passport), and must be listed on an approved security list before persons are permitted entrance. Persons not registered in advance will not be permitted into the CMS building and will not be permitted to attend the meeting.

We cannot assume responsibility for coordinating the receipt, transfer, transport, storage, set-up, safety, or timely arrival of any personal belongings or items used for the purpose of presentation.

Individuals requiring sign language interpretation or other special accommodation must contact the Designated Federal Officer specified in the **FOR FURTHER INFORMATION CONTACT** section of this notice by September 17, 2008.

(Catalog of Federal Domestic Assistance Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: August 19, 2008.

Kerry Weems,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. E8–19564 Filed 8–21–08; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0419]

Draft Guidance for Industry on Acute Bacterial Exacerbations of Chronic Bronchitis in Patients With Chronic Obstructive Pulmonary Disease: Developing Antimicrobial Drugs for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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Acute Bacterial Exacerbations of Chronic Bronchitis in Patients With Chronic Obstructive Pulmonary Disease: Developing Antimicrobial Drugs for Treatment.'' The purpose of this draft guidance is to assist clinical trial sponsors and investigators in the development of antimicrobial drugs for the treatment of acute bacterial exacerbations of chronic bronchitis in patients with chronic obstructive pulmonary disease (ABECB–COPD). The agency's thinking in this area has evolved in recent years, and this draft guidance, when finalized, will inform sponsors of the changes in our recommendations. In addition, it will fulfill a statutory requirement enacted in the Food and Drug Administration Amendments Act of 2007 (FDAAA) to publish such a guidance.

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comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by November 20, 2008.

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: Steven Gitterman, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 6134, Silver Spring, MD 20993–0002, 301–796–1600.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Acute Bacterial Exacerbations of Chronic Bronchitis in Patients With Chronic Obstructive Pulmonary Disease: Developing Antimicrobial Drugs for Treatment.'' The purpose of this draft guidance is to assist clinical trial sponsors and investigators in the development of antimicrobial drugs for the treatment of ABECB–COPD. This guidance revises the draft guidance regarding ABECB published in 1998. Section 911 of FDAAA (Public Law 110–85) adds section 511 to the Federal Food, Drug, and Cosmetic Act that directs the Secretary of Health and Human Services to ''issue guidance for the conduct of clinical trials with respect to antibiotic drugs, including antimicrobials to treat * * * acute bacterial exacerbation of chronic bronchitis.''

The design of ABECB clinical trials was discussed at a meeting of the Anti-Infective Drugs Advisory Committee on February 19, 2002, and an IDSA/PhRMA/FDA workshop on November 19 and 20, 2002. In addition, other advisory committee meetings have focused on the development of specific drugs for this indication. As a result of these public discussions, as well as review of applications at FDA, the agency's thinking in this area has evolved in recent years, and this draft guidance informs sponsors of the changes in our recommendations. Specifically, this draft guidance recommends that ABECB–COPD clinical trials be designed as superiority rather than noninferiority trials, and discusses some possible study designs that might be employed in an ABECB–COPD trial designed to show superiority. This draft guidance discusses patient-reported outcome instruments for assessing clinical response, and the use of time to resolution of symptoms as a possible approach to assessing the primary endpoint in clinical studies.

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 developing drugs for the treatment of ABECB–COPD. 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 number 0910–0014; the collections of information in 21 CFR part 314 have been approved under OMB control number 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 number 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.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at *http://www.regulations.gov*.

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: August 13, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–19490 Filed 8–21–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0447]

Achieving a Future Vision at the 2008 Parenteral Drug Association and the Food and Drug Administration Joint Regulatory Conference

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of meeting.

The Food and Drug Administration (FDA) is announcing the following meeting: Achieving a Future Vision at the 2008 Parenteral Drug Association and the Food and Drug Administration Joint Regulatory Conference. The topics to be discussed are: FDA's Pharmaceutical Inspectorate and the Global Harmonization Task Force; Trans Atlantic initiative; Product development; and legacy products; Supply chain; Combination products; and Recall root causes.

Date and Time: The meeting will be held on September 8 through 12, 2008, 7 a.m. to 6.

Location: The meeting will be held at Renaissance Hotel, 999 9th St., NW., Washington, DC 20001.

Contact: Wanda Neal-Ballard, Parenteral Drug Association, PDA Global Headquarters, Bethesda Towers, 4350 East West Hwy., Suite 200, Bethesda, MD 20814 or by telephone on 301–986–0293, ext. 111.

Registration and Meeting Information: See PDA Web site, *www.pda.org/pdafda2008* or contact Wanda Neal-Ballard on 301–986–0293, ext. 111. From now until August 25, 2008, registration fees are as follows: $1,600.00 for Members, $2,000.00 for Non-members, $615.00 for Government/Health Authority/Academic and $230.00 for Students. After August 25, 2008, registration fees are as follows: $1,800.00 for Members, $2,200.00 for Non-members, $700.00 for Government/Health Authority/Academic and $260.00 for Students.

If you need special accommodations due to a disability, please contact Wanda Neal-Ballard at least 7 days in advance.

Dated: August 18, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–19491 Filed 8–21–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; California Health Interview Survey Cancer Control Module (CHIS–CCM) 2009 (NCI)

SUMMARY: In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Cancer Institute (NCI), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Proposed Collection: Title: California Health Interview Survey Cancer Control Module (CHIS–CCM) 2009. *Type of Information Collection Request:* New. *Need and Use of Information Collection:* The NCI has sponsored four Cancer Control Modules in the California Health Interview Survey (CHIS), and will be sponsoring a fifth to be administered in 2009. CHIS is a telephone survey that collects population-based, standardized health-related data to assess California's progress in meeting Healthy People 2010 objectives for the nation and the state. The CHIS sample is designed to provide statistically reliable estimates statewide, for California counties, and for California's ethnically and racially diverse population. Initiated by the UCLA Center for Health Policy Research, the California Department of Health Services, and the California Public Health Institute, the survey is funded by a number of public and private sources. It was first administered in 2001 to 55,428 adults and subsequently in 2003 to 42,043 adults, in 2005 to 43,020 adults, and in 2007 to 48,150 adults. These adults are a representative sample of California's non-institutionalized population living in households. CHIS 2009, the fifth bi-annual survey, is planned for administration to 55,000 adult Californians. This study will allow NCI to examine patterns and trends in cancer screening and follow-up, as well as to study other cancer-related topics such as tobacco control, diet, physical activity, and obesity. Additionally, CHIS is designed to be comparable to the National Health Interview Survey (NHIS) data in order to conduct comparative analyses. CHIS provides enhanced estimates for cancer risk factors and screening among racial/ethnic minority populations. *Frequency of Response:* Once. *Affected public:* Individuals or households. *Types of Respondents:* U.S. adults and adolescents (persons 12 years of age and older). The total annual burden hours requested are 3,276.94 (see Table A). The annualized cost to respondents is estimated at: $55,071.88. There are no Capital Costs, Operating Costs, and/or Maintenance Costs to report.

TABLE A—ANNUALIZED BURDEN ESTIMATES FOR CHIS 2009

Type of respondent	Form type	Number of respondents	Frequency of response	Average time per response (hours)	Annual hour burden
Adults	Adult Pilot	75	1	8/60	10.00
	Adult Survey	24,000.00	1	8/60	3,200.00