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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

[Docket Nos. 98 N-0517 and 98D-0548]

Development and Use of Guidances on Antimicrobial Drug Products; Draft Guidances for Industry on the Development of Antimicrobial Drug Products; Reopening of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening until January 29, 1999, the comment period for two **Federal Register** notices regarding guidance documents on developing antimicrobial drug products: A notice requesting comment on the agency’s process for developing and using guidance documents on the development of antimicrobial drug products (63 FR 39096, July 21, 1998) and a notice announcing the availability of a general draft guidance for industry entitled “Developing Antimicrobial Drugs-General Considerations for Clinical Trials” and 17 draft guidances on developing antimicrobial drug products to treat individual indications (63 FR 40532, July 29, 1998). FDA is reopening the comment period for both notices to provide interested persons additional time for review and comment.

DATES: Written comments by January 29, 1999. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Copies of the 18 draft guidances for industry are available on the Internet at “http://www.fda.gov/cder/guidance/index.htm”. Submit written requests for single copies of the draft guidances to the Drug Information Branch (HFD-2 10), 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 guidances to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments are to be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Renata Albrecht, Center for Drug Evaluation and Research (HFD-590), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-2336.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of July 21, 1998 (63 FR 39096), FDA's Center for Drug Evaluation and Research (CDER) published a notice requesting comments on the development and use of guidance documents for antimicrobial drug products. CDER requested comment on the process the center is using to revise old and develop new guidances for industry on the development of antimicrobial drug products for the treatment of infections. In the **Federal Register** of July 29, 1998 (63 FR 40532), CDER published a notice announcing the availability of a general draft guidance for industry entitled "Developing Antimicrobial Drugs-General Considerations for Clinical Trials" and 17 draft guidances on issues related to developing antimicrobial drug products to treat individual indications. The July 21 and July 29, 1998, notices invited interested persons to submit written comments within 90 days.

The agency has decided to reopen the comment period for both notices until January 29, 1999, in response to requests for additional time for public review and comment on the documents because of the large number of draft guidances that were issued at one time.

Interested persons may, on or before January 29, 1999, submit written comments to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number

found in brackets in the heading of this document. The draft guidances and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 1 October 28, 1998
October 28, 1998



William K. Hubbard
Associate Commissioner for Policy Coordination

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