305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Charles A. Finder, Center for Devices and Radiological Health (HFZ–240), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–594–3332.

SUPPLEMENTARY INFORMATION:

I. Background

The MQSA was passed on October 27, 1992, to establish national quality standards for mammography. After October 1, 1994, the MQSA required all mammography facilities, except facilities of the U.S. Department of Veterans Affairs, to be accredited by an approved accreditation body and certified by the Secretary of Health and Human Services (the Secretary). The authority to approve accreditation bodies and to certify facilities was delegated by the Secretary to FDA. In the **Federal Register** of October 28, 1997 (62 FR 55852), FDA published the MQSA final regulations. The final regulations will become effective April 28, 1999, and will replace the interim regulations (58 FR 67558 and 58 FR 67565, December 21, 1993) which, under the MQSA, currently regulate mammography facilities. Development of this guidance document began in August 1998 and is based in part on discussions with, and input from, the National Mammography Quality Assurance Advisory Committee.

II. Significance of Guidance

This draft guidance document represents the agency's current thinking on the final regulations implementing the MQSA. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the applicable statute, regulations, or both.

The agency has adopted Good Guidance Practices (GGP's), which set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (62 FR 8961, February 27, 1997). This draft guidance document is issued as a Level 1 guidance consistent with GGP's.

III. Electronic Access

In order to receive ''Compliance Guidance: The Mammography Quality Standards Act Final Regulations Document #2'' via your fax machine, call the CDRH Facts–On–Demand (FOD) system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. At the first voice prompt press 1 to access DSMA Facts, at second voice prompt press 2, and then enter the document number (1498) followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the draft guidance may also do so using the World Wide Web (WWW). CDRH maintains an entry on the WWW for easy access to information including text, graphics, and files that may be downloaded to a personal computer with access to the WWW. Updated on a regular basis, the CDRH home page includes ''Compliance Guidance: The Mammography Quality Standards Act Final Regulations Document #2,'' device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, mammography matters, and other device-oriented information. The CDRH home page may be accessed at ''http://www.fda.gov/cdrh''. ''Compliance Guidance: The Mammography Quality Standards Act Final Regulations Document #2'' will be available at ''http://www.fda.gov/cdrh/dmqrp.html''.

IV. Comments

Interested persons may, on or before June 17, 1999, submit to Dockets Management Branch (address above) written comments regarding this draft guidance. 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 guidance document and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 10, 1999.

Linda S. Kahan,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 99–6665 Filed 3–18–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0697]

Compliance Guidance: The Mammography Quality Standards Act FinalRegulations Document #1; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ''Compliance Guidance: The Mammography Quality Standards Act Final Regulations Document #1.'' The final regulations implementing the Mammography Quality Standards Act of 1992 (the MQSA) will become effective April 28, 1999, and will replace the interim regulations which, under the MQSA, currently regulate mammography facilities. The guidance is intended to assist facilities and their personnel to meet the MQSA final regulations.

DATES: Written comments may be submitted at any time.

ADDRESSES: Submit written requests for single copies on a 3.5'' diskette of the guidance entitled ''Compliance Guidance: The Mammography Quality Standards Act Final Regulations Document #1'' to the Division of Small Manufacturers Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443–8818. See the SUPPLEMENTARY INFORMATION section for information on electronic access to the guidance.

Submit written comments on ''Compliance Guidance: The Mammography Quality Standards Act Final Regulations Document #1'' to the contact person listed below.

FOR FURTHER INFORMATION CONTACT: Charles A. Finder, Center for Devices and Radiological Health (HFZ–240), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–594–3332.

SUPPLEMENTARY INFORMATION:

I. Background

FDA published a notice of availability of a draft of this guidance for public comment in the **Federal Register** of August 27, 1998 (63 FR 45828). The agency discussed the draft guidance

with a working group of the Conference of Radiation Control Program Directors in October 1998 and with the National Mammography Quality Assurance Advisory Committee in November 1998. The guidance has been modified from the original draft proposal to address public comments and to conform to the changes mandated by the Mammography Quality Standards Reauthorization Act (MQSRA) of 1998. The major changes include:

1. New guidance for patient communication of results to conform to MQSRA,
2. Reinstatement of the exemption from adverse finding after continuing experience requalification for interpreting physicians and extension to radiologic technologists,
3. Modification of the Automatic Exposure Control mode guidance so that it applies to those modes used clinically at the facility,
4. Revision of the repeat analysis guidance to be consistent with currently accepted practice,
5. Inclusion of the fact that FDA has proposed changes to the collimation requirements,
6. Clarification of what constitutes a major change to the film processor,
7. Further clarification as to what constitutes a ''serious complaint'',
8. Raising inspection finding levels for failure to have a standard operating procedure for infection control and handling consumer complaints, and
9. Raising inspection finding levels for failure to comply with manufacturer's recommendations when performing digital mammography.

II. Significance of Guidance

This guidance represents the agency's current thinking on the final regulations implementing the MQSA. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the applicable statute, regulations, or both.

The agency has adopted good guidance practices (GGP's), which set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (62 FR 8961, February 27, 1997). This guidance is issued as a level 1 guidance consistent with GGP's.

III. Electronic Access

In order to receive ''Compliance Guidance: The Mammography Quality Standards Act Final Regulations Document #1'' via your fax machine, call the CDRH Facts-On-Demand (FOD) system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. At the first voice prompt press 1 to access DSMA Facts, at second voice prompt press 2, and then enter the document number (1499) followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may also do so using the World Wide Web (WWW). CDRH maintains an entry on the WWW for easy access to information including text, graphics, and files that may be downloaded to a personal computer with access to the WWW. Updated on a regular basis, the CDRH home page includes ''Compliance Guidance: The Mammography Quality Standards Act Final Regulations Document #1'', device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, mammography matters, and other device-oriented information. The CDRH home page may be accessed at ''http://www.fda.gov/cdrh''. The ''Compliance Guidance: The Mammography Quality Standards Act Final Regulations Document #1'' will be available at ''http://www.fda.gov/cdrh/dmqrp.html''.

IV. Comments

Interested persons may, at any time, submit to the contact person (address above) written comments regarding this guidance. Such comments will be considered when determining whether to amend the current guidance.

Dated: March 10, 1999.

Linda S. Kahan,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 99–6666 Filed 3–18–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–0296]

Draft Guidance for Industry on Formal Meetings with Sponsors and Applicants for PDUFA Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Formal Meetings with Sponsors and Applicants for PDUFA Products.'' This draft guidance document is intended to provide guidance to industry on procedures that will be adopted by the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) for formal meetings between the agency and sponsors or applicants concerning certain drug products.

DATES: Written comments on the draft guidance may be submitted by May 18, 1999. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Copies of the draft guidance for industry are available on the Internet at ''http://www.fda.gov/cder/guidance/index.htm'' or ''http://www.fda.gov/cber/guidelines.htm''. Submit written requests for single copies of ''Formal Meetings with Sponsors and Applicants for PDUFA Products'' to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research (CDER), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–3844, or FAX 888–CBERFAX. Send two self-addressed adhesive labels to assist that office in processing your requests. Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Requests and comments are to be identified with the docket number found in brackets in the heading of this document. After the comment period, comments may be submitted to the centers at the following addresses.

FOR FURTHER INFORMATION CONTACT:

Murray M. Lumpkin, Center for Drug Evaluation and Research (HFD–2), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5400, or

Rebecca A. Devine, Center for Biologics Evaluation and Research (HFM–10), 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–0373.

SUPPLEMENTARY INFORMATION:

I. Description of the Draft Guidance

FDA is announcing the availability of a draft guidance for industry entitled ''Formal Meetings with Sponsors and Applicants for PDUFA Products.'' CDER and CBER participate in many meetings each year with sponsors of