Dated: January 11, 2008.

Michelle Shortt,

Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. E8–909 Filed 1–17–08; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–R–185]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS) is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection Request:* Extension without change of a currently approved collection; *Title of Information Collection:* Granting and Withdrawal of Deeming Authority to Private Nonprofit Accreditation Organizations and of State Exemption Under State Laboratory Programs and Supporting Regulations in 42 CFR 493.551—493.557. *Form Number:* CMS–R–185 (OMB# 0938–0686); *Frequency:* On occasion; *Affected Public:* Private sector—Business or other for-profit and Not-for-profit institutions; *Number of Respondents:* 8; *Total Annual Responses:* 96; *Total Annual Hours:* 384.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS's Web site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995,* or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov,* or call the Reports Clearance Office on (410) 786–1326.

To be assured consideration, comments and recommendations for the proposed information collections must be received at the address below, no later than 5 p.m. on *March 18, 2008.*

CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development—A, Attention: Melissa Musotto, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: January 10, 2008.

Michelle Shortt,

Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. E8–911 Filed 1–17–08; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2008N–0004]

Draft Guidance for Industry on Acute Bacterial Otitis Media: 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 ''Acute Bacterial Otitis Media: Developing Drugs for Treatment.'' The purpose of this draft guidance is to assist clinical trial sponsors and investigators in the development of antimicrobial drug products for the treatment of acute bacterial otitis media (ABOM). 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 to publish such a guidance enacted in the Food and Drug Administration Amendments Act of 2007 (FDAAA).

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 April 17, 2008.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. 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 either *http://www.fda.gov/dockets/ecomments* or *http://www.regulations.gov*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: John Alexander, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 6134, Silver Spring, MD 20993–0002, 301–796–1400.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Acute Bacterial Otitis Media: Developing Drugs for Treatment.'' The purpose of this draft guidance is to assist clinical trial sponsors and investigators in the development of antimicrobial drug products for the treatment of ABOM. This guidance revises the draft guidance regarding ABOM 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 otitis media * * *.'' This draft guidance will fulfill this statutory requirement.

The design of clinical trials for ABOM was the subject of an Anti-Infective Drugs Advisory Committee meeting on July 11, 2002. In addition, other advisory committee meetings have focused on the development of specific drug products for this indication. As a result of these public discussions, as well as review of pending applications at FDA, the agency's thinking in this area has evolved in recent years, and this guidance informs sponsors of the changes in our recommendations. Specifically, this draft guidance recommends that ABOM clinical trials be designed as superiority rather than noninferiority trials, and discusses some possible study designs that might be employed in an ABOM trial designed to show superiority. This draft guidance