCP), the Society of Critical Care Medicine (SCCM), and the American Thoracic Society (ATS) regarding scientific issues in clinical trial design for hospital-acquired pneumonia (HAP) and ventilator-associated pneumonia (VAP). This public workshop is intended to provide information about, and gain perspective from, health care providers, academia, and industry on various aspects of antimicrobial drug development for HAP and VAP, including diagnosis of HAP and VAP, effect of antimicrobial treatment for HAP and VAP, endpoints for trials of HAP and VAP, and statistical issues in analysis of results of trials in HAP and VAP. The input from this public workshop will help in developing topics for further discussion.

Date and Time: The public workshop will be held on March 31, 2009, from 8 a.m. to 6 p.m. and on April 1, 2009, from 8 a.m. to 5 p.m.

Location: The public workshop will be held at the Crowne Plaza Hotel, Kennedy Ballroom, 8777 Georgia Ave., Silver Spring, MD 20910. Seating is limited and available only on a first-come, first-served basis.

Contact: Chris Moser or Lori Benner, Center for Drug Evaluation and Research, Food and Drug Administration, Office of Antimicrobial Products, 10903 New Hampshire Ave., Bldg. 22, rm. 6209, Silver Spring, MD 20993– 0002, 301–796–1300.

Registration: To register electronically, e-mail registration information (including name, title, firm name, address, telephone, and fax numbers) to *HAPwkshp@fda.hhs.gov* by March 23, 2009. Persons without access to the Internet can call 301–796–1300 to register. Registration is free for the public workshop. Interested parties are encouraged to register early because space is limited. Seating will be available on a first-come, first-served basis. Persons needing a sign language interpreter or other special accommodations should notify Chris Moser or Lori Benner (see Contact) at least 7 days in advance.

SUPPLEMENTARY INFORMATION: FDA is announcing a public workshop, cosponsored with IDSA, ACCP, SCCM, and ATS, regarding antimicrobial drug

development for HAP and VAP. This public workshop will focus on scientific considerations in designing clinical trials for HAP and VAP. Topics for discussion include the following: (1) Approaches to the diagnosis of HAP and VAP, (2) the effect of antimicrobial treatment for HAP and VAP, (3) various endpoints that might be considered as endpoints for trials of HAP and VAP, and (4) statistical issues in analysis of results from trials in HAP and VAP. The input from this public workshop will help in developing topics for further discussion.

The agency encourages individuals, patient advocates, industry, consumer groups, health care professionals, researchers, and other interested persons to attend this public workshop.

Transcripts: Transcripts of the public workshop may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 6–30, Rockville, MD 20857, approximately 20 working days after the public workshop at a cost of 10 cents per page. Transcripts will also be available on the Internet at *http://www.fda.gov/cder/meeting/hap_vap.htm* approximately 45 days after the workshop.

Dated: February 17, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–3832 Filed 2–23–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0664]

Arthritis Advisory Committee; Notice of Postponement of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is postponing the meeting of the Arthritis Advisory Committee scheduled for March 5, 2009. This meeting was announced in the **Federal Register** of January 29, 2009 (74 FR 5165). The postponement is due to the need to complete the review of additional data submitted by the applicant. Future meeting dates will be announced in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Nicole Vesely, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301–827–6793, FAX: 301–827–6776, e-mail: *nicole.vesely@fda.hhs.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512532. Please call the Information Line for up-to-date information on this meeting.

Dated: February 17, 2009.

Randall W. Lutter,

Deputy Commissioner for Policy.

[FR Doc. E9–3830 Filed 2–23–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health & Human Development; 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: National Institute of Child Health and Human Development Initial Review Group; Obstetrics and Maternal-Fetal Biology Subcommittee.

Date: March 23, 2009.

Time: 9 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications and/or proposals.

Place: Courtyard Gaithersburg Washingtonian Center, 204 Boardwalk Place, Gaithersburg, MD 20878.

Contact Person: Gopal M. Bhatnagar, PhD, Scientific Review Administrator, National Institute of Child Health and Human Development, National Institutes of Health, 6100 Executive Blvd., Rm. 5b01, Rockville, MD 20852, (301) 435–6889, *bhatnagg@mail.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: February 18, 2009.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E9–3952 Filed 2–23–09; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health & Human Development; 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: National Institute of Child Health and Human Development Initial Review Group. Population Sciences Subcommittee.

Date: March 26–27, 2009.

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

Agenda: To review and evaluate grant applications.

Place: The Madison Hotel, 1177 15th Street, NW., Washington, DC 20005.

Contact Person: Carla T. Walls, PhD, Scientific Review Administratior, Division of Scientific Review, National Institute of Child Health, and Human Development, NIH, 6100 Executive Blvd., Room 5B01, Bethesda, MD 20892, (301) 435–6898, *wallsc@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: February 18, 2009.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E9–3956 Filed 2–23–09; 8:45 am]

BILLING CODE 4140–01–P