allergenic extract or allergen patch test. 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 requirement of the applicable statute, regulations, or both. 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This draft guidance document is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this draft guidance document. Written comments may be submitted at any time, however, comments should be submitted by October 26, 1998, 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 using the World Wide Web (WWW). For WWW access, connect to CBER at ''http://www.fda.gov/cber/guidelines.htm''.

Dated: August 20, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–23024 Filed 8–26–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0307]

Draft Guidance for Industry; Exports and Imports Under the FDA Export Reform and Enhancement Act of 1996; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is extending to November 24, 1998, the comment period for the draft guidance document that appeared in the **Federal Register** of June 12, 1998 (63 FR 32219). The draft guidance document addressed issues concerning the exportation of human drugs, animal drugs, biologics, food additives, and devices under the FDA Export Reform and Enhancement Act, as well as the importation of components, parts, accessories, or other articles for incorporation or further processing into articles intended for export. This action is being taken in response to a request from the Health Industry Manufacturers Association.

DATES: Written comments by November 24, 1998.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Philip L. Chao, Office of Policy (HF–23), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3380.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of June 12, 1998 (63 FR 32219), FDA published a draft guidance document entitled ''FDA Draft Guidance for Industry on: Exports and Imports Under the FDA Export Reform and Enhancement Act of 1996.''

Enacted and later amended in 1996, the FDA Export Reform and Enhancement Act (Pub. L. 104–134, as amended by Pub. L. 104–180) significantly changed the export requirements for human drugs, animal drugs, biologics, devices, and, to a limited extent, food additives. For example, before the law was enacted, most exports of unapproved new drug products could only be made to 21 countries identified in section 802 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 382), and these exports were subject to various restrictions. The FDA Export Reform and Enhancement Act amended section 802 of the act to allow, among other things, the export of unapproved new drugs to any country in the world if the drug complies with the laws of the importing country and has valid marketing authorization from any of the following countries: Australia, Canada, Israel, Japan, New Zealand, Switzerland, South Africa, and the countries in the European Union (EU) and the European Economic Area (EEA). (Currently, the EU countries are Austria, Belgium, Denmark, Germany, Greece, Finland, France, Ireland, Italy, Luxembourg, the Netherlands, Portugal, Spain, Sweden, and the United Kingdom. The EEA countries are the EU countries, Iceland, Liechtenstein, and Norway. The list of countries will expand automatically if any country accedes to the EU or becomes a member of the EEA.)

The draft guidance document provides information on the statutory requirements for exporting human drugs, animal drugs, biologics, and medical devices; general requirements for products exported under section 801 of the act (21 U.S.C. 381); labeling requirements for drugs and biologics exported under section 801(e) of the act; requirements for exports of unapproved drugs, biologics, and devices under section 802(b) of the act; requirements for exports of unapproved drugs and devices for investigational use; requirements for exports of unapproved drugs and devices in anticipation of foreign approval; requirements for exports of drugs and devices for diagnosing, preventing, or treating a tropical disease or a disease ''not of significant prevalence in the United States;'' export notifications to FDA; and ''import for export.''

The draft guidance document represents the agency's current thinking on exports and imports-for-export under sections 801 and 802 of the act. 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 statute, regulations, or both.

On June 23, 1998, the Health Industry Manufacturers Association (HIMA) requested a 90-day extension of the comment period. HIMA explained that ''the complexity of the issues with the additional complication of summer vacation schedules prevents us from providing substantive comments within the time provided.'' The agency considered HIMA's request and, through this notice, is extending the comment period by 90 days until November 24, 1998.

Interested persons may submit to the Dockets Management Branch (address above) written comments on the draft guidance document. 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. A copy of the draft guidance document and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. The draft

guidance document may also be seen on FDA's web site at ''www.FDA.gov''.

Dated: August 21, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–23026 Filed 8–24–98; 3:45 pm]

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 Final Regulations Draft; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance document entitled ''Compliance Guidance: The Mammography Quality Standards Act Final Regulations.'' This draft guidance document is not 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 must be received by November 25, 1998.

ADDRESSES: 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'' 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 draft guidance.

Submit written comments on this draft guidance 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: Walid G. Mourad, 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. On October 28, 1997, FDA published the MQSA final regulations in the **Federal Register**. The final regulations will become effective April 28, 1999, and will replace the interim regulations (58 FR 67558 and 58 FR 67565) which, under the MQSA, currently regulate mammography facilities. Development of the guidance began in August 1997 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 the ''Compliance Guidance: The Mammography Quality Standards Act Final Regulations'' 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 (1259) 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 document 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 Web. Updated on a regular basis, the CDRH home page includes the ''Compliance Guidance: The Mammography Quality Standards Act Final Regulations'', 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'' will be available at http://www.fda.gov/cdrh/dmqrp.html.

IV. Comments

Interested persons may, on or before November 25, 1998, submit to the 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 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: August 7, 1998.

D.B. Burlington,

Director, Center for Devices and Radiological Health.

[FR Doc. 98–23030 Filed 8–26–98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–R–254]

Emergency Clearance: Public Information Collection Requirements Submitted to the Office of Management and Budget (OMB)

AGENCY: Health Care Financing Administration.