statement that the nominated substance meets the definition of bulk drug substance.

2. Description of the Bulk Drug Substance:

(a) Chemical name(s);

(b) common name(s);

(c) chemical grade (*e.g.,* USP–NF, ACS, etc.);

(d) description of the strength, stability, purity; and

(e) how the bulk drug substance is supplied (*e.g.,* powder, liquid).

3. Description of the Animal Drugs That Will be Compounded With the Bulk Drug Substance:

(a) dosage form(s) into which the bulk drug substance will be compounded (*e.g.,* capsule, tablet, suspension);

(b) strength(s) of the compounded drug(s); and

(c) intended route(s) of administration of the compounded drug(s).

4. Information Requested for FDA to Evaluate Bulk Drug Substances for Inclusion on the List:

(a) the species and condition(s) that the drug to be compounded with the nominated bulk drug substance is intended to treat;

(b) a bibliography of scientific literature containing safety and effectiveness data for the drug compounded using the nominated substance;

(c) a list of animal drugs, if any, that are FDA-approved, conditionally approved, or indexed for the condition(s) in the species that the drug compounded with the nominated substance is intended to address;

(d) if there are marketed FDA-approved, conditionally approved, or indexed drugs that address the same condition(s) in the same species, an explanation, supported by relevant scientific literature or other evidence, of why a compounded drug is necessary (*e.g.,* why the FDA-approved, conditionally approved, or indexed drug is not suitable for a particular animal population);

(e) confirmation, using supporting evidence, that there are no marketed FDA-approved animal or human drugs that could be prescribed in an extralabel manner under section 512(a)(4) and (a)(5) of the FD&C Act and 21 CFR part 530 to treat the condition(s) in the species that the drug compounded with the nominated substance is intended to address;

(f) If the bulk drug substance is an active ingredient in a marketed FDA-approved, conditionally approved, or indexed animal or human drug, an explanation, supported by appropriate scientific data or information, of why the animal drug cannot be compounded from the marketed FDA-approved, conditionally approved, or indexed animal or human drug.

(g) An explanation, supported by relevant scientific literature or other evidence, of why the animal drug to be compounded with the nominated bulk drug substance must be available to the veterinarian for immediate treatment to avoid animal suffering or death. Nominations should include specific information documenting that animal suffering or death will result if treatment is delayed until a compounded animal drug can be obtained pursuant to a prescription for an individually identified animal; and

(h) A description of any human user or animal safety concerns associated with use of the nominated bulk drug substance or finished compounded drug for the condition(s) in the species that the compounded drug is intended to address. If there are concerns, an explanation, supported by scientific literature or other evidence, of why the concerns should not preclude inclusion of that bulk drug substance on the List.

(i) For compounded drugs intended for use as antidotes to treat toxicoses in food-producing animals, relevant scientific literature or other evidence that demonstrates that the prescribing veterinarian has a basis for determining appropriate withdrawal, withholding, or discard time(s) for meat, milk, eggs, or any food which might be derived from the treated animal(s).

Dated: November 14, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–25140 Filed 11–19–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–5157]

2019 Public Meeting on Center for Drug Evaluation and Research Standard Core Sets: Clinical Outcome Assessments and Endpoints Grant Program; 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 public meeting entitled ''2019 Public Meeting on CDER Standard Core Sets: Clinical Outcome Assessments and Endpoints Grant Program.'' The purpose of the public meeting is to help 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, 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 December 5, 2019, from 8:30 a.m. to 12 p.m. Submit either electronic or written comments on this public meeting by January 6, 2020. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public meeting will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993. Entrance for the public meeting 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 January 6, 2020. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of January 6, 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–2019–N–5157 for ''2019 Public Meeting on CDER Standard Core Sets: Clinical Outcome Assessments and Endpoints Grant 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: Meena Savani, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6306, Silver Spring, MD 20993–0002, 240–402–1348, *CDER_StandardCoreCOAs@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

As part of our Patient Focused Drug Development 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, the 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. 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 development plans for the standard core COA sets and to receive feedback from stakeholders. FDA will provide an introduction and discuss plans for the pilot grant program including future public meetings.

III. Participating in the Public Meeting

Registration: Persons interested in attending this public meeting in person or via webcast must register online at *https://standard_core_coa_grant_program.eventbrite.com* by December 2, 2019, at 11:59 p.m. Eastern Time. Registration is free and based on space availability, with priority given to early registrants. Early registration for in person attendance 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 meeting/public workshop will be provided beginning at 8 a.m.

If you need special accommodations due to a disability, please contact Meena Savani no later than November 29, 2019.

Streaming Webcast of the Public Meeting: This public meeting will also be webcast. Webcast information will be provided upon completion of registration.

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 website addresses in this document, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

Transcripts: Please be advised that as soon as a transcript of the public meeting 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 *https://www.fda.gov/drugs/news-events-human-drugs/public-meeting-cder-standard-core-sets-clinical-outcome-assessments-and-endpoints-grant-program.*

Dated: November 15, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–25160 Filed 11–19–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–4533]

Compounding Animal Drugs From Bulk Drug Substances; Draft 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 draft guidance for industry (GFI) #256 entitled ''Compounding Animal Drugs from Bulk Drug Substances.'' The draft guidance, if finalized, will describe FDA's current thinking about compounding animal drugs from bulk drug substances. FDA has generally exercised enforcement discretion with regard to animal drug compounding from bulk drug substances under certain circumstances when no other medically appropriate treatment options exist. This draft guidance, a continuation of this practice, is intended to provide additional information and clarity to veterinarians and pharmacists about FDA's current thinking with respect to animal drug compounding from bulk drug substances. FDA previously published draft guidance on this issue for public comment in May 2015 (Draft GFI #230, ''Compounding Animal Drugs from Bulk Drug Substances''). We received over 150 comments on that draft guidance. Based on those comments, we decided to withdraw the May 2015 draft guidance and publish this draft guidance for public comment.

DATES: Submit either electronic or written comments on the draft guidance by February 18, 2020 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance. Submit either electronic or written comments on the proposed collection of information by February 18, 2020.

ADDRESSES: You may submit comments on any guidance at any time 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–2018–D–4533 for ''Compounding Animal Drugs From Bulk Drug Substances.'' 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 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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the guidance to the Policy and Regulations Staff (HFV–6), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: *With regard to this draft guidance:* Eric