in the body of your comments and you must identify the 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: Moon Hee V. Choi, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, Fax: 301–847–8533, email: *AADPAC@fda.hhs.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the FDA's website at *https://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: The committee will be asked to discuss new drug application (NDA) 210730, for oliceridine 1 milligram/milliliter injection, submitted by Trevena, Inc., for the management of moderate-to-severe acute pain in adult patients for whom an intravenous opioid is warranted. The committee will also be asked to discuss the efficacy and safety data and benefit-risk considerations.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's website after the meeting. Background material is available at *https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. All electronic and written submissions submitted to the Docket (see **ADDRESSES**) on or before October 3, 2018, will be provided to the committee. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before September 25, 2018. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by September 26, 2018.

Persons attending FDA's advisory committee meetings are advised that FDA is not responsible for providing access to electrical outlets.

For press inquiries, please contact the Office of Media Affairs at *fdaoma@fda.hhs.gov* or 301–796–4540.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Moon Hee V. Choi (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: September 4, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–19667 Filed 9–10–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–0286]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry: Formal Meetings Between the Food and Drug Administration and Biosimilar Biological Product Sponsors or Applicants

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by October 11, 2018.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0802. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Guidance for Industry: Formal Meetings between the Food and Drug Administration and Biosimilar Biological Product Sponsors or Applicants.

OMB Control No. 0910–0802—Extension.

This information collection supports the above captioned Agency guidance. The Biologics Price Competition and Innovation Act of 2009, the Biosimilar User Fee Act of 2012, and the recent passage of the Biosimilar User Fee Amendments of 2017 (BsUFA II) under Title IV of the FDA Reauthorization Act of 2017, authorize user fees for biosimilar biological products. FDA has committed to meeting certain performance goals in connection with the reauthorized biosimilar user fee program. To provide recommendations to industry on formal meetings between FDA and sponsors or applicants relating to the development and review of biosimilar biological products regulated by the Center for Drug Evaluation and Research (CDER) or the Center for Biologics Evaluation and Research (CBER) and assist sponsors and applicants in generating and submitting meeting requests and the associated meeting packages to FDA for biosimilar biological products, we developed guidance for industry entitled ''Formal Meetings Between FDA and Biosimilar Biological Products Sponsors or Applicants.'' The guidance describes our current thinking on how we intend to interpret and apply certain provisions of BsUFA II and provides information on specific performance goals for the management of meetings associated with the development and review of biosimilar biological products. The guidance document includes two types of information collection: (1) The submission of a meeting request containing certain information and (2) the submission of the information package(s) that accompany the meeting request.

A. Request for a Meeting

Under the guidance, a sponsor or applicant interested in meeting with CDER or CBER should submit a meeting request to the sponsor's or applicant's application (*i.e.,* investigational new drug application, biologics license application). If there is no application, a sponsor or applicant should submit the request to either the appropriate CDER division director, with a copy sent to the division's chief of project management staff, or to the division director of the appropriate product office within CBER, but only after first contacting the appropriate review division or the Biosimilars Program staff, CDER, Office of New Drugs to determine to whom the request should be directed, how it should be submitted, and the appropriate format for the request and to arrange for confirmation of receipt of the request. Under the guidance, FDA requests that sponsors and applicants incorporate certain information in the meeting request, including:

1. Product name,
2. application number (if applicable), proposed proper name or proper name (post licensure),
4. structure,
5. reference product name,
6. proposed indication(s) or context of product development,
7. meeting type being requested (the rationale for requesting the meeting type should be included),
8. a brief statement of the purpose of the meeting, including a brief background of the issues underlying the agenda. It can also include a brief summary of completed or planned studies and clinical trials or data the sponsor or applicant intends to discuss at the meeting, the general nature of the critical questions to be asked, and where the meeting fits in the overall development plans.
9. a list of specific objectives/outcomes expected from the meeting,
10. a proposed agenda, including times required for each agenda item,
11. a list of questions grouped by discipline and a brief explanation of the context and purpose of each question,
12. a list of all individuals with their titles and affiliations who will attend the requested meeting from the requestor's organization and consultants,
13. a list of FDA staff, if known, or disciplines asked to participate in the requested meeting,
14. suggested dates and times for the meeting, and
15. the proposed format of the meeting (*i.e.,* face to face meeting, teleconference, or videoconference).

This information will be used by FDA to determine the utility of the meeting, to identify FDA staff necessary to discuss proposed agenda items, and to schedule the meeting.

B. Information Package

FDA requests that a sponsor or applicant submit a meeting package to the appropriate review division with the meeting request. FDA recommends that the information packages generally include:

1. Product name and application number (if applicable),
2. proposed proper name or proper name (post licensure),
3. structure,
4. reference product name,
5. proposed indication(s) or context of product development,
6. dosage form, route of administration, dosing regimen (frequency and duration), and presentation(s),
7. a list of all sponsor's or applicant's attendees and consultants with their titles and affiliations who will attend the requested meeting,
8. background that includes a brief history of the development program and the status of product development (*e.g.,* chemistry, manufacturing, and controls; nonclinical; and clinical, including any development outside the United States, as applicable),
9. a brief statement summarizing the purpose of the meeting,
10. the proposed agenda,
11. a list of questions for discussion grouped by discipline and with a brief summary for each question to explain the need or context for the question, and
12. data to support discussion organized by discipline and question.

The purpose of the meeting package is to provide FDA staff the opportunity to adequately prepare for the meeting, including the review of relevant data concerning the product.

Description of Respondents: A sponsor or applicant for a biosimilar biological product who requests a formal meeting with FDA regarding the development and review of a biosimilar biological product.

In the **Federal Register** of June 18, 2018 (83 FR 28234), we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

GFI: Formal meetings between FDA and biosimilar biological product sponsors or applicants	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
CDER Meeting Requests	36	2.5	89	15	1,335
CBER Meeting Requests	2	1	2	15	30
CDER Information Packages	29	2.2	64	30	1,920

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

GFI: Formal meetings between FDA and biosimilar biological product sponsors or applicants	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
CBER Information Packages	2	2	4	30	120
Total					3,405

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Since last OMB approval, there has been an increase in meeting requests with CDER and a corresponding increase in the number of information packages. Accordingly, we have adjusted our estimate upward by six respondents to CDER meeting requests. We attribute this change to an increase in biosimilar product development.

Dated: September 4, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–19674 Filed 9–10–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–3151]

Postapproval Changes to 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 a draft guidance for industry entitled ''Postapproval Changes to Drug Substances.'' This draft guidance provides recommendations to holders of approved new drug applications, abbreviated new drug applications, new animal drug applications, abbreviated new animal drug applications, and holders of drug master files and veterinary master files who may want to make a change to the drug substance manufacturing process during the drug product application postapproval period. The draft guidance applies to synthetic drug substances and the synthetic steps involved in the preparation of semisynthetic drug substances. The draft guidance covers facility, scale, and equipment changes associated with all steps of drug substance manufacturing; specification changes to starting materials, raw materials, intermediates, and the unfinished and final drug substance; synthetic manufacturing process changes; changes in the source of drug substance; and change to container closure system of the drug substance.

DATES: Submit either electronic or written comments on the draft guidance by November 13, 2018 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

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–3151 for ''Postapproval Changes to 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