products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product ENTEREG (alvimopan). ENTEREG is a peripherally acting μ-opioid receptor antagonist indicated to accelerate the time to upper and lower gastrointestinal recovery following partial large or small bowel resection surgery with primary anastomosis. Subsequent to this approval, the Patent and Trademark Office received patent term restoration applications for ENTEREG (U.S. Patent Nos. 5,250,542 and 5,434,171) from Eli Lilly and Company, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated February 26, 2009, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of ENTEREG represented the first permitted commercial marketing or use of the product. Thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for ENTEREG is 5,305 days. Of this time, 3,879 days occurred during the testing phase of the regulatory review period, while 1,426 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(i)) became effective*: November 12, 1993. The applicant claims November 11, 1993, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was November 12, 1993, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the act: June 25, 2004*. FDA has verified the applicant's claim that the new drug application (NDA) 21–775 was submitted on June 25, 2004.

3. *The date the application was approved*: May 20, 2008. FDA has verified the applicant's claim that NDA 21–775 was approved on May 20, 2008.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its applications for patent extension, this applicant seeks 1,827 days of patent term extension for U.S. Patent No. 5,250,542 and 1,826 days of patent term extension for U.S. Patent No. 5,434,171.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments and ask for a redetermination by December 8, 2009. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by April 7, 2010. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Division of Dockets Management. Three copies of any mailed information 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. Comments and petitions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 31, 2009.

Jane A. Axelrad,

Associate Director for Policy, Center for Drug Evaluation and Research.

[FR Doc. E9–24457 Filed 10–8–09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–D–0448]

Draft Guidance for Industry and Food and Drug Administration Staff; the Mammography Quality Standards Act Final Regulations: Modifications and Additions to Policy Guidance Help System #13; 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 ''The Mammography Quality Standards Act Final Regulations: Modifications and Additions to Policy Guidance Help System #13.'' This document is intended to provide guidance to mammography facilities and their personnel. It represents FDA's current thinking on the final regulations implementing the Mammography Quality Standards Act of 1992 (MQSA). This guidance document updates previous guidance. This draft guidance is not final nor is it in effect at this time.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by January 7, 2010.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled ''The Mammography Quality Standards Act Final Regulations: Modifications and Additions to Policy Guidance Help System #13'' to the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4613, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301–847–8149. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov*. Identify comments with the docket number

found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Charles Finder, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4646, Silver Spring, MD 20993–0002, 301–796–5715.

SUPPLEMENTARY INFORMATION:

I. Background

MQSA (Pub. L. 102–539) was signed into law on October 27, 1992, to establish national quality standards for mammography. It is codified at 42 U.S.C. 263b. The MQSA requires that, in order to lawfully provide mammography services after October 1, 1994, all facilities, except facilities of the Department of Veterans Affairs, must be accredited by an approved accreditation body and certified by the Secretary of Health and Human Services (the Secretary) or by an approved State certification agency (section 354(b) of the MQSA; 42 U.S.C. 263b(b)). In June 1993, the authority to approve accreditation bodies and State certification agencies and to certify facilities was delegated by the Secretary to the FDA (58 FR 32543). On October 28, 1997, the FDA first published final regulations implementing the MQSA in the **Federal Register** (21 CFR part 900) (62 FR 55852). The MQSA has twice been amended since its enactment, through the Mammography Quality Standards Reauthorization Acts (MQSRA) of 1998 and 2004 (Pub. L. 105–248 and Pub. L. 108–365).

This draft guidance updates the Policy Guidance Help System and addresses or contains the following:

1. Updated contact information for accreditation bodies and certification agencies;
2. General guidance regarding Additional Mammography Reviews (AMRs);
3. Previously approved alternative standards;
4. Centers for Medicare and Medicaid Services (CMS) reimbursement;
5. Mechanisms to inform physicians and patients of mammography results;
6. Labeling of mammographic images;
7. Mammographic modality and its impact on personnel experience requirements;
8. Clarification of the personnel 6-month exemption period;
9. Information on calibrating the air kerma measuring instrument;
10. Medical physicist involvement as it applies to cassette replacement;
11. Full Field Digital Mammography (FFDM) and use of single-use cushion pads;
12. Quality control testing of computer controlled compression devices;
13. Mammography equipment evaluations of laser printers;
14. Quality control testing of monitors and laser printers;
15. Mammography equipment evaluations of new FFDM units; and
16. Mammography equipment evaluations of off-site laser printers and monitors.

In November 1998, FDA compiled all to-date final FDA guidances related to MQSA and put them into a computerized searchable database called the Policy Guidance Help System (PGHS). The PGHS is available on the Internet at *http://www.fda.gov/cdrh/mammography/robohelp/start.htm.*

FDA periodically updates the information in the PGHS, and this document serves as a further update. Individuals wishing to receive automatic notification of future updates may subscribe to our e-mail ListServ by visiting *http://service.govdelivery.com/service/subscribe.html?code=USFDA_45* and following the directions there.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on ''The Mammography Quality Standards Act Final Regulations: Modifications and Additions to Policy Guidance Help System #13.'' 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 and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by using the Internet. To receive ''The Mammography Quality Standards Act Final Regulations: Modifications and Additions to Policy Guidance Help System #13,'' you may either send an e-mail request to *dsmica@fda.hhs.gov* to receive an electronic copy of the document or send a fax request to 301–847–8149 to receive a hard copy. Please use the document number (1695) to identify the guidance you are requesting.

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 Internet access. Updated on a regular basis, the CDRH home page includes 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 web site may be accessed at *http://www.fda.gov/cdrh*. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/cdrh/guidance.html*. Guidance documents are also available at *http://www.regulations.gov*.

IV. Paperwork Reduction Act

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 900 have been approved under OMB Control No. 0910–0309.

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 1, 2009.

Jeffrey Shuren,

Acting Director, Center for Devices and Radiological Health.

[FR Doc. E9–24435 Filed 10–8–09; 8:45 am]

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