with administrators, staff, and/or clients in each of the approximately six sites. OPRE will field client and/or staff surveys in order to hear from a breadth of perspectives. In addition to interviews, focus groups, and surveys, OPRE anticipates observing program activities and reviewing documents and administrative data. This information will be critical to diagnosing where and why programs are facing challenges and which behavioral interventions may have an impact.

During the testing phase OPRE anticipates conducting mixed-methods evaluations consisting of implementation, impact, and cost research for the approximately two tests in each of the approximately six total sites that will be engaged across the two program areas included under this clearance, TANF and Child Welfare (for a total of 12 tests). To better understand how the intervention is being implemented and its effects, OPRE anticipates conducting interviews and focus groups with program administrators, staff, and/or clients in each site. Because not all outcomes of interest (for example, improved understanding of and/or satisfaction with the foster parent recruitment process) are reflected in administrative records, OPRE anticipates conducting client surveys and staff surveys.

Interest in participating in BIAS–NG is expected to be high, and it is not expected that systematic recruitment of sites will be necessary. Within each site, we do not intend to do any active recruitment as all those who are eligible will be enrolled in the study and randomization will be conducted using a list of those who meet the eligibility criteria. Findings from these tests will be publicized through multiple dissemination channels, which may include but are not limited to reports on individual tests, a final synthesis report, presentations at conferences and meetings, scholarly journal articles, webinars, social media, press outreach, newsletters, etc.

Respondents: (1) Program Administrators, (2) Program Staff and (3) Program Clients.

TOTAL BURDEN HOURS

Instrument	Total number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Diagnosis and Design Phase				
Administrator interviews/focus groups	24	1	1	24
Staff interviews/focus groups	48	1	1	48
Client interviews/focus groups	48	1	1	48
Client survey	600	1	.25	150
Staff Survey	120	1	.25	30
Evaluation Phase				
Administrator interviews/focus groups	48	1	1	48
Staff interviews/focus groups	96	1	1	96
Client interviews/focus groups	96	1	1	96
Client Survey	6,000	1	.25	1,500
Staff survey	120	1	.25	30

Estimated Total Burden Hours: 2,070 hours.

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 330 C Street SW., Washington, DC 20201, Attn: OPRE Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: *OPREinfocollection@acf.hhs.gov*.

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Email: *OIRA_SUBMISSION@OMB.EOP.GOV*, Attn: Desk Officer for the Administration for Children and Families.

Mary Jones,

ACF/OPRE, Certifying Officer.

[FR Doc. 2017–15523 Filed 7–24–17; 8:45 am]

BILLING CODE 4184–07–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–4180]

Voluntary Medical Device Manufacturing and Product Quality Program; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the following public workshop entitled ''Voluntary Medical Device Manufacturing and Product Quality Program.'' The purpose of the public workshop is to announce the proposed framework and preliminary outline of a voluntary pilot program that recognizes an independent assessment of manufacturing and product quality. The workshop is intended to discuss the framework of the voluntary pilot program, information on the independent assessment, details of participation, rules of engagement, monitoring and performance expectations, as well as potential modifications to FDA's oversight actions in response to demonstrated manufacturing quality performance. FDA is soliciting public feedback to aid in the development of science-based approaches to regulatory decision making for assessing manufacturing quality, extent of manufacturing related submissions, and how to better allocate resources to lower the regulatory burden on manufacturers and FDA.

DATES: The public workshop will be held on October 10, 2017, from 8 a.m. to 4:30 p.m. Submit either electronic or written comments on this public workshop by October 18, 2017. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public workshop will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Bldg. 31, Rm. 1503 (the Great Room), Silver Spring, MD 20993–0002. Entrance for the public workshop participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to *https://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before October 18, 2017. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of October 18, 2017. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2017–N–4180 for ''Voluntary Medical Device Manufacturing and Product Quality Program.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- *Confidential Submissions*—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Francisco Vicenty, Food and Drug Administration, Center for Devices and Radiological Health, 10903 New Hampshire Ave., Bldg. 66, Rm. 3426, Silver Spring, MD 20993, 301–796–5577, email: *Francisco.Vicenty@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The FDA's Center for Devices and Radiological Health (CDRH or the Center) launched the Case for Quality initiative (Ref. 1) in 2011 to identify those practices that can promote a culture of quality and the implementation of a quality management approach that fosters continuous product quality. Since then, CDRH has engaged with a wide variety of stakeholders from the medical device ecosystem, including industry, patients, governmental and academic partners, and payer/provider counterparts to identify key factors affecting medical device quality and develop innovative ways to afford patient access to higher quality medical devices. As part of CDRH's 2016–2017 strategic priority to ''Promote a Culture of Quality and Organizational Excellence'' (Ref. 2), CDRH envisions a future state where the medical device ecosystem is inherently focused on device features and manufacturing practices that have the greatest impact on product quality and patient safety. The purpose of the public workshop is to present the proposed framework of a voluntary pilot program to recognize independent evaluation of product and manufacturing quality to strengthen product and manufacturing quality within the medical device ecosystem. This workshop will explore approaches to increase manufacturing and product quality, which may translate into better patient safety and outcomes, and discuss new approaches that are intended to lower the regulatory burden on demonstrating quality assurance, and acknowledge alternate methods for assuring safety and effectiveness during product development and manufacturing.

Historically, the FDA has evaluated manufacturers' compliance with regulations governing the design and production of devices. Compliance with the Quality System regulation (Ref. 3) is a baseline requirement for medical

device manufacturing firms. Focusing on elevating manufacturing quality practices gives greater emphasis to these practices, which should correlate to higher quality outcomes. This will allow FDA to adjust how we recognize and incentivize how the safety and effectiveness of a medical device is assured. CDRH intends to continue working with stakeholders to assess and promote manufacturers' implementation of manufacturing quality practices in day-to-day device design and production.

Through collaboration with the Medical Device Innovation Consortium (MDIC) over the last 2 years, a maturity model and appraisal system (*i.e.,* Capability Maturity Model Integration (CMMI) system) that can be adapted for the medical device industry was selected (Ref. 4) for this voluntary pilot program. The CMMI system is a process level improvement, training, and appraisal program. This program is administered by the CMMI Institute and helps organizations discover the true value they can deliver by building capability in their people and processes (Ref. 5). This model has been successfully used in various industries, including information technology, healthcare, automotive, defense, and aerospace, to consistently deliver high quality products and reduce waste and defects. The CMMI institute certifies and coordinates third party appraisers evaluating voluntary industry participants and any data necessary to demonstrate product performance. The appraiser would evaluate the firm's quality system maturity and manufacturing processes, and identify any gaps or where a participating firm is performing above a compliance baseline. The CMMI maturity appraisal process is not intended to serve as an FDA inspection nor is it intended to be a new regulatory requirement. Conducting independent-assessments using a maturity model is intended to be a driver of continuous process and product improvement and business value to voluntary participants in the pilot program.

Assessments under the CMMI Institute are classified as Standard CMMI Appraisal Method for Process Improvement (SCAMPI) elements. As noted, a gap assessment (SCAMPI–C) will be a part of the voluntary pilot program. SCAMPI–C is a critical tool for developing an in-depth understanding of the medical device manufacturer's current state of process performance. SCAMPI–C is a short and flexible appraisal. It is used to assess the adequacy of planned approaches to process implementation and to provide a quick analysis between the organization's processes and CMMI practices. It provides a rich dataset that reflects organizational performance and a comparison of the medical device manufacturer's performance against the CMMI model.

The next steps for Case for Quality and key discussion topics for this public workshop are the announcement of a maturity model appraisal framework and implementation plan for a voluntary pilot program. These will incorporate an independent assessment of manufacturing and product quality into the way medical devices are regulated while maintaining organizational excellence. Further, this workshop is intended to discuss least burdensome opportunities as incentives for manufacturers that participate in the voluntary pilot program and have demonstrated high performance in manufacturing quality.

II. Topics for Discussion at the Public Workshop

Following are a list of topics that are planned to be included for discussion at the public workshop:

- Background on Case for Quality and proposed use of the CMMI Assessments.
- Proposed Voluntary Program Framework and Implementation Plan:
  - Enrollment and participation;
  - Assessment strategy;
  - Audit credentials—Details on how assessors will be evaluated and accredited;
  - Cost of the independent assessment and sustaining a voluntary program;
  - Monitoring requirements and frequency of progress updates;
  - Data collection requirements; metrics that can be trended over time to provide assurance of sustained performance versus inspection or assessment; and
  - Data sharing guidelines; information shared between industry and third party, and industry and FDA.
- Possible modifications to decrease FDA regulatory burdens for manufacturers with demonstrated high quality:
  - Inspectional strategies;
  - Manufacturing submissions—Reducing burden and accelerating time to market, and
  - Regulatory activities—Recognizing alternate methods for demonstrating product quality assurance and problem solving and resolution before escalating to enforcement actions.
- Health outcomes to patients, value to industry, and benefits to health care.
- Identifying new risks and mitigation strategies.

III. Participating in the Public Workshop

Registration: To register for the public workshop, please visit FDA's Medical Devices News & Events—Workshops & Conferences calendar at *https://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm.* (Select this public workshop from the posted events list.) Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone.

Registration is free and based on space availability, with priority given to early registrants. Persons interested in attending this public workshop must register by September 29, 2017, at 4 p.m. Eastern Time. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. Registrants will receive confirmation when they have been accepted. If time and space permit, onsite registration on the day of the public workshop will be provided beginning at 8 a.m. We will let registrants know if registration closes before the day of the public workshop.

If you need special accommodations due to a disability, please contact Peggy Roney at Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5231, Silver Spring, MD 20993–0002, 301–796–5671, email: *Peggy.Roney@fda.hhs.gov,* no later than September 26, 2017.

Requests for Oral Presentations: During online registration you may indicate if you wish to present during a public comment session or participate in a specific session, and which topic(s) you wish to address. We will do our best to accommodate requests to make public comments and requests to participate in the focused sessions. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations, and request time for a joint presentation, or submit requests for designated representatives to participate in the focused sessions. Following the close of registration, we will determine the amount of time allotted to each presenter and the approximate time each oral presentation is to begin, and will select and notify participants by October 4, 2017. All requests to make oral presentations must be received by the close of registration on September 29, 2017. If selected for presentation, any presentation materials must be emailed to the Francisco Vicenty (see **FOR FURTHER INFORMATION CONTACT**) no

later than October 3, 2017. No commercial or promotional material will be permitted to be presented or distributed at the public workshop.

Streaming webcast of the public workshop: This public workshop will also be webcast. The webcast link will be available on the registration Web page after October 3, 2017. Organizations are requested to register all participants, but to view using one connection per location.

If you have never attended a Connect Pro event before, test your connection at *https://collaboration.fda.gov/common/help/en/support/meeting_test.htm.* To get a quick overview of the Connect Pro program, visit *https://www.adobe.com/go/connectpro_overview.* FDA has verified the Web site addresses in this document, as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.

Transcripts: Please be advised that as soon as a transcript of the public workshop is available, it will be accessible at *https://www.regulations.gov.* It may be viewed at the Dockets Management Staff (see **ADDRESSES**). A link to the transcript will also be available on the Internet at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm.* (Select this public workshop from the posted events list.)

IV. References

The following references are on display in the Dockets Management Staff (see **ADDRESSES**), and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at *https://www.regulations.gov.* FDA has verified the Web site addresses, as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.

1. FDA's CDRH Case for Quality Initiative is available at: *https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/MedicalDeviceQualityandCompliance/ucm378185.htm.*

2. CDRH, 2016–2017 ''Promote a Culture of Quality and Organizational Excellence'' available at: *https://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHVisionandMission/UCM481588.pdf.*

3. The Quality System regulation available at: *https://www.ecfr.gov/cgi-bin/text-idx?SID=54a4a38f9c25eeab900b1c8f6c0f4212&mc=true&node=pt21.8.820&rgn=div5.*

4. MDIC available at: *http://mdic.org/.*

5. CMMI system available at: *http://cmmiinstitute.com/.*

Dated: July 18, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–15542 Filed 7–24–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2004–D–0369]

Animal Drug User Fees and Fee Waivers and Reductions; Revised Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a guidance for industry (GFI) #170 entitled ''Animal Drug User Fees and Fee Waivers and Reductions.'' This revised guidance document describes the types of fees that FDA is authorized to collect under the Animal Drug User Fee Act of 2003, as amended, and how to request waivers and reductions of these fees.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2004–D–0369 for ''Animal Drug User Fees and Fee Waivers and Reductions.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments