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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 900

[Docket No. 99N-1502]

Medical Devices: Quality Mammography Standards; Delay of Effective Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Direct final rule; delay of effective date.

SUMMARY: The Food and Drug Administration (FDA) published a direct final rule in the **Federal Register** of June 17, 1999 (64 FR 32404). The document notified the public of FDA's intention to amend the regulations that govern mammography quality standards to incorporate changes required by the Mammography Quality Standards Reauthorization Act. This document delays the effective date of the direct final rule.

EFFECTIVE DATE: The effective date of the direct final rule published at 64 FR 32404 is delayed until January 28, 2000.

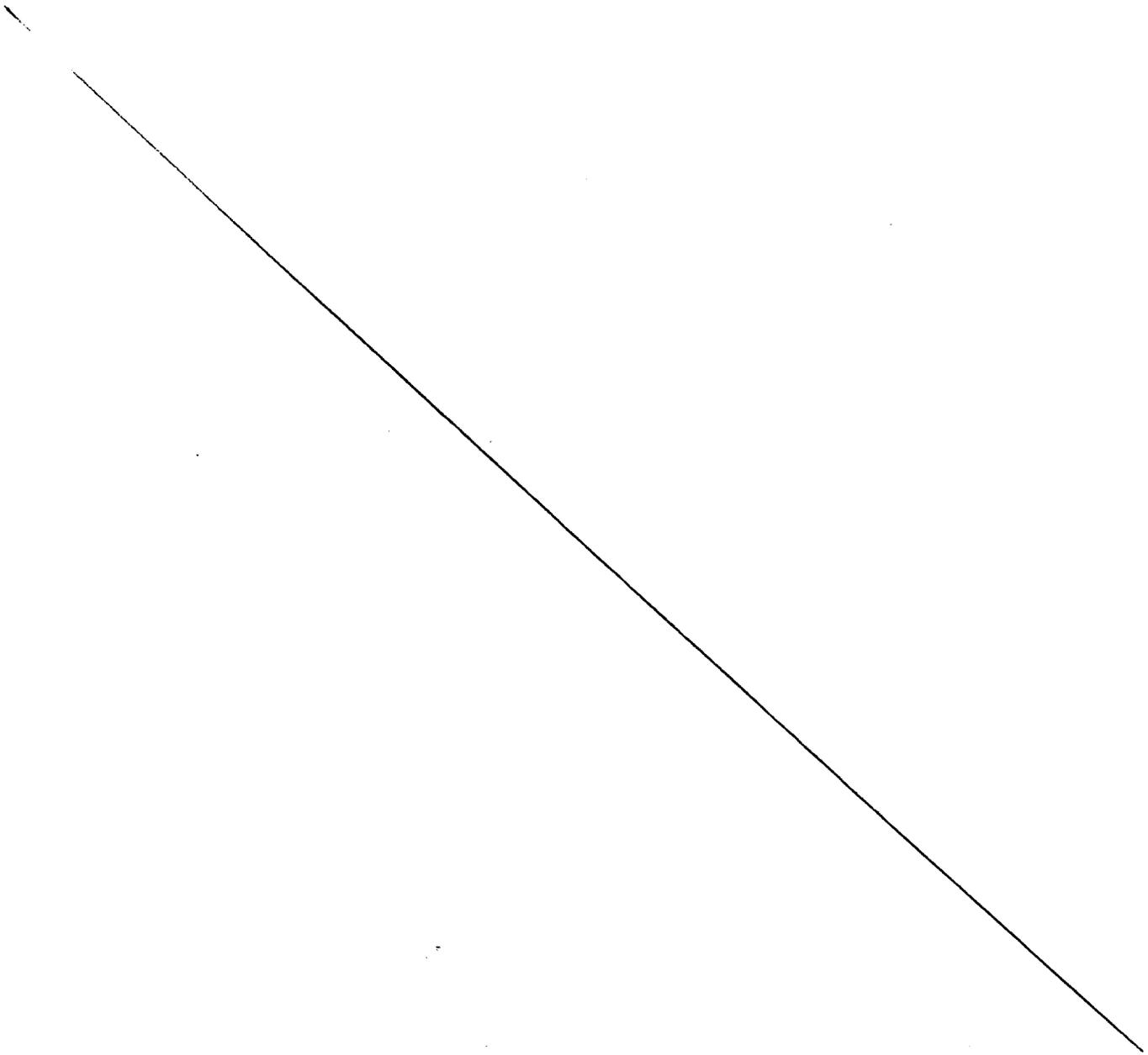
FOR FURTHER INFORMATION CONTACT: Roger L. Burkhart, Center for Devices and Radiological Health (HFZ-240), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20857, 301-594-3332.

SUPPLEMENTARY INFORMATION: FDA solicited comments concerning the direct final rule for a 75-day period ending August 31, 1999. FDA stated that the effective date of the direct final rule would be on November 1, 1999, 60 days after the end of the comment period, unless any significant adverse comment was submitted to FDA during the comment period. FDA did not receive any significant adverse comment.

However, FDA has not yet received approval under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520) of the information collection requirements in this rule. Therefore, FDA is revising the effective date of this rule to ^{January} February 28, 2000. By that date, FDA expects to have received clearance from the Office of Management and Budget for the information collection requirements in the rule. This document delays the effective date of the direct final rule.

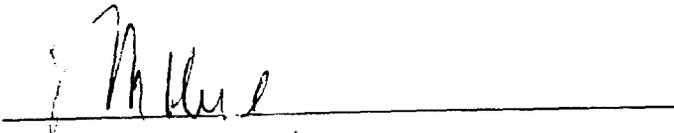
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Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, notice is given that no significant adverse comments



were filed on the June 17, 1999, direct final rule. Accordingly, the amendments issued thereby are effective January 28, 2000.

Dated: 9/21/99
September 27, 1999.



Margaret M. Dotzel
Acting Associate Commissioner for Policy.

[FR Doc. 99-???? Filed ??-??-99; 8:45 am]

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