

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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DDM

Food and Drug Administration

Clinical Trial Design for Community-Acquired 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), regarding scientific issues in clinical trial design for community-acquired pneumonia. This public workshop is intended to provide information for and to gain perspective from health care providers, academia, and industry on various aspects of antimicrobial drug development for community-acquired pneumonia, including diagnosis of community-acquired pneumonia, effect of antimicrobial treatment for community-acquired pneumonia, endpoints for trials of community-acquired pneumonia, and statistical issues in analysis of results of trials in community-acquired pneumonia. The input from this public workshop will help in developing topics for further discussion.

Date and Time: The public workshop will be held on January 17, 2008, from 8 a.m. to 6 p.m. and on January 18, 2008, from 8 a.m. to 5 p.m.

Location: The public workshop will be held at the Crowne Plaza Hotel, Kennedy Room, 8777 Georgia Ave., Silver Spring, MD 20910, 301-589-0800. Seating is limited and available only on a first-come, first-served basis.

Contact Person: Chris Moser or Lori Benner, Center for Drug Evaluation and Research, Office of Antimicrobial Products, Food and Drug

Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 6413, Silver Spring, MD 20993-0002, 301-796-0767, or 301-796-0849.

Registration: There is no registration fee for the public workshop. Space is limited; therefore, interested parties are encouraged to register early. Seating will be available on a first-come, first-served basis. To register electronically, e-mail registration information (including name, title, firm name, address, telephone, and fax number) to *CAPwkshp@fda.hhs.gov* by January 9, 2008. Persons without access to the Internet can call 301-796-1300 to register. Persons needing a sign language interpreter or other special accommodations should notify Chris Moser or Lori Benner (see *Contact Person*) at least 7 days in advance.

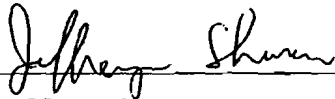
SUPPLEMENTARY INFORMATION: FDA is announcing a public workshop, cosponsored with IDSA, regarding antimicrobial drug development. This public workshop will focus on scientific considerations in designing clinical trials for community-acquired pneumonia. The topics for discussion include approaches to the diagnosis of community-acquired pneumonia, the effect of antimicrobial treatment for community-acquired pneumonia, various endpoints that might be considered as endpoints for trials of community-acquired pneumonia, and statistical issues in analysis of results from trials in community-acquired pneumonia. 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.

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Dated: December 18, 2007.



Jeffrey Shuren,
Assistant Commissioner for Policy.

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