

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

DMB

Display Date 8-5-03

Publication Date 8-6-03

Certifier J. Hawkins

Food and Drug Administration and National Institute of Allergy and
Infectious Diseases; 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 National Institute of Allergy and Infectious Diseases (NIAID), regarding clinical trial design of febrile neutropenia and antifungal combination therapy. The public workshop is intended to provide information for and gain perspectives from advocacy groups, interested health care providers, academia, and industry organizations on various aspects of febrile neutropenic and antifungal drug development.

DATES: The public workshop will be held on Thursday, September 4, 2003, from 1 p.m. to 5 p.m.

ADDRESSES: The public meeting will be held at the Hyatt Regency Bethesda, One Bethesda Metro Center, Bethesda, MD 20814. Seating is limited and available on a first-come, first-served basis. See the **SUPPLEMENTARY INFORMATION** section for information on electronic registration.

FOR FURTHER INFORMATION CONTACT: John Powers or Leo Chan, Center for Drug Evaluation and Research (HFD-104), Food and Drug Administration, 9201 Corporate Blvd., Rockville, MD 20850, 301-827-2530.

SUPPLEMENTARY INFORMATION: FDA is announcing a public workshop, cosponsored with NIAID, regarding two drug development scenarios: (1)

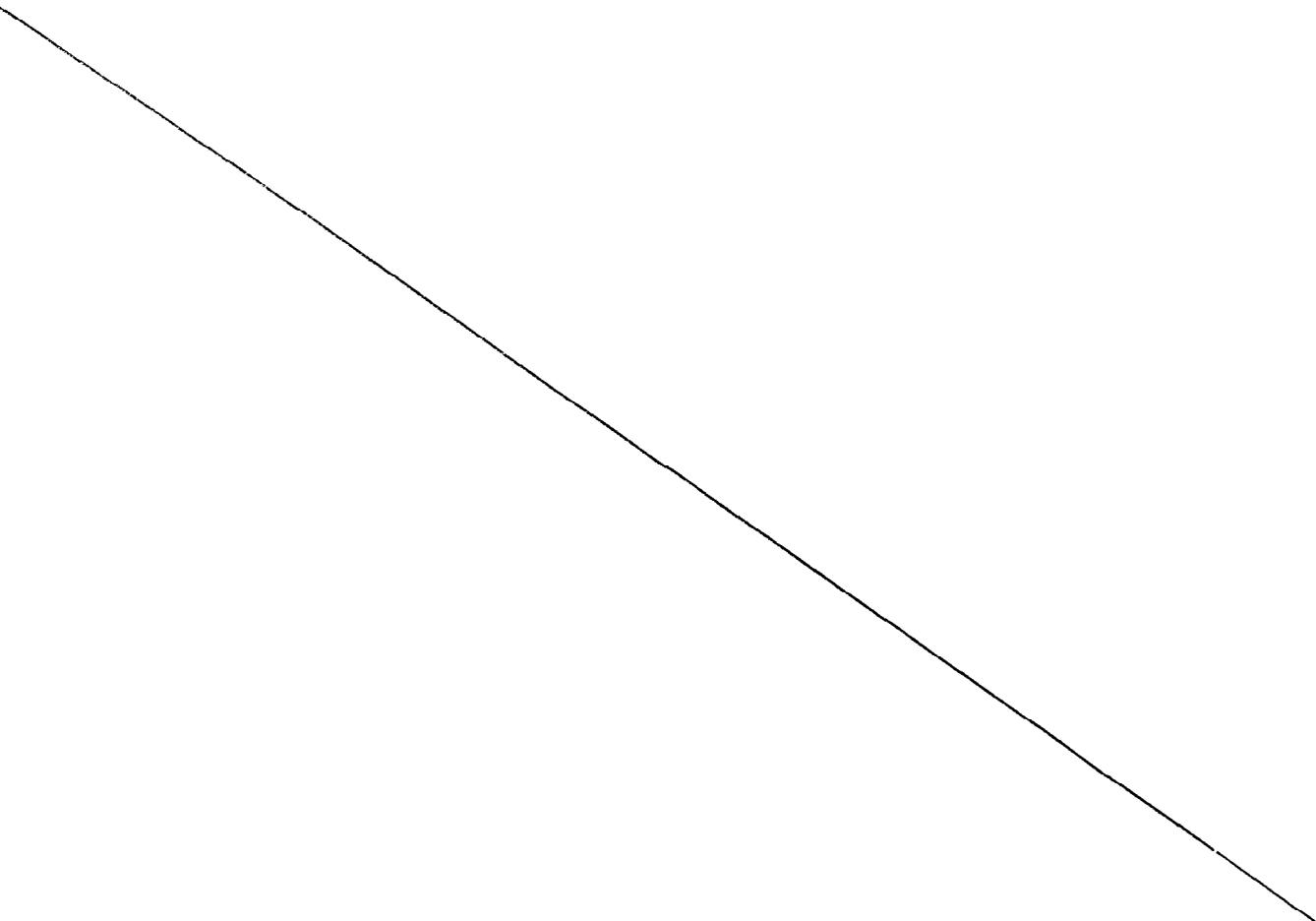
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Studies of empirical therapy in febrile neutropenic patients; and (2) clinical trial design considerations necessary to adequately determine safety and efficacy of antifungal combination therapies. Both agencies encourage individuals, patient advocates, industry, consumer groups, health care professionals, researchers, and other interested persons to attend this public workshop. The input from this public workshop will be used to develop topics for discussion at future meetings of the Antiviral Drugs Advisory Committee.

Because seating is limited, we are asking interested persons to register on a first-come, first-served basis. To register electronically, go to FDA's Web site at www.fda.gov/cder/drug/antimicrobial/default.htm. Those without access to the Internet can call 301-827-2530 to register.



Dated: JUL 30 2003
July 30, 2003.



Jeffrey Shuren,
Assistant Commissioner for Policy.

[FR Doc. 02-????? Filed ??-??-02; 8:45 am]

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