The project will benefit AHRQ, the medical community, policy makers, health service researchers, and ultimately patients in the following ways:

- AHRQ will be able to monitor how their current format and content are serving their intended audiences;
- AHRQ will be able to assess how the Clearinghouse is affecting future development of guidelines and their implementation in clinical practices;
- AHRQ will be able to use the evaluation results to refine the site, thereby making it more useful for the medical community and other professionals who use guidelines in care management;
- Individual clinicians will be better able to obtain timely guidance about the management of complex clinical problems;
- Federal, State, and private purchasers will be able to encourage contracted or prospective plans and providers to adopt clinical practices that are consistent with the best available standards of care; and,
- Public policy experts will be better able to obtain unbiased, evidence-based guidelines and information for decisionmaking and policy purposes.

Method of Collection

Electronic mail will be used to transmit the written survey responses. The written survey will also be linked to the NGC Website. Users can complete the survey on-line, and their responses will be automatically submitted. By using e-mail and the Web link to target our audience we are ensuring that our respondents are Web-based users. This approach significantly reduces the burden to non-Web users who would be unable to contribute information useful to this data collection. Additionally, this use of information technology minimizes the burden on the targeted respondents by improving the ease in which they can submit their survey responses.

ESTIMATED ANNUAL RESPONDENT BURDEN

Annual number of respondents	Estimated time per respondent (in hours)	Estimated total annual burden hours	Estimated annual cost to the Government
1,359	.5	408	$249,993

The survey instrument is short and poses minimal burden on the time of respondents. Estimates of time required to complete the survey during the pilot phase range from 7 to 20 minutes. The annual hour burden calculation assumes each survey will last 15 minutes, therefore the total of annualized hourly costs to participants is estimated to be $30,040.

Dated: February 16, 2000.

John M. Eisenberg,

Director.

[FR Doc. 00–4521 Filed 2–24–00; 8:45 am]

BILLING CODE 4160–90–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–0302]

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 guidance entitled ''Compliance Guidance: The Mammography Quality Standards Act Final Regulations Document 2.'' The guidance document is intended to assist facilities and their personnel to meet the Mammography Quality Standards Act of 1992 (the MQSA) final regulations. The final regulations implementing the MQSA became effective April 28, 1999, replacing the interim regulations.

DATES: Submit written comments concerning this guidance at any time.

ADDRESSES: Submit written requests for single copies on a 3.5″″ diskette of the 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. 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 2'' 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

The MQSA was passed on October 27, 1992, to establish national quality standards for mammography. The MQSA required that to provide mammography services legally after October 1, 1994, all facilities, except facilities of the U.S. Department of Veterans Affairs, must 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, FDA published the MQSA final regulations. The final regulations became effective April 28, 1999, and replaced the interim regulations (58 FR 67558 and 58 FR 67565, December 21, 1993) which, under the MQSA, previously regulated mammography facilities. The document addresses new questions that FDA has received since the publication of ''Compliance Guidance: The Mammography Quality Standards Act Final Regulations'' on August 27, 1998.

The guidance document was published as a draft proposal for public comment on March 19, 1999 (64 FR 13589). It was discussed with the National Mammography Quality Assurance Advisory Committee in November 1998 and a working group of the Conference of Radiation Control Program Directors in May 1999. The document has been modified from the original draft proposal to address public comments. While there are many clarifying changes in the document,

there were no major substantive changes.

II. Significance of Guidance

This 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 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 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 guidance may also do so using the Internet. CDRH maintains an entry on the Internet for easy access to information, including text, graphics, and files that may be downloaded to a personal computer with access to the Internet. 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/mammography.

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. 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.

Dated: February 9, 2000.

Linda S. Kahan,

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

[FR Doc. 00–4406 Filed 2–24–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–1267]

Guidance for Industry on NDAs: Impurities in Drug Substances; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''NDAs: Impurities in Drug Substances.'' This document recommends that applicants submitting new drug applications (NDA's) and holders of supporting Type II drug master files (DMF's) for drug substances not considered new drug substances refer to the guidance for industry on reporting drug substance impurities in the International Conference on Harmonisation (ICH) guidance document entitled ''Q3A Impurities in New Drug Substances.''

DATES: Submit written comments on agency guidances at any time.

ADDRESSES: Copies of this guidance for industry are available on the Internet at http://www.fda.gov/cder/guidance/index.htm. Submit written requests for single copies of this guidance to the Drug Information Branch (HFD–210), 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 guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Eric P. Duffy, Center for Drug Evaluation and Research (HFD–150), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5765.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a guidance for industry entitled ''NDAs: Impurities in Drug Substances.'' Although ICH ''Q3A Impurities in New Drug Substances,'' which was published in the **Federal Register** on January 4, 1996 (61 FR 372), provided guidance to industry on the reporting, identification, and qualification of impurities in new drug substances produced by chemical syntheses, FDA believes that the guidance provided in ICH Q3A should also be considered when evaluating drug substances produced by chemical syntheses that are not considered new drug substances. FDA recommends that applicants preparing NDA's and holders preparing Type II DMF's refer to the information contained in that ICH document.

In the **Federal Register** of January 21, 1999 (64 FR 3303), FDA announced the availability of a draft version of this guidance. The January 1999 document gave interested persons an opportunity to submit comments through April 21, 1999. All comments received during the comment period have been carefully reviewed and the guidance has been revised, where appropriate.

This level 1 guidance is being issued consistent with FDA's good guidance practices (62 FR 8961, February 27, 1997). The guidance represents the agency's current thinking on reporting impurities in drug substances for certain NDA's and DMF's. 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 requirements of the applicable statutes, regulations, or both.

Interested persons may, at any time, submit written comments on the guidance 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 guidance 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: February 15, 2000.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 00–4405 Filed 2–24–00; 8:45 am]

BILLING CODE 4160–01–F