Format for Abbreviated 510(k)s for Early Growth Response 1 (EGR1) Gene Fluorescence In-Situ Hybridization (FISH) Test System for Specimen Characterization Devices.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

III. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

IV. Paperwork Reduction Act of 1995

This guidance refers to currently 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 807, subpart E, are currently approved under OMB control number 0910–0120 and the collections of information in 21 CFR 809.10 are currently approved under 0910–0485.

V. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments 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, and will be posted to the docket at *http://www.regulations.gov.*

Dated: June 12, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–14881 Filed 6–16–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0389]

Medical Device User Fee Amendments; Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

The Food and Drug Administration (FDA) is announcing a public meeting on the reauthorization of the Medical Device User Fee Amendments (MDUFA) for fiscal years 2018 through 2022. The current legislative authority for the medical device user fee program expires on October 1, 2017, and new legislation will be required for FDA to continue collecting user fees for the medical device program in future fiscal years. The Federal Food, Drug, and Cosmetic Act (FD&C Act) requires that before FDA begins negotiations with the regulated industry on MDUFA reauthorization, we publish a notice in the **Federal Register** requesting public input on the reauthorization, hold a public meeting at which the public may present its views on the reauthorization, provide a period of 30 days after the public meeting to obtain written comments from the public suggesting changes to MDUFA, and publish the comments on FDA's Web site. FDA invites public comment on the medical device user fee program and suggestions regarding the commitments FDA should propose for the next reauthorized program.

Date and Time: The public meeting will be held on July 13, 2015, from 9 a.m. to 5 p.m.

Location: The public meeting will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993. Entrance for public meeting participants (non-FDA employees) is through Building 1 where routine security screening procedures will be performed. For parking and security information, please refer to *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

Contact Person: Aaron Josephson, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5449, Silver Spring, MD 20993, 301–796–5178, email: *Aaron.Josephson@fda.hhs.gov.*

Registration: Registration is required to attend this meeting in person or to view the Webcast. Registration is free and available on a first-come, first-served basis. Persons interested in participating in the meeting must register online by July 2, 2015, at 4 p.m. Early registration is recommended because space is limited and, therefore, FDA may limit the number of participants from each organization. If time and space permit, onsite registration on the day of the meeting will be provided beginning at 8 a.m.

If you have registered and need special accommodations, please contact Susan Monahan, 301–796–5661, email: *Susan.Monahan@fda.hhs.gov,* no later than July 1, 2015.

To register for the public meeting, please visit FDA's Medical Devices News & Events—Workshops & Conferences calendar at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm.* (Select this public meeting from the posted events list.) Please provide complete contact information for each attendee, including name, title, affiliation, email, and telephone number. Those without Internet access should contact Susan Monahan to register. All registrants will receive confirmation after they have been successfully registered. Registrants not confirmed to participate, but added to a waiting list, will be notified of that as well.

Streaming Webcast of the Public Meeting: This public meeting will be Webcast. Persons interested in viewing the Webcast must register online (see Web link above) by July 2, 2015, at 4 p.m. Early registration is recommended because Webcast connections are limited. FDA requests that organizations with multiple registrants in the same location register all participants individually but view the Webcast using one connection per location. Webcast participants will be sent technical system requirements upon confirmation and will be sent connection access information after July 6, 2015. If you have not previously attended an event hosted by Connect Pro, it is recommended that you test your connection in advance at *https://collaboration.fda.gov/common/help/en/support/meeting_test.htm.* A short overview of the Connect Pro program is available at *http://www.adobe.com/go/connectpro_overview.*

Requests for Oral Presentations: This public meeting includes public comment and topic-focused sessions. During registration you may indicate if you wish to present during a public comment session or participate in a topic-focused session, and specify the topic(s) you wish to address. FDA has included general topics in this document. FDA will do its best to accommodate all persons who wish to speak. FDA encourages individuals and organizations with common interests to consolidate or coordinate their presentations, and request time for a joint presentation, or submit requests for designated representatives to participate in the topic-focused sessions. After

registration closes, FDA will determine the amount of time allotted to each presenter and the approximate time each oral presentation is to begin, and will notify selected speakers by July 7, 2015. All requests to make oral presentations must be received by the close of registration on July 2, 2015, at 4 p.m. Presenters should submit all presentation materials via email to Aaron Josephson (see *Contact Person*) no later than July 10, 2015. No commercial or promotional material should be presented or distributed at the public meeting.

Comments: FDA is holding this public meeting to hear stakeholder views on the medical device user fee program. In order to obtain a broad range of public comment, FDA is soliciting either electronic or written comments on all aspects of the public meeting topics. The deadline for submitting comments related to this public meeting is August 12, 2015.

Regardless of attendance at the public meeting, interested persons may submit either electronic comments regarding reauthorization of MDUFA to *http://www.regulations.gov* or written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. In addition, when responding to specific questions as outlined in section I, please identify the question you are addressing. Received comments may be viewed in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

Transcripts: As soon as a transcript is available, it will be accessible at *http://www.regulations.gov.* It may also be viewed in person at the Division of Dockets Management (see *Comments*). A link to the transcript will also be available approximately 45 days after the public workshop on the Internet at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm.* (Select this public meeting from the posted events list.)

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing its intention to hold a public meeting on the reauthorization of the Medical Device User Fee Amendments of 2012 (MDUFA III), which currently authorizes FDA to collect user fees and use them for the process for the review of device applications until October 1, 2017. Without new legislation, referred to as reauthorization, FDA will not be able to collect user fees after fiscal year (FY) 2017 to fund the medical device review process.

Prior to reauthorization, FDA must consult with the regulated industry and make recommendations to Congress regarding the goals for the process for the review of device applications (see 21 U.S.C. 379j–1(b)(1)(F)). Before beginning negotiations with the regulated industry on user fee reauthorization, section 738A(b)(2) of the FD&C Act (21 U.S.C. 379j–1(b)(2)) requires that FDA do the following: (1) Publish a notice in the **Federal Register** requesting public input on the reauthorization; (2) hold a public meeting at which the public may present its views on the reauthorization, including specific suggestions for changes to the goals set under MDUFA III; (3) provide a period of 30 days after the public meeting to obtain written comments from the public suggesting changes to MDUFA; and (4) publish the comments on FDA's Web site. This notice, the public meeting, the 30-day comment period after the meeting, and the posting of the comments on FDA's Web site will satisfy these requirements.

The purpose of the meeting is to hear stakeholder views on medical device user fee reauthorization as we consider FDA's recommendation to Congress for the next medical device user fee program. FDA is interested in responses to the following two general questions and welcomes any other pertinent information stakeholders would like to share:

1. What is your assessment of the overall performance of the medical device user fee program under MDUFA III?

2. What aspects of the medical device user fee program should be retained, changed, or discontinued to further strengthen and improve the program?

The following information is provided to help potential meeting participants better understand the history and evolution of the medical device user fee program and its current status.

II. What is the Medical Device User Fee Program? What does it do?

In the years preceding enactment of the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) (Pub. L. 107–250), FDA's medical device program suffered a long-term, significant loss of resources that undermined the program's capacity and performance. MDUFMA was enacted ''in order to provide FDA with the resources necessary to better review medical devices, to enact needed regulatory reforms so that medical device manufacturers can bring their safe and effective devices to the American people at an earlier point in time, and to ensure that reprocessed medical devices are as safe and effective as original devices'' (H. Rept. 107–728 at 21 (2002)). MDUFMA had a 5-year life and contained two particularly important features which relate to reauthorization:

- *User fees* for the review of medical device premarket applications, reports, supplements, and premarket notification submissions provided additional resources to make FDA reviews more timely, predictable, and transparent to applicants. MDUFMA fees and appropriations for the medical device program helped FDA expand available expertise, modernized its information management systems, provided new review options, and provided more guidance to prospective submitters. The ultimate goal was for FDA to approve and clear safe and effective medical devices more rapidly, benefiting applicants, the health care community, and most importantly, patients.
- *Negotiated performance goals* for many types of premarket reviews provided FDA with benchmarks for measuring review improvements. These quantifiable goals became more demanding each year and included FDA decision goals and cycle goals (cycle goals refer to FDA actions prior to a final action on a submission). Under MDUFMA, FDA also agreed to several other commitments that did not have specific timeframes or direct measures of performance, such as expanding the use of meetings with industry, maintenance of current performance in review areas where specific performance goals had not been identified, and publication of additional guidance documents.

Medical device user fees and increased appropriations are essential to support high-quality, timely medical device reviews, and other activities critical to the device review program.

MDUFMA provided for fee discounts and waivers for qualifying small businesses. Small businesses make up a large proportion of the medical device industry, and these discounts and waivers helped reduce the financial impact of user fees on this sector of the medical device industry, which plays an important role in fostering innovation.

Since MDUFMA was first passed in 2002, it has been reauthorized twice: The 2007 Medical Device User Fee Amendments (MDUFA II) and the 2012 Medical Device User Fee Amendments (MDUFA III). Under MDUFA III, which

has been in effect since 2012 and will expire in 2017, FDA has met or exceeded nearly all submission performance goals while implementing program enhancements designed to ensure more timely access to safe and effective medical devices.

- Premarket Notifications (510(k)s): Comparison of outcomes for receipt cohorts at the same levels of completion (or ''closure'') show a 16 percent decrease in total review time between FY 2010 and FY 2013 when the cohort is 99.8 percent closed, and 10 percent decrease in total review time between FY 2010 and FY 2014 when the cohort is 75.8 percent closed.
- Premarket Approvals (PMAs): Comparison of outcomes for receipt cohorts at the same closure levels show a 32 percent decrease in total review times between FY 2009 and FY 2012 when the cohort is 98 percent closed, and a 26 percent decrease in total review times between FY 2009 and FY 2014 when the cohort is 41 percent closed.

FDA has met or exceeded all MDUFA III performance goals for FDA time to decisions in FY 2013 and FY 2014. More information about FDA's performance is available in the yearly MDUFA performance reports, which are available online at *http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/UserFeeReports/PerformanceReports/UCM2007450.htm.*

User fees and related performance goals have played an important role in providing resources and supporting the process for the review of device applications.

III. What information should you know about the meeting?

Through this notice, we are announcing a public meeting to hear stakeholder views on the reauthorization of MDUFA for fiscal years 2018 through 2022, including specific suggestions for any changes to the program that we should consider. We will conduct the meeting on July 13, 2015. In general, the meeting format will include presentations by FDA and a series of panels representing different stakeholder interest groups (such as patient advocates, consumer protection groups, industry, health care professionals, and academic researchers). FDA will also provide an opportunity for individuals to make presentations during the meeting and for organizations and individuals to submit written comments to the docket after the meeting. The presentations should focus on program improvements and funding issues, including specific suggestions for changes to performance goals, and not focus on other general policy issues.

Dated: June 11, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–14885 Filed 6–16–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0473]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Irradiation in the Production, Processing, and Handling of Food

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by July 17, 2015.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0186. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Road; COLE–14526, Silver Spring, MD 20993–0002 *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Irradiation in the Production, Processing, and Handling of Food—21 CFR Part 179 (OMB Control Number 0910–0186)—Extension

Under sections 201(s) and 409 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 321(s) and 348), food irradiation is subject to regulation under the food additive premarket approval provisions of the FD&C Act. The regulations providing for uses of irradiation in the production, processing, and handling of food are found in part 179 (21 CFR part 179). To ensure safe use of a radiation source, § 179.21(b)(1) requires that the label of sources bear appropriate and accurate information identifying the source of radiation and the maximum (or minimum and maximum) energy of the emitted radiation. Section 179.21(b)(2) requires that the label or accompanying labeling bear adequate directions for installation and use and a statement supplied by us that indicates maximum dose of radiation allowed. Section 179.26(c) requires that the label or accompanying labeling bear a logo and a radiation disclosure statement. Section 179.25(e) requires that food processors who treat food with radiation make and retain, for 1 year past the expected shelf life of the products up to a maximum of 3 years, specified records relating to the irradiation process (*e.g.,* the food treated, lot identification, scheduled process, etc.). The records required by § 179.25(e) are used by our inspectors to assess compliance with the regulation that establishes limits within which radiation may be safely used to treat food. We cannot ensure safe use without a method to assess compliance with the dose limits, and there are no practicable methods for analyzing most foods to determine whether they have been treated with ionizing radiation and are within the limitations set forth in part 179. Records inspection is the only way to determine whether firms are complying with the regulations for treatment of foods with ionizing radiation.

In the **Federal Register** of March 31, 2015 (80 FR 17055), FDA published a 60-day notice requesting public comment on the proposed collection of information. One comment was received but did not respond to any of the four information collection topics solicited and is therefore not addressed by the Agency.

Description of respondents: Respondents are businesses engaged in the irradiation of food.

We estimate the burden of this collection of information as follows: