

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N-1394]

Medical Devices; CLIA Waiver Criteria; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; extension of comment period.

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SUMMARY: The Food and Drug Administration (FDA) is extending to October 16, 2000, the comment period for the notice of a public workshop that appeared in the **Federal Register** of July 21, 2000 (65 FR 45384). That notice announced FDA's intention to review the criteria used to determine whether specific laboratory tests are waived from certain requirements of the Clinical Laboratory Improvement Amendments of 1988 (CLIA). This extension of the comment period is intended to allow interested persons additional time to submit comments on the CLIA waiver criteria.

DATES: Submit written comments by October 16, 2000.

ADDRESSES: Submit written comments on the notice of public workshop to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Clara A. Sliva, Center for Devices and Radiological Health (HFZ-440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301-827-0496.

SUPPLEMENTARY INFORMATION:

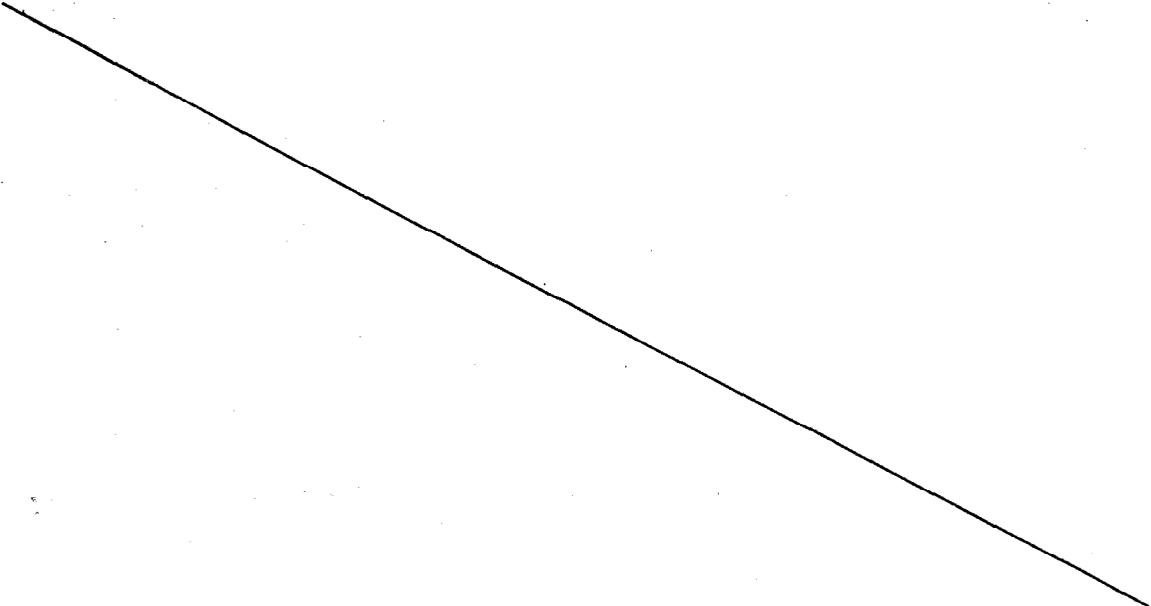
I. Extension of Comment Period

In the **Federal Register** of July 21, 2000 (65 FR 45384), FDA published a notice of a public workshop to review the criteria used to determine whether specific laboratory tests are waived from certain requirements of the CLIA. FDA is soliciting comments from interested persons concerning the review of criteria and the process that the agency should use to determine when a particular test is waived. CLIA specifies that laboratory requirements be based on the complexity of the tests performed and establishes criteria for categorizing a test as waived. Responsibility for determining whether a particular test is waived was transferred from the Centers for Disease Control and Prevention (CDC) to FDA on January 31, 2000.

FDA received several requests to extend the comment period for an additional month to allow adequate time to respond. In response to the requests, FDA is extending the comment period until October 16, 2000.

II. Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this notice by October 16, 2000. 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. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: SEP 12 2000

William K. Hubbard

William K. Hubbard,

Senior Associate Commissioner for Policy,
Planning, and Legislation.

[FR Doc. 00-???? Filed ??-??-00; 8:45 am]

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