Dated: August 14, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–18254 Filed 8–19–20; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–1727]

Public Meeting on the Center for Drug Evaluation and Research Standard Core Sets: Clinical Outcome Assessments and Endpoints Grant Program—Summer 2020; Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the following virtual public meeting entitled ''Public Meeting on CDER Standard Core Sets: Clinical Outcome Assessments and Endpoints Grant Program—Summer 2020.'' The purpose of the public meeting is to ensure that as standard core sets of clinical outcome assessments (COAs) are developed as part of the FDA pilot grant program, the identified concepts, COAs, and endpoints reflect what is most important to patients and relevant to regulatory and potentially other stakeholder decision making. To facilitate this, stakeholders including patients, care partners, FDA reviewers, drug developers, as well as other government and academic researchers, health care providers, health technology assessors and health payers are encouraged to attend the meeting.

DATES: The public meeting will be held on Friday, August 28, 2020, from 8:30 a.m. to 12:30 p.m. Eastern Time. Submit either electronic or written comments on this public meeting by Wednesday, October 28, 2020. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: Please note that due to the impact of the COVID–19 pandemic, all meeting participants will be joining this public meeting via an online teleconferencing platform.

FDA is establishing a docket for public comment on this meeting. The docket number is FDA–2020–N–1727. The docket will close on October 28, 2020. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before Wednesday, October 28, 2020. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of Wednesday, October 28, 2020. 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–2020–N–1727 for ''Public Meeting on CDER Standard Core Sets Clinical Outcome Assessments and Endpoints Grant Program—Summer 2020.'' 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, 240–402–7500.

- 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.govinfo.gov/content/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, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Lyna Merzoug, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6308, Silver Spring, MD 20993–0002, 301–796–6001, *CDER_StandardCoreCOAs@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

As part of our Patient Focused Drug Development (PFDD) efforts, FDA developed a pilot grant program to support the development of publicly available standard core set(s) of COAs

and their related endpoints for specific disease indications. On September 11, 2019, FDA made three awards under this grant program in the areas of: (1) Migraine, (2) acute pain in infants and young children, and (3) physical function across a range of chronic conditions.

The purpose of this public meeting is to ensure that, as these standard core sets of clinical outcome assessments are developed, the identified concepts, COAs, and endpoints reflect what is most important and relevant to patients and support regulatory and potentially other stakeholder decision making.

COAs are often endpoints in clinical trials used to support drug approval and labeling claims or other communications regarding clinical benefit. Clinical benefit is defined as a positive clinically meaningful effect of an intervention on how an individual feels, functions, or survives. FDA uses COAs primarily to determine whether a drug has been shown to provide clinical benefit to patients. The severity of side effects or treatment burden can also be measured by COAs.

A standard core set of COAs can include different types of COAs such as patient-reported outcome (PRO), clinician-reported outcome (ClinRO), observer-reported outcome (ObsRO), and performance outcome (PerfO) instruments and their related endpoints. These sets should assess a minimum list of impacts that matter most to patients, are likely to demonstrate change (including differences in trial arms related to disease burden, treatment burden, and if applicable, physical function), and should be assessed during a clinical trial. A standard core set might be relevant across several disease populations or subgroups or be focused on attributes of a specific disease.

II. Topics for Discussion at the Public Meeting

This meeting will provide an opportunity for grantees funded as part of the FDA Standard Core COAs and Endpoints Pilot Grant Program to share their progress on the standard core COA sets and to receive feedback from stakeholders.

III. Participating in the Public Meeting

Registration: Persons interested in attending this public meeting via webcast must register online at *https://www.eventbrite.com/e/public-meeting-on-cder-standard-core-sets-clinical-outcome-assessments-registration-108754210772* by August 28, 2020, at 12 p.m. Eastern Daylight Time. Registration is free and based on availability, with priority given to early registrants. FDA may limit the number of participants from each organization. Registrants will receive confirmation when they have been accepted. Webcast information will be provided upon completion of registration. Closed captioning will be provided.

Streaming webcast of the public meeting: This public meeting will be streamed via a webcast only. To register for the webcast, please visit *https://www.eventbrite.com/e/public-meeting-on-cder-standard-core-sets-clinical-outcome-assessments-registration-108754210772.* The webcast can be accessed via: *http://fda.yorkcast.com/webcast/Play/50353b66f81e463ea7c0df6e31e225a11d.* Click on the link and hit the ''play'' button and it will start. The webcast link will be activated 30 minutes prior to the start of the meeting.

Transcripts: Please be advised that as soon as a transcript of the public meeting is available, it will be accessible on the meeting website at *https://www.fda.gov/drugs/news-events-human-drugs/public-meeting-cder-standard-core-sets-clinical-outcome-assessments-and-endpoints-grant-program-0.*

Dated: August 12, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–18238 Filed 8–19–20; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–E–1945]

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

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 OXERVATE and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application 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 biological product.

DATES: Anyone with knowledge that any of the dates as published (see **SUPPLEMENTARY INFORMATION**) are incorrect may submit either electronic or written comments and ask for a redetermination by October 19, 2020. 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 February 16, 2021. 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 October 19, 2020. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of October 19, 2020. 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'').

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