TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN FOR REGULATORS[1]

Types of Records	No. of Recordkeepers	Annual Frequency of Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
Voluntary Food Safety Management System Evaluation (includes validation, verification, and completion of verification inspection checklist)	50,000	1	50,000	16	800,000
Total Annual Burden for Regulators					800,000

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

It is difficult to predict the number of State, local, and tribal regulatory jurisdictions that will use the Regulator's Manual. But, FDA anticipates that retail and foodservice establishments which voluntarily develop and implement a food safety management system based on the Operator's Manual will request their regulatory authorities to conduct an evaluation of their system. The estimates in table 2 of this document for the annual burden to State, local, and tribal regulators that follow the recommendations in the Regulator's Manual were calculated based on the usual time needed for one person to evaluate a voluntarily-implemented food safety management system and record the findings. The number of times an inspector may be asked by an operator to evaluate a voluntarily-implemented system is not expected to exceed once per year.

Dated: March 11, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–6168 Filed 3–19–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–D–0136]

Draft Guidance for Industry on Community-Acquired Bacterial Pneumonia: Developing Drugs for Treatment; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Community-Acquired Bacterial Pneumonia: Developing Drugs for Treatment.'' This draft guidance informs industry of FDA's current thinking regarding the overall development program and clinical trial designs for drugs to support an indication for treatment of community-acquired bacterial pneumonia (CABP). This draft guidance does not address the development of drugs for other purposes or populations, such as treatment of patients with hospital-acquired pneumonia or ventilator-associated pneumonia. This draft guidance revises the draft guidance for industry entitled ''Community-Acquired Pneumonia-Developing Antimicrobial Drugs for Treatment'' published July 1998.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by June 18, 2009.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT:

Sumathi Nambiar, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 6232, Silver Spring, MD 20993–0002, 301–796–1400; or

Edward Cox, Center for Drug Evaluation and Research, 10903 New Hampshire Ave., Bldg. 22, rm. 6212, Silver Spring, MD 20993–0002, 301–796–1300.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Community-Acquired Bacterial Pneumonia: Developing Drugs for Treatment.'' Since FDA published the draft guidance on the development of antimicrobial drugs for the treatment of community-acquired pneumonia in 1998, there have been public discussions regarding clinical trial designs to study CABP, including an FDA–Infectious Disease Society of America (IDSA) workshop and a meeting of the Anti-Infective Drugs Advisory Committee. These discussions have focused on clinical trial designs for CABP and other important issues such as the following:

- Noninferiority versus superiority design
- Justification of an appropriate noninferiority margin
- Classification of severity of illness
- Classification of CABP based on hospitalization (inpatient versus outpatient)
- Enrollment criteria
- Application of appropriate diagnostic criteria, including microbiologic diagnosis
- Use of appropriate definitions of clinical outcomes, including mortality
- Timing of outcome assessments
- Use of prior antibacterial drugs

Important changes from the 1998 draft guidance that are based on these discussions have been incorporated into this revised draft guidance.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on the development of antibacterial drugs for CABP including appropriate clinical trial designs to evaluate drugs for the treatment of CABP. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach

satisfies the requirements of the applicable statutes and regulations.

II. The Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 312 have been approved under OMB control no. 0910–0014; the collections of information in 21 CFR part 314 have been approved under OMB control no. 0910–0001; and the collections of information referred to in the guidance ''Establishment and Operation of Clinical Trial Data Monitoring Committees'' have been approved under OMB control no. 0910–0581.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/cder/guidance/index.htm* or *http://www.regulations.gov*.

Dated: March 13, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–6145 Filed 3–19–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Nursing Research; 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 Nursing Research, Special Emphasis Panel, NINR Loan Repayment Program Review (L30/L40).

Date: April 16, 2009.

Time: 10 a.m. to 3 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, One Democracy Plaza, 6701 Democracy Boulevard, Bethesda, MD 20892. (Telephone Conference Call).

Contact Person: Yujing Liu, PhD, MD, Chief, Office of Review, Division of Extramural Activities, National Institute of Nursing Research, National Institutes of Health, 6701 Democracy Blvd., Ste 710, Bethesda, MD 20892. (301) 451–5152. *yujing_liu@nih.gov*.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

(Catalogue of Federal Domestic Assistance Program Nos. 93.361, Nursing Research, National Institutes of Health, HHS)

Dated: March 10, 2009.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E9–5995 Filed 3–19–09; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HOMELAND SECURITY

Transportation Security Administration

New Agency Information Collection Activity Under OMB Review: Security Program Training Feedback for Hazardous Materials Motor Carriers & Shippers

AGENCY: Transportation Security Administration, DHS.

ACTION: 30 Day Notice.

SUMMARY: This notice announces that the Transportation Security Administration (TSA) has forwarded the new Information Collection Request (ICR) abstracted below to the Office of Management and Budget (OMB) for review and approval under the Paperwork Reduction Act. The ICR describes the nature of the information collection and its expected burden. TSA published a **Federal Register** notice, with a 60-day comment period soliciting comments, of the following collection of information on November 20, 2008, 73 FR 70359. TSA will provide a voluntary security-related training course to the Hazardous Materials (Hazmat) motor carrier and shipper industry, to include an evaluation for respondents to complete. TSA will use this data to measure the program's effectiveness at achieving its goal of heightened security awareness levels throughout the hazmat motor carrier and shipper industry.

DATES: Send your comments by April 20, 2009. A comment to OMB is most effective if OMB receives it within 30 days of publication.

ADDRESSES: Interested persons are invited to submit written comments on the proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget. Comments should be addressed to Desk Officer, Department of Homeland Security/TSA, and sent via electronic mail to *oira_submission@omb.eop.gov* or faxed to (202) 395–6974.

FOR FURTHER INFORMATION CONTACT: Ginger LeMay, Office of Information Technology, TSA–11, Transportation Security Administration, 601 South 12th Street, Arlington, VA 20598–6011; telephone (571) 227–3616; e-mail *ginger.lemay@dhs.gov*.

SUPPLEMENTARY INFORMATION:

Comments Invited

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The ICR documentation is available at *http://www.reginfo.gov*. Therefore, in preparation for OMB review and approval of the following information collection, TSA is soliciting comments to—

(1) Evaluate whether the proposed information requirement is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including using appropriate automated, electronic, mechanical, or other technological