regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: Must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (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.

Submit petitions electronically to *https://www.regulations.gov* at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: October 17, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–23057 Filed 10–22–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–3623]

Fostering Medical Innovation: Voluntary Pilot Program To Streamline Review of Premarket Notification (510(k)) Submissions for Ophthalmic Optical Coherence Tomography Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration's (FDA) Center for Devices and Radiological Health, Office of Device Evaluation recognizes that an efficient, risk-based approach to regulating ophthalmic Optical Coherence Tomography (OCT) technology will foster innovation designed to improve ophthalmic healthcare. To make premarket review of OCT devices more efficient, we are announcing a new voluntary OCT Premarket Notification (510(k)) Pilot Program, designed to develop and refine individual premarket testing recommendations for OCT devices through the pre-submission process to yield more consistent premarket submissions and improve predictability of the 510(k) review process. We are planning to achieve these goals through increased interactive engagement with manufacturers of OCT devices. FDA intends to use the voluntary OCT 510(k) Pilot Program to assess whether the individual testing recommendations provided through the pre-submission process and increased interactive engagement improve the premarket review process and reduce the overall total time to decision (TTD), a shared FDA-industry commitment goal, in support of the Medical Device User Fee Amendments of 2017.

DATES: FDA is seeking participation in the voluntary OCT 510(k) Pilot Program beginning October 23, 2018. See the ''Voluntary OCT 510(k) Pilot Program Procedures'' section for instructions on how to submit a request to participate. The voluntary OCT 510(k) Pilot Program will select the first nine eligible participants.

FOR FURTHER INFORMATION CONTACT: Brad Cunningham, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2430, Silver Spring, MD 20993, 301–796–6620, email: *Bradley.Cunningham@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

OCT devices are devices for viewing, imaging, measurement, and analysis of ocular structures and may be used to aid in the detection and management of various ocular diseases. These devices are classified under 21 CFR 886.1570 and are assigned the product code OBO; they are Class II devices requiring premarket notification (510(k)) prior to marketing. In their 510(k) submission, for purposes of premarket clearance, manufacturers must demonstrate substantial equivalence to a legally marketed predicate in terms of intended use, technological characteristics, and performance. This is typically achieved through evaluation of non-clinical and/or clinical data, among other information.

Currently, there are no FDA-recognized consensus standards or published guidance documents available that describe performance testing recommendations for OCT devices. As such, 510(k) submissions, when initially submitted to FDA, often do not include adequate testing to support substantial equivalence. This is evidenced by consistent requests for additional information (including new data and analyses) across OCT 510(k) submissions, which are unforeseen by manufacturers and may greatly contribute to an increase in TTD for an individual 510(k) submission. Therefore, there is a need for a better understanding of premarket testing expectations for OCT devices and dialogue between FDA and OCT manufacturers in order to reduce the need for additional data requests during the 510(k) submission review.

II. Description of the Voluntary OCT 510(k) Pilot Program

FDA intends to achieve the goals of the voluntary OCT 510(k) Pilot Program, that are described in Section III, by: (1) Communicating and obtaining feedback related to individual recommendations regarding non-clinical and clinical evaluation of OCT devices; and (2) facilitating discussion between FDA and individual OCT device manufacturers regarding these risk-based testing recommendations. Specifically, participants in the voluntary OCT 510(k) Pilot Program will have the opportunity to discuss premarket performance testing recommendations for their OCT device in an interactive format (by phone or in-person meeting) with the FDA review team, including engineers, medical officers, and managers. FDA will interactively communicate and solicit feedback on its individual testing recommendations to yield a mutual, clear understanding of the information necessary to demonstrate substantial equivalence in a 510(k) submission for the OCT device and to streamline 510(k) submission and review.

Participation eligibility in this voluntary OCT 510(k) Pilot Program is determined based on the factors listed in Section IV. Due to resource constraints, we intend to limit this voluntary pilot program to the first nine eligible participants.

To evaluate success of the voluntary OCT 510(k) Pilot Program, we intend to assess 510(k) TTD and feedback on the pre-submission and 510(k) processes from participants in the pilot program.

This voluntary pilot program is limited to OCT devices, not already cleared for marketing through 510(k), which could be classified under 21 CFR 886.1570.

III. Goals of the Voluntary OCT 510(k) Pilot Program

FDA has the following goals for the voluntary OCT 510(k) Pilot Program:

1. Improve consistency and predictability of the 510(k) premarket review process for OCT devices.

2. Reduce TTD for OCT 510(k) submissions, noting that ''FDA and applicants share the responsibility for achieving this objective of reducing the average Total Time to Decision, while

maintaining standards for safety and effectiveness'' (Ref. 1).

3. Increase collaboration between FDA and individual manufacturers to refine non-clinical and/or clinical testing recommendations.

IV. Participation Eligibility

Eligibility for participation in the voluntary OCT 510(k) Pilot Program will be based on the following factors:

1. Intent to submit a Traditional 510(k) for an OCT device, that could be classified under 21 CFR 886.1570, within 1 year of acceptance to the voluntary OCT 510(k) Pilot Program.

2. Commitment to support an interactive review process and to respond interactively and in a timely manner, as requested, during the 510(k) review, including response to any FDA requests for additional information.

3. Based on pre-submission interactions, commitment to incorporate FDA feedback, including recommendations provided on the testing plan, into the testing that will be conducted to support the Traditional 510(k) submission.

At its discretion, FDA may withdraw a manufacturer from the OCT 510(k) Pilot Program for not carrying out any of the commitments mentioned previously.

V. Voluntary OCT 510(k) Pilot Program Procedures

A. Enrollment and Interaction for OCT Pre-submission

To be considered for the voluntary OCT 510(k) Pilot Program, an OCT device manufacturer should submit a ''statement of interest'' for participation to *bradley.cunningham@fda.hhs.gov.* The ''statement of interest'' should include the following: (1) Manufacturer's name and contact information; (2) explanation of why the manufacturer believes it meets the participation eligibility factors outlined in Section IV; and (3) the intended use (including indications for use) and critical technological characteristics of the OCT device for which a Traditional 510(k) will be submitted under the pilot program as well as the proposed predicate device.

The following captures the process for the enrollment and pre-submission phase of the voluntary OCT 510(k) Pilot Program:

1. Upon receiving a ''statement of interest,'' FDA will determine eligibility based on the factors outlined in Section IV.

2. FDA intends to notify the manufacturer via email whether the manufacturer is eligible and/or whether the manufacturer is enrolled as a participant in the voluntary OCT 510(k) Pilot Program. Based on the intended use and critical technological characteristics of the OCT device and the proposed predicate device, provided in the ''statement of interest,'' FDA also intends to provide initial feedback regarding testing (non-clinical and/or clinical) recommendations for the specific OCT device.

3. If eligible and enrolled as a participant, the OCT manufacturer should subsequently, yet in a timely manner (*e.g.,* three months from notification of enrollment as a participant), submit a pre-submission that includes applicable information recommended in FDA's Pre-submission guidance (Ref. 2), including specific questions for which the manufacturer is seeking FDA input, along with the proposed testing plan for its OCT device, after considering FDA's initial feedback, including recommendations, provided in response to the ''statement of interest.''

4. During the pre-submission phase of the pilot program, FDA intends to provide feedback on the proposed testing plan and any specific questions included in the pre-submission within 35 calendar days. In addition, and if requested by the manufacturer, FDA intends to schedule a meeting to occur within one week after issuing feedback to the manufacturer during the pre-submission phase to clarify or discuss alternative testing approaches. As a goal of the pilot program is to positively impact and reduce TTD for OCT 510(k) submissions, FDA expects that the OCT manufacturer will implement the testing plan, including any modifications to the plan based on feedback and dialogue, discussed during this pre-submission phase, during development of the 510(k) submission. FDA welcomes feedback on our testing recommendations as part of the voluntary OCT 510(k) Pilot Program. We recognize that manufacturers may propose appropriate alternatives to FDA recommendations, and we intend to provide feedback on any proposed alternatives in the context of a pre-submission submitted per Section V.A., as part of the pilot program.

B. Refuse To Accept (RTA) and Substantive 510(k) Review for OCT 510(k)s

Once the 510(k) for an OCT device enrolled in the voluntary OCT 510(k) Pilot Program is received by FDA, it will be screened to assess whether it meets a minimum threshold of acceptability for substantive review, as described in FDA's guidance on its Refuse to Accept (RTA) Policy for 510(k)s (Ref. 3). As stated in this guidance, ''[a]n acceptance review will only begin for 510(k) submissions for which the appropriate user fee has been paid and a validated eCopy has been received.'' As recommended in the guidance, the 510(k) should include a separate section with information on the pre-submission under Section V.A., including the pre-submission number, a copy of the FDA feedback (*e.g.,* letter, meeting minutes), and a statement of how or where in the 510(k) this prior feedback, including each of the testing recommendations, was addressed. Consistent with FDA's RTA policy as described in the guidance, FDA intends to complete the acceptance review for the 510(k) submission within 15 calendar days.

Once the OCT 510(k) has been accepted for review, FDA intends to complete review of the 510(k) submission within a TTD of 90 calendar days. To help achieve this, during the 510(k) review, FDA intends to resolve any identified deficiencies through an interactive process without placing the OCT 510(k) submission on hold. Consistent with the participation eligibility factors under Section IV, FDA expects manufacturers to provide timely responses to FDA in response to deficiencies identified as part of an interactive review process. To facilitate FDA-industry interaction, we will provide a ''point of contact'' to ensure open, continual interaction during the review process. Through the ''point of contact'' person, the participants will be able to communicate with the FDA review team (which intends to respond within two business days) to expeditiously address any issues related to the 510(k) submission. FDA will evaluate the 510(k) consistent with existing 510(k) review processes and procedures, including those outlined in FDA's 510(k) Program Guidance (Ref. 4).

C. Assessment of the Voluntary OCT 510(k) Pilot Program

Following completion of the review of 510(k)s in the voluntary OCT 510(k) Pilot Program, participating manufacturers will have the opportunity to provide individual feedback on the voluntary OCT 510(k) Pilot Program and its impact on consistency and predictability of the 510(k) review process and FDA/manufacturer collaboration during the pilot program. FDA intends to solicit feedback from pilot program participants electronically through an email questionnaire. TTD will also be evaluated.

VI. Duration of the OCT 510(k) Pilot Program

FDA intends to accept requests for participation in the voluntary OCT 510(k) Pilot Program from the date of publication in the **Federal Register** through one year, or until the time when a total of nine participants have been enrolled.

VII. Paperwork Reduction Act of 1995

This notice refers to previously approved collections of information found in FDA regulations and guidance. 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 have been approved under OMB control number 0910–0120. The collections of information in ''Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff'' have been approved under OMB control number 0910–0756.

VIII. References

The following references are on display at the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 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 website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

1. MDUFA IV Commitment Letter, available at *https://www.fda.gov/downloads/ForIndustry/UserFees/MedicalDeviceUserFee/UCM535548.pdf.*
2. FDA Guidance for Industry and FDA Staff ''Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff'' dated September 29, 2017, available at *https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM311176.*
3. FDA Guidance for Industry and FDA Staff ''Refuse to Accept Policy for 510(k)s'' dated January 30, 2018, available at *https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM315014.*
4. FDA Guidance for Industry and FDA Staff ''The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]'' dated July 28, 2014, available at: *https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM284443.*

Dated: October 17, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–23059 Filed 10–22–18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–1533]

Agency Information Collection Activities; Proposed Collection; Comment Request; National Panel of Tobacco Consumer Studies

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the National Panel of Tobacco Consumer Studies.

DATES: Submit either electronic or written comments on the collection of information by December 24, 2018.

ADDRESSES: 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 December 24, 2018. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of December 24, 2018. 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–2014–N–1533 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; National Panel of Tobacco Consumer Studies.'' 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