registration. For foreign entities the Web site is *http://www.grants.gov/RequestaDUNS.gov*.In order to access grants.gov an applicant will be required to register with the Credential Provider. Information about this is available at *https://apply.grants.gov/OrcRegister*.

A copy of the complete RFA can also be viewed on FDA's Center for Food Safety and Applied Nutrition Web site at *http://www.cfsan.fda.gov/list.html*. (FDA has verified the Web site and its address but we are not responsible for changes subsequent to the Web site or its address after this document publishes in the **Federal Register**).

IV. Agency Contacts

For issues regarding the programmatic aspects of this document, contact Christine L. Hileman, Center for Food Safety and Applied Nutrition (HFS-006), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1674, or e-mail: *christine.hileman@fda.hhs.gov*.

For issues regarding the administrative and financial management aspects of this document contact, Gladys Melendez-Bohler at 301–827–7168 or by e-mail: *gladys.melendez-bohler@fda.hhs.gov*.

Dated: June 26, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–13046 Filed 7–5–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007N–0238]

Medical Devices: The Mammography Quality Standards Act of 1992 and Subsequent Mammography Quality Standards Reauthorization Act and Amendments; Inspection Fees

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the increased fees the agency will assess for inspections of mammography facilities starting October 1, 2007. The Mammography Quality Standards Act of 1992 (the MQSA) requires FDA to assess and collect fees from mammography facilities to cover the costs of annual inspections required by the MQSA. Because these costs have increased, FDA is raising the fees to ensure the program is able to meet its objective of ensuring that high quality mammography remains available to women. This document explains which facilities are subject to payment of inspection fees, provides information on the costs included in developing inspection fees, and provides information on the inspection billing and collection processes.

DATES: Effective October 1, 2007, for all inspections conducted under section 354(g) of the Public Health Service Act (PHS Act) (42 U.S.C. 263b(g)). Submit written or electronic comments by October 1, 2007.

ADDRESSES: Submit written comments 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.fda.gov/dockets/ecomments*. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Helen J. Barr, Center for Devices and Radiological Health (HFZ–240), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 240–276–3332, FAX: 240–276–3272.

SUPPLEMENTARY INFORMATION:

I. Background

The MQSA requires all mammography facilities, other than facilities of the Department of Veterans Affairs, to be accredited by an approved accreditation body and certified by the Secretary of Health and Human Services, as meeting quality standards (section 354(b) and (d) of the PHS Act). The MQSA requires FDA to establish and operate the following: (1) A Federal certification and inspection program for mammography facilities, (2) regulations and standards for accreditation bodies, and (3) standards for equipment, personnel, quality assurance, and recordkeeping and reporting by mammography facilities (section 354(c), (e), (f), and (g) of the PHS Act). The MQSA requires annual facility inspections to determine compliance with the quality standards (section 354(g) of the PHS Act). Section 354(r) of the PHS Act requires FDA to assess and collect fees for inspections of mammography facilities, other than governmental entities as determined by FDA, to cover the costs of inspections.

An updated resource review has demonstrated that the recoverable costs of the MQSA inspection program have increased since the last notice on fees in 2003 (68 FR 5289, September 4, 2003). In addition, the annual amount of fees collected under the current fee schedule has been well below the level authorized by Congress. FDA needs to be able to collect the full cost of mammography inspections to ensure it has the resources to ensure high quality mammography remains available to women. Accordingly, the fees have been recalculated so that the aggregate amount of fees collected will equal the aggregate recoverable costs of the inspections conducted, as mandated by the MQSA. Therefore, FDA is providing notice of the increased fees to be assessed starting on October 1, 2007, and additional information relating to those fees.

II. Inspections Under the Mammography Quality Standards Act of 1992

Section 354(g)(1) of the PHS Act requires FDA, States as Certifier (SAC) States, or a State or local agency acting on behalf of the FDA, to conduct an annual inspection of each mammography facility. The purpose of the annual inspection is to determine facility compliance with quality standards established under the MQSA. Inspectors who have met Federal training requirements and who are qualified by FDA will conduct inspections.

Under ordinary circumstances, inspections will be conducted during the regular business hours of the facility or at a mutually agreed time. FDA normally will provide 5 working days advance notice of each annual inspection. If a significant deficiency is identified during an inspection, FDA will provide information on necessary corrective action and, in appropriate cases, will schedule a followup inspection after the facility has had a reasonable time to correct the deficiency. FDA normally will provide 5 working days advance notice of each followup inspection. FDA may make unannounced inspections or may provide shorter notice if prompt action is necessary to protect the public health (see section 354(g)(4) of the PHS Act).

III. Costs Included in the Fees to Be Assessed Beginning on October 1, 2007

Section 354(r) of the PHS Act requires FDA to assess and collect fees from persons who own or lease mammography facilities, or their agents, to cover the costs of inspections conducted by FDA, SAC States, or a State or local agency acting on behalf of FDA. Section 354(r) of the PHS Act limits FDA's discretion in setting inspection fees in three ways: (1) Fees must be set so that, for a given fiscal year (FY), the aggregate amount of fees collected will equal the aggregate costs of inspections conducted; (2) a facility's

liability for fees must be reasonably based on the proportion of the inspection costs that relate to the facility; and (3) governmental entities, as determined by FDA, are exempt from payment of fees. FDA has determined that the following categories of costs are recoverable under section 354(r) of the PHS Act and has included them in the fees to be assessed beginning on October 1, 2007. These categories represent the same costs that have been assessed in fees since the beginning of the inspection program. Facilities are not being assessed for any new costs associated with inspections.

Cost categories are as follows: (1) Personnel costs of annual and followup inspections of mammography facilities, including administration and support; (2) purchase of equipment, calibration of instruments used in the inspections, and modification and maintenance of training facilities and laboratories to support the MQSA operations; (3) design, programming, and maintenance of data systems necessary to schedule and track inspections and to collect data during inspections; (4) training and qualification of inspectors (both FDA and State inspectors); (5) costs of billing facilities for fees due for annual and followup inspections and collecting facility payments; (6) tracking, coordination, and direction of inspections; and (7) overhead and support attributable to facility inspections.

Because most equipment used for inspections is durable and can be used for a period of years, it is not appropriate to recover the full costs of such expenditures in the year of purchase. To do so would result in the MQSA inspection fee varying widely from one year to the next. Instead, FDA recovers these costs over the useful life of the asset.

The recoverable portions of all fixed costs of the inspection program and appropriate variable costs are recovered in the annual inspection fee. This fee will vary depending on how many mammography units are used by a facility. All mammography facilities, except governmental entities, are subject to an inspection fee. If the annual inspection of a facility identifies a deficiency that necessitates a followup inspection, the facility will be assessed an additional fee to recover the costs of that additional inspection (unless it is a governmental entity). Facilities that do not require a followup inspection are not subject to this fee.

IV. Inspection Fees to be Assessed Beginning on October 1, 2007

FDA reviewed the past methodologies for calculating the inspection fee, which accounted for differences in facility size. The same method was adopted for calculating the fees FDA will assess beginning on October 1, 2007 (Ref. 1). A facility's inspection fee will be based on the number of mammography units used by the facility.

The total recoverable aggregate cost of the MQSA inspection program is estimated to be $15.77 million in FY 2008. This is below the $16.4 million authorized by Congress for collections in FY 2004, the last time fees were increased, and well below the $18.4 million authority requested from Congress for MQSA user fee collections in FY 2008. To recover the costs of the inspection program, the facility portion of the fee is $1,900 and each unit portion is $250. The cost of each additional unit must be added to the facility portion of the fee to determine the total inspection fee. This new fee of $2,150 for a facility with one unit replaces the current fee of $1,749 for a facility with one unit.

FDA will assess the following fees, beginning on October 1, 2007, for facility inspections, as shown in table 1 of this document:

TABLE 1.—ANNUAL INSPECTION FEE BY NUMBER OF UNITS

Number of Units	Fee
1	$2,150
2	$2,400
3	$2,650
4	$2,900
5	$3,150
6	$3,400
7	$3,650
8	$3,900
9	$4,150
10	$4,400
Followup Inspection Fee	$1,144

FDA will continue to charge separately for annual and followup inspections. FDA believes it is more appropriate and equitable for the costs of followup inspections to be borne entirely by the facilities that require such inspections. FDA has again chosen to adopt a flat fee for followup inspections over an hourly rate that would vary the fee by the length of the inspection. This approach eliminates concerns about variations among inspectors and differential treatment of facilities. The fee schedule is subject to change each year to ensure that the aggregate amount of fees collected during any year equals the aggregate amount of costs for that year's facility inspections. FDA will monitor the adequacy of the fee on an annual basis to account for any major programmatic and budget changes.

FDA continues to use a uniform national fee structure. The methodology adopted by FDA to determine inspection fees does not pass on the costs of inspecting governmental entities to other facilities. The entire cost of inspecting governmental entities has been and will continue to be borne by appropriated funds.

V. Facilities Subject to Payment of Inspection Fees

Under the MQSA, all mammography facilities, except governmental entities as determined by FDA, are subject to payment of inspection fees (see section 354(r) of the PHS Act). FDA will continue to use the definition that was previously developed and applied to determine whether a facility qualifies as a governmental entity for the purpose of determining whether a facility is exempt from payment of inspection fees under section 354(r) of the PHS Act. A facility may qualify as a governmental entity in two ways. First, a facility may qualify if any Federal department, State, district, territory, possession, Federally-recognized Indian tribe, city, county, town, village, municipal corporation, or similar political organization does the following: (1) Operates the facility; (2) pays the entire salary of all onsite personnel for the facility; (3) owns, rents, or leases all of the facility's mammography equipment; and (4) has the ultimate authority to make day-to-day decisions concerning the management and operation of the facility.

Second, a facility may qualify as a governmental entity if the facility provides services under the Breast and Cervical Cancer Mortality Prevention Act of 1990, (*http://apps.nccd.cdc.gov/cancercontacts/nbccedp/contacts.asp*) and at least 50 percent of the mammography screening examinations provided during the preceding 12 months were funded under that statute. (FDA has verified the Web site address, but FDA is not responsible for any subsequent changes to the Web site after this document publishes in the **Federal**

Register.) Facilities providing mammography services using grants under other statutes will not qualify as government entities. FDA does not recognize, as a governmental entity, a facility providing Medicare/Medicaid services unless that facility qualifies as a governmental entity as described in the previous paragraph.

VI. Billing and Collection Procedures

Within 30 days following inspection, FDA mails a bill and a ''Governmental Entity Declaration'' form (Form 3422) to the inspected facility. Facilities who believe they meet the governmental entity criteria complete the form and return it in lieu of the inspection fee payment. The bill sets forth the type of inspection conducted (annual or followup), the fee to be paid, and the date payment is due (30 days after billing date). Inspection fees are billed to and collected from the party that operates the facility. If the facility is owned or controlled by an entity other than the operator, it is up to the parties to establish, through contract or otherwise, how the costs of facility inspections will be allocated.

If full payment is not received by the due date, a second bill is sent. At that time, interest begins to accrue at the prevailing rate set by the Department of the Treasury, a 6 percent late payment penalty is assessed in accordance with 45 CFR 30.13, and a $20 administrative fee is assessed for each 30-day period that a balance remains due. If payment is not received within 30 days of a third and final bill, FDA may initiate action to collect unpaid balances (with interest and penalties), including the use of collection agencies, the reporting of delinquencies to commercial credit reporting agencies, and forwarding delinquent accounts to the Department of the Treasury. Any questions or concerns about the billing and collection procedures may be addressed to Billing Inquiries c/o Mammography Quality Assurance Program, P.O. Box 6057, Columbia, MD 21045, 1–800–838–7715.

VII. Request for Comments

Although the MQSA does not require FDA to solicit comments on fee exemption, assessment, and collection, FDA is inviting comments from interested persons in order to have the benefit of additional views and information, as the agency continues to evaluate its fee assessment procedures.

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.

VIII. References

The following reference is on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. U.S. Food and Drug Administration, MQSA Inspection Fees: Methodology and Fees for Fiscal Year 2008.

Dated: June 27, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–13044 Filed 7–5–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

ADDRESSES: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: 301/496–7057; fax: 301/402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Potential Serum Bio-Markers for Alpha-Fetoprotein (AFP) Negative Hepatocellular Carcinoma

Description of Technology: This technology relates to improved methods of detecting hepatocellular carcinoma (HCC) by using new biomarkers. The overexpression of Gpc3, Mdk, SerpinI1, PEG–10 and QP–C correlates with the presence of HCC, even in small tumors. By comparing the expression levels of at least three of these markers in subject samples with their expression levels in control samples, the presence of HCC can be diagnosed. The method can also be used to monitor the progression, and regression of HCC.

HCC is a common and aggressive cancer with a high mortality rate. The high mortality rate stems from an inability to diagnose the cancer at an early stage in patients, due to the lack of available biomarkers for HCC. Currently, HCC is diagnosed by measuring the levels of serum alpha-fetoprotein (AFP); however, AFP is not always present in HCC tumors, especially small tumors.

Applications: Protein markers useful for screening HCC more accurately and with increased sensitivity; The proteins can also serve as prognostic and therapeutic response biomarkers.

Advantages: Highly sensitive, secretory markers that can be easily identified in patient serum; Markers can identify HCC in patients with small tumors that would previously go undetected.

Benefits: HCC affects 20,000 people in U.S. or over half a million worldwide every year and 90% of them die of the disease. Improving the quality of life and duration of life for people suffering from this disease will depend a lot on early detection of the disease and this technology can contribute significantly to that social cause. Furthermore, the cancer diagnostic market is estimated to grow to almost $10 billion dollars in the next 5 years.

Inventors: *Xin Wei Wang* (NCI) et al.

U.S. Patent Status: Pending PCT Application PCT/US2006/042591, published as WO 2007/053659 (HHS Reference No. E–333–2005/0–PCT–02).

Licensing Contact: David A. Lambertson, PhD; Phone: (301) 435–4632; Fax: (301) 402–0220; E-mail: *lambertsond@mail.nih.gov.*

Collaborative Research Opportunity: The National Cancer Institute, Laboratory of Human Carcinogenesis, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize new biomarkers for hepatocellular carcinoma (HCC). Please contact John D. Hewes, PhD at 301–435–3121 or *hewesj@mail.nih.gov* for more information.