TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (hours)	Total hours
Request for discontinuation from BPD program.	2	1	2	1	2
Request to move products to discontinued section of the biosimilar list.	5	1	5	0.5 (30 minutes)	2.5
Small business waiver of the BsUFA application fee.	1	1	1	16	16
Small business waiver reconsiderations	1	1	1	24	24
Small business waiver appeals	1	1	1	12	12
Annual Fee Determination Survey	35	1	35	1	35
Annual BsUFA fees correspondence	35	1	35	2	70
Total					161.5

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

This guidance also refers to previously approved collections of information found in FDA forms developed to support its user fee program. Specifically, the guidance refers to Form FDA 3792; Forms FDA 3913 and 3914; and Form FDA 3971, which have been approved under OMB control numbers 0910–0718, 0910–0719, 0910–0805, and 0910–0693, respectively. The guidance also refers to previously approved collections of information found in FDA regulations. The collections of information in 21 CFR part 312 are currently approved under OMB control number 0910–0014; the collections of information regarding new drug applications under the FD&C Act are approved under OMB control number 0910–0001; and biologics license applications under sections 351(a) or 351(k) of the Public Health Service Act are approved under OMB control numbers 0910–0338 and 0910–0719, respectively.

This final guidance contains information collection provisions subject to review by OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). Except for the provisions listed in table 1, the information collections already have been approved. The applicable provisions are shaded in the guidance to identify those for which OMB approval has not yet been obtained. When approval of these provisions has been received, FDA will provide notice. BsUFA II provides the statutory authority to collect user fees from FY 2018 through FY 2022. Consistent with the statutory requirements of BsUFA II, FDA is issuing this guidance to facilitate understanding and enhancing implementation of the policies and processes in the assessment of biosimilar user fees in upcoming fiscal years.

III. Electronic Access

Persons with access to the internet may obtain the guidance at either *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm*, *https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm*, or *https://www.regulations.gov*.

Dated: June 26, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–14049 Filed 6–28–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–1967]

Agency Information Collection Activities; Proposed Collection; Comment Request; Biosimilars User Fee Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the 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 of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection supporting the Agency's Biosimilars User Fee Program.

DATES: Submit either electronic or written comments on the collection of information by August 28, 2018.

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 August 28, 2018. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of August 28, 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 No. FDA–2018–N–1967 for ''Biosimilars User Fee 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: 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. 3501–3520), 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 for members of the public when submitting reports, keeping records, or providing 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 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.

Biosimilars User Fee Program

OMB Control Number 0910–0718—Extension

This information collection supports FDA's Biosimilars User Fee Program. The Biologics Price Competition and Innovation Act of 2009 (BPCI Act), amended the Public Health Service Act (PHS Act) by adding section 351(k) (42 U.S.C. 262(k)) to create an abbreviated approval pathway for biological products shown to be biosimilar to or interchangeable with an FDA-licensed reference biological product. This allows a company to apply for licensure of a biosimilar or interchangeable biological product (351(k) application). The BPCI Act also amended section 735 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379g) to include 351(k) applications as a type of application under ''human drug application'' for the purposes of the prescription drug user fee provisions.

The Biosimilar User Fee Act of 2012 (BsUFA) authorized FDA to assess and collect user fees for certain activities in connection with biosimilar biological product development (BPD). BsUFA was reauthorized for an additional 5 years in August 2017 (BsUFA II). FDA's biosimilar biological product user fee program requires FDA to assess and collect user fees for certain meetings concerning biosimilar BPD (BPD meetings), investigational new drug applications (INDs) intended to support a biosimilar biological product application, and biosimilar biologic license applications (BLAs).

Form FDA 3792, entitled ''Biosimilars User Fee Cover Sheet'', is submitted by each new BPD entrant (identified via a new meeting request or IND submission) and new BLAs. Form FDA 3792 requests the minimum necessary information to identify the request and determine the amount of the fee to be assessed, and to account for and track user fees. The form provides a cross-reference of the fees submitted for an activity with the actual submission or activity by using a unique number tracking system. The information collected is used by FDA's Center for Drug Evaluation and Research and Center for Biologics Evaluation and Research to initiate the administrative screening of biosimilar biological product INDs, and BLAs, and to account for and track user fees associated with BPD meetings.

In addition to the Biosimilars User Fee Cover Sheet, the information collection includes an annual survey of all BsUFA II participants designed to provide information to FDA of anticipated BsUFA II activity in the upcoming fiscal year. This information helps FDA set appropriate annual BsUFA II fees.

FDA has also developed the draft guidance entitled, ''Assessing User Fees Under the Biosimilar User Fee Amendments of 2017'' to assist industry in understanding when fees are incurred and the process by which applicants can

submit payments. The draft guidance also explains how respondents can request discontinuation from the BPD program as well as how respondents can request to move products to the discontinued section of the biosimilar list. Finally, the draft guidance provides information on the consequences of failing to pay BsUFA II fees, as well as processes for submitting reconsideration and appeal requests. The draft guidance is available on our website at *https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM584984.pdf.*

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Information collection title	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (hours)	Total hours
Biosimilar User Fee Cover Sheet; Form FDA 3792	35	1	35	0.5 (30 minutes)	17.5
Annual Survey	35	1	35	1	35
Request for discontinuation from BPD program	2	1	2	1	2
Request to move products to discontinued section of the biosimilar list.	5	1	5	0.5 (30 minutes)	2.5
Total					57

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

We have increased our estimate by an additional 15 respondents since last OMB approval of the information collection. This estimated increase is based on our expectation that participation in the BPD program will continue to grow, consistent with our experience since establishment of the information collection in 2012.

Dated: June 26, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–14057 Filed 6–28–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–1903]

Modernizing Pharmaceutical Quality Systems; Studying Quality Metrics and Quality Culture; Quality Metrics Feedback Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) Center for Drug Evaluation and Research (CDER) is announcing two new efforts to gather feedback on the use of quality metrics to modernize pharmaceutical quality systems and advance innovation based on stakeholder feedback. These efforts include Type C formal meeting requests and pre-abbreviated new drug application (pre-ANDA) meeting requests, and a pilot study to gain feedback from those establishments for which Type C formal meetings or pre-ANDA meetings do not apply (*e.g.,* active pharmaceutical ingredients (API) establishments, contract manufacturing organizations, over-the-counter (OTC) monograph products establishments, or marketed unapproved finished drug products establishments). Participation in either of these efforts is voluntary and the programs are intended to foster the joint efforts of FDA and stakeholders to further develop an FDA Quality Metrics Program. The FDA Quality Metrics Program aims to evaluate a new approach for regulatory oversight of pharmaceutical products through the collection of certain quality information developed and maintained in the course of manufacturing drugs under current good manufacturing practices. FDA intends to use quality metrics data to further develop the Agency's risk-based inspection scheduling (*e.g.,* decreased surveillance inspection frequency for certain establishments) to improve the efficiency and effectiveness of establishment inspections, improve FDA's evaluation of drug manufacturing and control operations, and identify situations in which there may be a risk for drug supply disruption.

DATES: Submit a written request to participate in the program by July 29, 2019. See sections II and III.B of this notice for information to include in such requests. FDA will start accepting requests beginning July 30, 2018.

FOR FURTHER INFORMATION CONTACT: Tara Gooen Bizjak, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2109, Silver Spring, MD 20993, 301–796–3257, *Tara.Gooen@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

More than a decade ago, FDA launched an initiative to encourage the implementation of a modern, risk-based pharmaceutical quality assessment system. As part of this initiative, and in recognition of the increasing complexity of pharmaceutical manufacturing, FDA developed a 21st century vision for manufacturing and quality with input from academia and industry. The desired state was described as follows: ''A maximally efficient, agile, flexible pharmaceutical manufacturing sector that reliably produces high-quality drug products without extensive regulatory oversight.'' [1]

There has been significant progress toward this vision in the intervening years, as evidenced by programs and guidance from FDA around major initiatives such as pharmaceutical development and quality by design, quality risk management and pharmaceutical quality systems, process validation, and process analytical technology, among other initiatives. These programs and guidances are intended to promote effective use of the most current pharmaceutical science and engineering principles and knowledge throughout the life cycle of a product.

While much progress has been made, we have not fully realized our 21st century vision for manufacturing and quality. Rather than focusing on use of science- and risk-based principles as described in current good manufacturing practices, many establishments continue to focus on minimum requirements (*e.g.,* check-box approach). Recalls and drug shortages, which are often indications of serious product quality defects caused by drug

[1] See ''FDA Pharmaceutical Quality Oversight: One Quality Voice'' at *https://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/UCM442666.pdf.*