being made available for comment purposes only and is not intended for use by the industry. The agency has adopted good guidance practices (GGP's) that 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 This draft guidance document is being issued as a draft level 1 guidance document consistent with the GGP's.

This draft guidance document represents the agency's current thinking on immunization of Source Plasma donors using IRBC obtained from an outside supplier. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. However, manufacturers should conform to the specific criteria set forth in this draft guidance document for voluntary participation in this program. Manufacturers who want to use an alternative approach must submit a detailed BLA supplement under 21 CFR 601.12 or otherwise satisfy FDA that an exemption from that requirement is justified under 21 CFR 640.120. As with other guidance documents, FDA does not intend this document to be all-inclusive and cautions that not all information may be applicable to all situations. The document is intended to provide information and does not set forth requirements.

II. Comments

This draft guidance document is being distributed for comment purposes only and is not intended for implementation at this time. CBER intends to revise this draft guidance document based on comments received from the public. Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this draft guidance document and the pilot program, including those comments expressing interest in participating in the pilot program. Written comments may be submitted at any time, however, comments are to be submitted by September 18, 2000, to ensure adequate consideration in preparation of the final document. Two copies of any comments are to be submitted, except individuals may submit one copy. Comments should be identified with the docket number found in the brackets in the heading of this document. A copy of the document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at http://www.fda.gov/cber/guidelines.htm.

Dated: July 5, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00–18059 Filed 7–17–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–4910]

Compliance Guidance: The Mammography Quality Standards Act Final Regulations Document #3; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance document entitled ''Compliance Guidance: The Mammography Quality Standards Act Final Regulations Document #3.'' The final regulations implementing the Mammography Quality Standards Act of 1992 (the MQSA) became effective April 28, 1999, replacing the interim regulations. The guidance document is intended to assist facilities and their personnel to meet the MQSA final regulations.

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

ADDRESSES: Submit written requests for single copies on a 3″ diskette of the guidance document entitled ''Compliance Guidance: The Mammography Quality Standards Act Final Regulations Document #3'' to the Division of Small Manufacturers Assistance (HFZ–220), Center for Devices and Radiological Health (CDRH), 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 document. Submit written comments on the guidance document 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

This guidance document was published as a draft proposal for public comment in the **Federal Register** of December 8, 1999 (64 FR 68696). It has been discussed with the National Mammography Quality Assurance Advisory Committee at two separate meetings (July 1999 and January 2000). The guidance document has been modified from the original draft proposal to address public comments. While there are several clarifying changes in the guidance 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 #3'' via your fax machine, call the CDRH Facts-On-Demand system at 800–899–0381 or 301–827–0111 from a touchtone telephone. At the first voice prompt press 1 to access DSMA Facts, at second voice prompt press 2, and then enter the document number (1496) followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance document 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 previously issued ''Compliance Guidance for the Mammography Quality Standards Act Final Regulations Document #3,'' 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 #3 will be available at http://www.fda.gov/cdrh/mammography/guidance-rev.html.

IV. Comments

Interested persons may submit to the contact person (address above) written comments regarding this guidance at any time. 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: June 29, 2000.

Linda S. Kahan,

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

[FR Doc. 00–18060 Filed 7–17–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–2152]

Guidance for Industry and FDA Reviewers on Medical Device Use—Safety: Incorporating Human Factors Engineering into Risk Management; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance document entitled ''Medical Device Use—Safety: Incorporating Human Factors Engineering into Risk Management.'' This guidance describes how to incorporate human factors techniques and theory into risk management during medical device design and development. The guidance is intended to assist reviewers of premarket device submissions, design control documentation, and manufacturers that develop devices. The guidance is necessary to decrease problems with the use of medical devices that impact safety and effectiveness, and help ensure safer and more effective devices.

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

ADDRESSES: Submit written requests for single copies on a 3.5″ diskette of the guidance document entitled ''Medical Device Use—Safety: Incorporating Human Factors Engineering into Risk Management'' 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. Submit written comments on ''Medical Device Use—Safety: Incorporating Human Factors Engineering into Risk Management'' to the contact person listed below. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Ron D. Kaye, Center for Devices and Radiological Health (HFZ–230), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–443–2436.

SUPPLEMENTARY INFORMATION:

I. Background

The guidance is intended to provide a suggested approach for integrating human factors within risk management for medical device design and development. It also contains an introduction to both risk management and human factors and a discussion of how they are linked. The focus is on reducing hazards related specifically to the use of medical devices. Human factors techniques are discussed within the context of applying risk management. The guidance also suggests how human factors-risk management efforts should be documented and included in premarket submissions. This guidance document was published for public comment on August 3, 1999, as a draft guidance entitled ''Device Use Safety: Incorporating Human Factors in Risk Management.'' The document has been modified from the original draft version to address public comments. There were changes made in the document for the purposes of clarity, but there were no major substantive changes.

II. Significance of Guidance

This guidance document represents the agency's current thinking on the application of human factors to new medical device design and development to help ensure that intended users can use a device safely and effectively. 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 ''Medical Device Use—Safety: Incorporating Human Factors Engineering into Risk Management'' via your fax machine, call the CDRH Facts-On-Demand (FOD) system at 800–899–0381 or 301–827–0111 from a touchtone telephone. At the first voice prompt press 1 to access DSMA Facts, at second voice prompt press 2, and then enter the document number (1497) 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 ''Medical Device Use—Safety: Incorporating Human Factors Engineering into Risk Management,'' 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. ''Medical Device Use—Safety: Incorporating Human Factors Engineering into Risk Management'' is also available at http://www.fda.gov/cdrh/HumanFactors.html.

IV. Comments

Interested persons may, at any time, submit written comments on the guidance to the contact person (address above). 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