TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section/environmental impact considerations	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
25.15(a) and (d) (to cover CEs under 25.32(i))	47	1	47	8	376
25.15(a) and (d) (to cover CEs under 25.32(o))	1	1	1	8	8
25.15(a) and (d) (to cover CEs under 25.32 (q))	3	1	3	8	24
25.40(a) and (c) EAs	57	1	57	180	10,260
Total					10,668

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

The estimates for respondents and numbers of responses are based on the annualized numbers of petitions and notifications qualifying for CEs listed under § 25.32(i) and (q) (21 CFR 25.32(i) and (q)) that we have received in the past 3 years. To avoid counting the burden attributed to § 25.32(o) as zero, we have estimated the burden for this categorical exclusion at one respondent making one submission a year for a total of one annual submission. The burden for submitting a categorical exclusion is captured under 21 CFR 25.15(a) and (d).

To calculate the estimate for the hours per response values, we assumed that the information requested in this guidance for each of these three categorical exclusions is readily available to the submitter. For the information requested for the exclusion in § 25.32(i), we expect that the submitter will need to gather information from appropriate persons in the submitter's company and to prepare this information for attachment to the claim for categorical exclusion. We believe that this effort should take no longer than 8 hours per submission. For the information requested for the categorical exclusions in § 25.32(o) and (q), the submitters will copy existing documentation and attach it to the claim for categorical exclusion. We believe that collecting this information should take no longer than 8 hours per submission.

For the information requested for the environmental assessments in 21 CFR 25.40(a) and (c), we believe that submitters will submit an average of 57 environmental assessments annually. We estimate that each submitter will prepare an EA within 3 weeks (120 hours) and revise the EA based on Agency comments (between 40 to 60 hours), for a total preparation time of 180 hours.

Based on a current review of the information collection, we have made no adjustments to the currently approved estimate.

Dated: November 14, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–25370 Filed 11–21–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0129]

Agency Information Collection Activities; Proposed Additional Collection; Comment Request; General Licensing Provisions; Section 351(k) Biosimilar Applications; Formal Meetings Between the Food and Drug Administration and Sponsors or Applicants

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) 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/revision of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on ''General Licensing Provisions; Section 351(k) Biosimilar Applications; Formal Meetings Between the FDA and Sponsors or Applicants.''

DATES: Submit either electronic or written comments on the collection of information by January 21, 2020.

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 January 21, 2020. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of January 21, 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–2012–N–0129 for ''General Licensing Provisions; Section 351(k) Biosimilar Applications; Formal Meetings Between the FDA and Sponsors or Applicants.'' 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: 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: Under the PRA (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following additional collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

General Licensing Provisions; Section 351(k) Biosimilar Applications; Formal Meetings Between the FDA and Sponsors or Applicants

OMB Control Number 0910–0719—Revision

The Biologics Price Competition and Innovation Act of 2009 (BPCI Act) amended the Public Health Service Act (PHS Act) and other statutes to create an abbreviated licensure pathway for biological products shown to be biosimilar to, or interchangeable with an FDA-licensed reference product. Section 351(k) of the PHS Act (42 U.S.C. 262(k)), added by the BPCI Act, sets forth the requirements for an application for a proposed biosimilar product and an application or a supplement for a proposed interchangeable product. In addition to the submission requirements associated with a 351(k) application for a proposed biosimilar or interchangeable biological product, FDA is committed to meeting certain performance goals in connection with the FDA Reauthorization Act of 2017 (FDARA) and its Biosimilar User Fee (BsUFA) program. These performance goals are found in the commitment letter entitled, ''Biosimilar Biological Product Reauthorization Performance Goals and Procedures Fiscal Years 2018 Through 2022'' available from our website at: *https://www.fda.gov/media/100573/download.* Included in the performance goals is information collection associated with meetings and other communications with FDA, and we are therefore revising the information collection to cover these provisions. Also consistent with the commitment letter, we have developed the associated guidance document entitled ''Formal Meetings Between the FDA and Sponsors or Applicants of BsUFA Products.'' The guidance document discusses the BsUFA meeting management goal provisions set forth in the commitment letter and provides instruction and recommendations to respondents 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). The guidance is intended to assist sponsors or applicants in generating and submitting meeting requests and associated meeting packages to FDA for biosimilar biological products. A formal meeting includes any meeting that is requested by a sponsor or applicant following the procedures provided in the guidance and includes meetings conducted in any format (*i.e.,* face to face, teleconference/videoconference, written response only (WRO)). The guidance, available from our website at *https://www.fda.gov/media/113913/download,* includes the following recommendations pertaining to BsUFA meeting requests and information packages:

A. Request for a Meeting

We recommend that a sponsor or applicant interested in meeting with CDER or CBER submit a meeting request electronically 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. We recommend the following information be included in the meeting request:

1. Application number (if previously assigned),
2. development-phase code name of the product (if prelicensure),
3. proper name (if post licensure),
4. structure (if applicable),
5. proper and proprietary names of the reference product,
6. proposed indication(s) or context of product development,
7. pediatric study plans, if applicable,
8. human factors engineering plan, if applicable,
9. combination product information (*e.g.,* constituent parts, including details of the device constituent part, intended packaging, planned human factors studies), if applicable,
10. meeting type being requested (the rationale for requesting the meeting type should be included),
11. proposed format of the meeting (face to face, tele-conference/video-conference/WRO),
12. 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.
13. a list of specific objectives/outcomes expected from the meeting,
14. a proposed agenda, including times required for each agenda item,
15. a list of questions grouped by discipline and a brief explanation of the context and purpose of each question,
16. a list of all individuals with their titles and affiliations who will attend the requested meeting from the requestor's organization and any consultants and interpreters,
17. a list of FDA staff, if known, or disciplines asked to participate in the requested meeting, and
18. suggested dates and times for the meeting.

We use the information 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

We recommend that a sponsor or applicant submit a meeting package to the appropriate review division with the meeting request and that the following information be included in the package:

1. Application number (if previously assigned),
2. development-phase code name of product (if pre-licensure) or proper name (if post-licensure),
3. structure (if applicable),
4. proprietary and proper names of the reference product,
5. proposed indication(s) or context of product development,
6. dosage form, route of administration, dosing regimen (frequency and duration), and presentation(s),
7. pediatric study plans, if applicable,
8. human factors engineering plan, if applicable,
9. combination product information, if applicable,
10. a list of all individuals with their titles and affiliations who will attend the requested meeting from the requestor's organization and any consultants and interpreters,
11. 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),
12. a brief statement summarizing the purpose of the meeting,
13. the proposed agenda, and
14. 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 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.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

BsUFA information collection	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
CDER Information Packages	29	2.2	64	30	1,920
CBER Meeting Requests	2	1	2	15	30
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 review of the information collection we have increased our burden estimate by 95 annual responses and 1,965 annual hours. This adjustment corresponds with an increase in submissions received by the Agency over the past 3 years.

Dated: November 13, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–25328 Filed 11–21–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–D–0369]

Product-Specific Guidances; Draft and Revised Draft Guidances for Industry; Availability

AGENCY: Food and Drug Administration, HHS.