FDA estimates that the confirmation or updating of establishment registration and product listing information as required by section 905 of the FD&C Act will take 10 minutes annually per confirmation or update per establishment. Based on FDA's experience with current establishment registration and product listings submitted to the Agency, the Agency estimates that on average 3,578 establishments will each submit one confirmation or updated report each year, which is expected to take 0.16 hour (10 minutes) for a total 572 burden hours.

FDA estimates that we have received most tobacco product ingredient submissions for large manufacturers of deemed products. Small manufacturers' deadline for ingredient submissions is November 2018. This is based on the counts we have to date (July 2018), including statutorily regulated products (based on information in our tracking system).

FDA estimates that the submission of ingredient listings required by section 904(a)(1) of the FD&C Act for each establishment will take 2 hours initially. Because this burden estimate covers a timeframe of 3 years, we anticipate almost all section 904(a)(1) tobacco ingredient submissions to have been received before the expiration of the current approval (prior to 11/8/2018 for small manufacturers and large manufacturers, 5/8/18). We are estimating approximately 30 manufacturers may miss their deadline. This is based on estimates of how many large manufacturers we are aware of that have missed their deadline. Because this burden estimate covers 3 years, we are dividing by 3, to yield 10 respondents as a yearly average for this estimate. Therefore, FDA estimates that 10 establishments will initially submit one report annually at 2 hours per report, for a total of 20 hours.

Submissions under 904(c) of the FD&C Act are for any new product that is not yet on the market (*e.g.,* if on the market due to deeming compliance period), newly deemed product manufacturers should have submitted under section 904(a)(1) of the FD&C Act. This includes any statutorily regulated product that would receive a marketing authorization and any new deemed product not subject to the deeming compliance period. For deemed product categories, while we anticipate receiving a large number of premarket applications, there is a portion of these applicants who will have reported their ingredients under section 904(a)(1) as most of these submissions are expected to be for products subject to the deeming compliance period.

Based on FDA's experience and the actual number of product ingredient listings submitted over the past 3 years, FDA estimates that 35 establishments will each submit two reports (one every 6 months). FDA also estimates that the confirmation or updating of product (ingredient) listing information required by section 904(c) of the FD&C Act is expected to take 0.40 hour (24 minutes) and will take 48 minutes annually for two confirmations or updates per establishment, for a total 28 burden hours. FDA estimates that obtaining a DUNS (data universal numbering system) number will take 30 minutes. FDA assumes that all new establishment facilities that will be required to initially register under section 905 of the FD&C Act would obtain a DUNS number. FDA estimates that up to 100 establishments that would need to obtain this number each year. The total industry burden to obtain a DUNS number is 50 hours.

FDA estimates the total burden for this collection to be 830 hours. We have adjusted our burden estimate, which has resulted in a decrease of 93,086 hours to the currently approved burden. Based on data we reviewed from the past 3 years and projecting the number of remaining establishments that have not registered and submitted product ingredient listings, we revised the number of respondents and burden hours in this information collection.

Dated: October 17, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–23056 Filed 10–22–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2017–E–3617, FDA–2017–E–3619, and FDA–2017–E–3618]

Determination of Regulatory Review Period for Purposes of Patent Extension; NUPLAZID

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for NUPLAZID and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of applications to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human drug product.

DATES: Anyone with knowledge that any of the dates as published (see the **SUPPLEMENTARY INFORMATION** section) are incorrect may submit either electronic or written comments and ask for a redetermination by December 24, 2018. 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 22, 2019. See ''Petitions'' in the **SUPPLEMENTARY INFORMATION** section for more information.

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 Nos. FDA–2017–E–3617, FDA–2017–E–3619, and FDA–2017–E–3618 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; NUPLAZID.'' 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 § 10.20 (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: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993, 301–796–3600.

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug 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 USPTO 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 has approved for marketing the human drug product, NUPLAZID (pimavanserin tartrate). NUPLAZID is indicated for treatment of hallucinations and delusions associated with Parkinson's disease psychosis. Subsequent to this approval, the USPTO received patent term restoration applications for NUPLAZID (U.S. Patent Nos. 7,601,740; 7,659,285; and 7,732,615) from ACADIA Pharmaceuticals Inc., and the USPTO requested FDA's assistance in determining the patents' eligibility for patent term restoration. In a letter dated September 20, 2017, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of NUPLAZID represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for NUPLAZID is 4,557 days. Of this time, 4,315 days occurred during the testing phase of the regulatory review period, while 242 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 (FD&C Act) (21 U.S.C. 355(i)) became effective:* November 9, 2003. FDA has verified the applicant's claim that the date the investigational new drug application became effective was November 9, 2003.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the FD&C Act:* September 1, 2015. FDA has verified the applicant's claim that the new drug application (NDA) for NUPLAZID (NDA 207–318) was initially submitted on September 1, 2015.

3. *The date the application was approved:* April 29, 2016. FDA has verified the applicant's claim that NDA 207–318 was approved on April 29, 2016.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its applications for patent extension, this applicant seeks 1,197 days, 1,256 days, or 1,316 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination

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