necessary for resolution of the issue(s); and

• A statement that the previous supervisory level has already had the opportunity to review all of the material relied on for dispute resolution. The information that the agency suggests submitting with a formal request for dispute resolution consists of: (1) Statements describing the issue from the perspective of the person with a dispute, (2) brief statements describing the history of the matter, and (3) documents previously submitted to FDA under an OMB approved collection of information (see previous discussion).

Based on FDA's experience with dispute resolution, the agency expects that most persons seeking formal dispute resolution will have gathered the materials listed previously when identifying the existence of a dispute with the agency. Consequently, FDA anticipates that the collection of information attributed solely to the guidance will be minimal.

Description of Respondents: A sponsor, applicant, or manufacturer of a drug or biologic product regulated by the agency under the act or section 351 of the PHS Act who requests formal resolution of a scientific or procedural dispute.

Burden Estimate: Table 1 of this document provides an estimate of the annual reporting burden for requests for dispute resolution. In fiscal year (FY) 1998, 39 sponsors and applicants (respondents) submitted requests for formal dispute resolution to CDER and 12 respondents submitted requests for formal dispute resolution to CBER. Although the procedures for requesting formal dispute resolution that are set forth in the draft guidance document were not in place in FY 1998, FDA estimates that the number of respondents who would submit requests for dispute resolution under the guidance would remain the same. The total annual responses are the total number of requests submitted to CDER and CBER in 1 year, including requests for dispute resolution that a single respondent submits more than one time. In FY 1998, CDER received approximately 49 requests and CBER received approximately 15 requests. The agency estimates that the total annual responses will remain the same, averaging to 1.26 responses per respondent. The hours per response is the estimated number of hours that a respondent would spend preparing the information to be submitted with a request for formal dispute resolution in accordance with this draft guidance, including the time it takes to gather and copy brief statements describing the issue from the perspective of the person with the dispute, brief statements describing the history of the matter, and supporting information that has already been submitted to the agency. Based on experience, FDA estimates that approximately 8 hours on average would be needed per response. Therefore, FDA estimates that 512 hours will be spent per year by respondents requesting formal dispute resolution under the guidance.

FDA invites comments on this analysis of information collection burdens.

TABLE 1.—Estimated Annual Reporting Burden[1]

Requests for Formal Dispute Resolution	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Hours per Response	Total Hours
CDER	39	1.26	49	8	392
CBER	12	1.25	15	8	120
Total					512

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

In compliance with section 3507(d) of the PRA (44 U.S.C. 3507(d)), the agency has submitted the information collection provisions of this draft guidance to OMB for review. Interested persons are requested to send comments on this information collection by April 19, 1999, to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Desk Officer for FDA.

Dated: March 15, 1999.

William K. Hubbard,

Acting Deputy Commissioner for Policy.

[FR Doc. 99–6749 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–0302]

Draft ''Compliance Guidance: The Mammography Quality Standards Act Final Regulations Document #2;'' Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''Compliance Guidance: The Mammography Quality Standards Act Final Regulations Document #2.'' This draft guidance is neither final nor is it in effect at this time. 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 draft guidance document is intended to assist facilities and their personnel to meet the MQSA final regulations.

DATES: Written comments concerning this draft guidance must be received by June 17, 1999.

ADDRESS: See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the draft guidance. Submit written requests for single copies on a 3.5″ diskette of the draft guidance document entitled ''Compliance Guidance: The Mammography Quality Standards Act Final Regulations Document #2'' 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. Written comments concerning this draft guidance must be submitted to the Dockets Management Branch (HFA–

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