DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: *infocollection@acf.hhs.gov.*

OMB Comment:

OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Email: *OIRA_SUBMISSION@OMB.EOP.GOV*, Attn: Desk Officer for the Administration for Children and Families.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2015–24270 Filed 9–23–15; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–3155]

Interim Results of Study of Workload Volume and Full Costs Associated With Review of Biosimilar Biological Product Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the interim results of a study of the workload volume and full costs associated with the process for the review of biosimilar biological product applications (interim report). This study was conducted by an independent consulting firm, and it fulfills FDA's statutory requirement under the first authorization of the Biosimilar User Fee Act of 2012 (BsUFA), which enables FDA to collect user fees for the review of biosimilar biological applications for fiscal years 2013 to 2017. This notice solicits comments on the interim report.

DATES: The interim report will be released on September 24, 2015, and will be available at *http://www.fda.gov/downloads/ForIndustry/UserFees/BiosimilarUserFeeActBsUFA/UCM459686.pdf.* Submit either electronic or written comments on the interim report by October 26, 2015.

ADDRESSES: Submit electronic comments on the interim report to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Mark Ascione, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1150, Silver Spring, MD 20993–0002, 301–796–7652, FAX: 301–847–8443.

SUPPLEMENTARY INFORMATION:

I. Background

The Patient Protection and Affordable Care Act of 2010 (Pub. L. 111–148) amended the Public Health Service Act to create an abbreviated licensure pathway for biological products that are demonstrated to be ''biosimilar'' to or ''interchangeable'' with an FDA-licensed biological product. The Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by BsUFA (Title IV of the Food and Drug Administration Safety and Innovation Act, Pub. L. 112–144), authorizes FDA to assess and collect fees for biosimilar biological products from October 2012 through September 2017. FDA uses these fees to expedite the review process for biosimilar biological products. Biosimilar biological products represent an important public health benefit, with the potential to offer life-saving or life-altering benefits at reduced cost to the patient. BsUFA facilitates the development of safe and effective biosimilar products for the American public.

As part of BsUFA, FDA is required to contract with an independent accounting or consulting firm to study the workload volume and full costs associated with the process for the review of biosimilar biological product applications. This notice solicits comments on the interim report, and the final report is due no later than September 30, 2016. The interim report is described in section 744I(d) of the FD&C Act (21 U.S.C. 379j–53(d)) (*http://uscode.house.gov/view.xhtml?req=granuleid:U.S.C.-prelim-title21-section379j-53&num=0&edition=prelim*), as amended by the Food and Drug Administration Safety and Innovation Act enacted in 2012.

II. Comments

FDA is issuing this notice to request public comment on the interim report. Interested persons may submit either electronic comments to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

III. Electronic Access

The interim report can be accessed at *http://www.fda.gov/downloads/ForIndustry/UserFees/BiosimilarUserFeeActBsUFA/UCM459686.pdf.*

Dated: September 18, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–24227 Filed 9–23–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–1837]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Electronic User Fee Payment Request Forms

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) 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 26, 2015.

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 title Electronic User Fee Payment Request Forms. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455

Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *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.

Electronic User Fee Payment Request Forms—(OMB Control Number 0910—NEW)

The Government Paperwork Elimination Act (GPEA) (Pub. L. 105–277, title XVII), was signed into law on October 21, 1998. GPEA requires Federal Agencies to allow individuals or entities that deal with the Agencies the option to submit information or transact business with the Agency electronically, when practicable, and to maintain records electronically, when practicable. Its goal is to encourage Agencies to incorporate technologically improved respondent reporting, as this process typically lowers the burden on the respondent. GPEA allows FDA to collect information relating to a user fee payment refund request and transfer request.

Form FDA 3913, User Fee Payment Refund Request, is designed to provide the minimum necessary information for FDA to review and process a user fee payment refund. The information collected includes the organization, contact, and payment information. The information is used to determine the reason for the refund, the refund amount, and who to contact if there are any questions regarding the refund request. A submission of the User Fee Payment Refund Request form does not guarantee that a refund will be issued. FDA estimates an average of 0.40 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed, and complete and review the collection of information. The estimated hours are based on past FDA experience with the user fee payment refund request.

In fiscal year 2014, approximately 1,741 user fee refunds were processed for cover sheets and invoices including 27 for Animal Drug User Fee Act, 5 for Animal Generic Drug User Fee Act, 3 for Biosimilar Drug User Fee Act, 1 for a Center for Tobacco Products Civil Money Penalties, 216 for Export Certificate Program, 79 for Freedom of Information Act requests, 523 for Generic Drug User Fee Amendments, 539 for Medical Device User Fee Amendments, 266 for Mammography inspection fee, 81 for Prescription Drug User Fee Act, and 1 for a Tobacco product fee.

Form FDA 3914, User Fee Payment Transfer Request, is designed to provide the minimum necessary information for FDA to review and process a user fee payment transfer request. The information collected includes payment and organization information. The information is used to determine the reason for the transfer, how the transfer should be performed, and who to contact if there are any questions regarding the transfer request. A submission of the User Fee Payment Transfer Request form does not guarantee that a transfer will be performed. FDA estimates an average of 0.25 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed, and complete and review the collection of information. FDA estimated hours are based on past FDA experience with the user fee payment transfer request.

In fiscal year 2014, approximately 1,291 user fee payment transfers were processed for cover sheets and invoices including 21 for Animal Drug User Fee Act, 2 for Animal Generic Drug User Fee Act, 544 for Generic Drug User Fee Amendments, 627 for Medical Device User Fee Amendments, and 97 for Prescription Drug User Fee Act.

Respondents for the electronic request forms include domestic and foreign firms (including pharmaceutical, medical device, etc.). Specifically, refund request forms target respondents who submitted a duplicate payment or overpayment for a user fee cover sheet or invoice. Respondents may also include firms that withdrew an application or submission. Transfer request forms target respondents who submitted payment for a user fee cover sheet or invoice and need that payment to be re-applied to another cover sheet or invoice (transfer of funds).

The electronic user fee payment request forms will streamline the refund and transfer processes, facilitate processing, and improve the tracking of requests. The burden for this collection of information is the same for all customers (small and large organizations). The information being requested or required has been held to the absolute minimum required for the intended use of the data. Customers will be able to request a user fee payment refund and transfer online at *http://www.fda.gov/forindustry/userfees/default.htm.* This electronic submission is intended to reduce the burden for customers to submit a user fee payment refund and transfer request.

In the **Federal Register** of June 26, 2015 (80 FR 36822), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
User Fee Payment Refund Request—Form FDA 3913.	1,700	1	1,700	0.40 (24 minutes)	680
User Fee Payment Transfer Request—Form FDA 3914.	1,700	1	1,700	0.25 (15 minutes)	425
Total	.....	.....	.....	.....	1105

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

Dated: September 17, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–24228 Filed 9–23–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–1939]

Use of Investigational Tobacco Products; Draft Guidance for Industry and Investigators; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry and investigators entitled ''Use of Investigational Tobacco Products.'' The draft guidance, when finalized, will describe FDA's current thinking regarding the definition of ''investigational tobacco product'' and will discuss the kind of information FDA intends to consider in making enforcement decisions regarding the use of investigational tobacco products until regulations governing the use of investigational tobacco products become effective or FDA provides written notice of its intent to change its enforcement policy.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), 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 draft by November 23, 2015. Submit either electronic or written comments on the proposed collection of information by November 23, 2015.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Center for Tobacco Products, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the draft guidance may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance, including comments on the proposed collection of information, to *http://www.regulations.gov.* Submit written comments on the draft guidance, including comments on the proposed collection of information, to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

With regard to the draft guidance: Laura Rich or Deirdre Jurand, Center for Tobacco Products, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 1–877–287–1373, *CTPRegulations@fda.hhs.gov*, *laura.rich@fda.hhs.gov*, or *Deirdre.Jurand@fda.hhs.gov.*

With regard to the proposed collection of information: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry and investigators entitled ''Use of Investigational Tobacco Products.'' This draft guidance, when finalized, will describe FDA's current thinking regarding the definition of ''investigational tobacco product'' and will discuss the kind of information FDA intends to consider in making enforcement decisions regarding the use of investigational tobacco products until regulations governing the use of investigational tobacco products become effective or FDA provides written notice of its intent to change its enforcement policy. It is intended to provide guidance not only to persons who currently intend to submit study information to FDA, but to all persons who conduct ''nonclinical laboratory studies,'' as that term is used in the draft guidance, and ''clinical investigations,'' as that term is used in the draft guidance, using investigational tobacco products.

The draft guidance also discusses that for clinical investigations, a sponsor (as defined in the guidance) may submit information regarding a proposed use of an investigational tobacco product to FDA for review prior to enrolling subjects. As discussed in the guidance, FDA encourages this type of voluntary submission because it will allow FDA to work with a sponsor to help ensure that the factors FDA considers in making enforcement decisions are appropriately accounted for. FDA has created a form to assist sponsors in submitting information. While use of the form is voluntary, it will help ensure that complete information is provided for FDA's consideration and will facilitate FDA's processing and review. A copy of the form is attached as Appendix A to this guidance.

On June 22, 2009, the President signed the Family Smoking Prevention and Tobacco Control Act (Pub. L. 111–31) (Tobacco Control Act) into law. The Tobacco Control Act amends the Federal Food, Drug, and Cosmetic Act (the FD&C Act) and grants FDA authority to regulate the manufacture, marketing, and distribution of tobacco products to protect public health generally and to reduce tobacco use by minors.

To introduce or deliver for introduction into interstate commerce a new tobacco product, there must be in effect a marketing authorization order issued by FDA for the tobacco product under section 910(c)(1)(A)(i) of the FD&C Act (21 U.S.C. 387j(c)(1)(A)(i)) unless, in brief:

- A substantial equivalence order under section 910(a)(2)(A)(i) of the FD&C Act is in effect for the tobacco product;
- FDA has granted a request for an exemption of the tobacco product from the requirement to obtain a substantial equivalence order and the manufacturer has made the required submission under section 905(j)(1)(A)(ii) of the FD&C Act and waited 90 days before introducing its product to the market; or
- The manufacturer has submitted a substantial equivalence report in accordance with section 910(a)(2)(B) of the FD&C Act and there is no order finding that the tobacco product is not substantially equivalent.

To introduce or deliver for introduction into interstate commerce a modified risk tobacco product, there must be in effect an order under section 911(g) of the FD&C Act (21 U.S.C. 387k(g)) and the applicant must satisfy any applicable premarket review requirements under section 910 of the FD&C Act.

Further, a tobacco product must conform in all respects with applicable tobacco product standards established under section 907 of the FD&C Act (21 U.S.C. 387g).

Persons intending to file submissions with FDA to demonstrate that a tobacco product meets the criteria for marketing set forth in section 910 or 911 of the FD&C Act, and other researchers seeking to study tobacco products, may need to conduct or sponsor studies involving tobacco products that do not have marketing authorization or that do not comply with an applicable tobacco product standard.