20852, 301–796–8867, *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 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 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.

Application for Participation in FDA Fellowship Programs (Formerly Application for Participation in the FDA Commissioner's Fellowship Program)

OMB Control Number 0910–0780—Extension

Sections 1104, 1302, 3301, 3304, 3320, 3361, 3393, and 3394 of Title 5 of the United States Code authorize Federal agencies to rate applicants for Federal jobs. The proposed information collection involves brief online applications completed by applicants applying to FDA's fellowship programs. These voluntary online applications will allow the Agency to easily and efficiently elicit and review information from students and healthcare professionals who are interested in becoming involved in FDA-wide activities. The process will reduce the time and cost of submitting written documentation to the Agency and lessen the likelihood of applications being misrouted within the Agency mail system. It will assist the Agency in promoting and protecting the public health by encouraging outside persons to share their expertise with FDA.

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

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Commissioner's Fellowship Program	600	1	600	1.33	798
Regulatory Science Internship Program	250	1	250	1	250
Medical Device Fellowship Program	250	1	250	1	250
Total					1,298

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

Dated: June 14, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–12781 Filed 6–19–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–1429]

Agency Information Collection Activities: Proposed Collection; Comment Request; Guidance for Industry on Registration of Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act

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 of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection in the guidance on registration of human drug compounding outsourcing facilities under the Federal Food, Drug, and Cosmetic Act (the FD&C Act).

DATES: Submit either electronic or written comments on the collection of information by August 21, 2017.

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 21, 2017. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of August 21, 2017. 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–2013–N 1429 for ''Guidance for Industry on Registration of Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act.'' 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 10A63, 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 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 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.

Guidance for Industry on Registration of Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act: OMB Control Number 0910–0777—Extension

A facility that compounds drugs may elect to register with FDA as an outsourcing facility under section 503B of the FD&C Act (21 U.S.C. 353b), as added by the Drug Quality and Security Act (DQSA). Drug products compounded in a registered outsourcing facility can qualify for exemptions from the FDA approval requirements in section 505 of the FD&C Act (21 U.S.C. 355), the requirement to label products with adequate directions for use under section 502(f)(1) of the FD&C Act (21 U.S.C. 352(f)(1)), and drug supply chain security requirements in section 582 of the FD&C Act (21 U.S.C. 360eee) if the requirements in section 503B are met.

After the initial registration, under section 503B(b) of the FD&C Act, a facility that elects to register with FDA as an outsourcing facility must also do so annually between October 1 and December 31. Upon registration, the outsourcing facility must provide its name, place of business, a unique facility identifier, and a point of contact email address. The outsourcing facility must also indicate whether it intends to compound, within the next calendar year, a drug that appears on FDA's drug shortage list in effect under section 506E of the FD&C Act (21 U.S.C. 356e), and whether it compounds from bulk drug substances, and, if so, whether it compounds sterile or non-sterile drugs from bulk drug substances.

Outsourcing facilities that elect to register should submit the following registration information to FDA for each facility:

• Name of the facility;
• Place of business;
• Unique facility identifier;
• Point of contact email address and phone number;
• Whether the facility intends to compound drugs that appear on FDA's drug shortage list in effect under section 506E of the FD&C Act; and

• An indication of whether the facility compounds from bulk drug substances, and if so, whether it compounds sterile or nonsterile drugs from bulk drug substances.

Registration information should be submitted to FDA electronically using the Structured Product Labeling (SPL) format and in accordance with section IV of the FDA guidance entitled ''Providing Regulatory Submissions in Electronic Format—Drug Establishment Registration and Drug Listing.'' Under the final guidance, outsourcing facilities may request a waiver from the SPL electronic submission process by submitting a written request to FDA explaining why the use of electronic means is not reasonable.

This information collection supports the Agency guidance discussed above. We estimate that approximately 62 outsourcing facilities (''number of respondents'' and ''total annual responses'' in table 1, row 1) will annually submit to FDA registration information using the SPL format as specified in the guidance, and that preparing and submitting this information will take approximately 4.5 hours per registrant (''average burden per response'' in table 1, row 1). We expect to receive no more than one waiver request from the electronic submission process annually (''number of respondents'' and ''total annual responses'' in table 1, row 2), and that each request should take approximately 1 hour to prepare and submit to us (''average burden per response'' in table 1, row 2).

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Compounding outsourcing facility	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Electronic Submission of Registration Information Using SPL Format	62	1	62	4.5	279
Waiver Request From Electronic Submission of Registration Information	1	1	1	1	1
Total					280

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

Dated: June 15, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning Legislation, and Analysis.

[FR Doc. 2017–12838 Filed 6–19–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Findings of Research Misconduct

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: Notice is hereby given that the Office of Research Integrity (ORI) has taken final action in the following case:

Brandi M. Baughman, Ph.D., National Institutes of Health (NIH): Based on Respondent's admission and analysis conducted by ORI, ORI found that Dr. Brandi M. Baughman, former Intramural Research Training Awardee, National Institute of Environmental and Health Sciences (NIEHS), NIH, engaged in research misconduct in research supported by National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), NIH, grant R01 DK101645 and the NIEHS, NIH, Postdoctoral Intramural Research Training Award (IRTA).

ORI found that falsified and/or fabricated data were included in eleven (11) figures in *PLoS One* 11(10):e0164378, 2016 (hereafter referred to as ''*PLoS One* 2016'').

ORI found that Respondent falsified and/or fabricated data and text published in *PLoS One* 2016, in Figures 2, 3, 4, 5, 6, 8, S1, S2, S3, S4, and S5, by claiming that a screening strategy of the kinase focused libraries, PKIS and 5K, was performed, when original data do not exist to support the claims. Respondent also claimed that three (3) inhibitory compounds for the inositol phosphate kinase, PPIP5K, were identified from the 5K library, when these compounds, UNC10112646, UNC10225354, and UNC10225498, were not part of the data set for the 5K library. Specifically, Respondent falsified and/or fabricated the characterization of the inhibitor compounds in:

• Figures 2 and 3 results for Z'-factor, %CV, signal:background ratio, and a 10-point dose response titration experiment for inhibitor UNC10225354

• claims in the text of *PLoS One* 2016 that eight molecules from the PKIS library and fifteen molecules from the 5K library inhibited PPIP5K activity by >50%

• Figure 4D results for the inhibition by UNC10112646, UNC10225354, and UNC10225498, in dose response assays against the kinase domain of PPIP5K

• Figures 5A and 5B results for isothermal titration calorimetry (ITC) assays for quantifying intermolecular interactions between PPIP5K and the inhibitors, UNC1011264 and UNC10225498, and Figure S5 for UNC10225354

• Figure 6 results for the analysis of the mechanisms of inhibition of PPIP5K by UNC10112646 and UNC10225498

• Figures 8A and 8B results for high performance liquid chromatography (HPLC) analysis for the effects of UNC10112646 or UNC10225498 on PPIP5K activity and IP6K activity

• Figures S1–S4 for experimental results further characterizing UNC10112646, UNC10225498, and other inhibitors, when the results were not supported by the experimental records.

As a result of Respondent's admission, NIH recommended that the *PLoS One* 2016 paper be retracted.

Dr. Baughman has entered into a Voluntary Settlement Agreement with ORI, in which she voluntarily agreed:

(1) To have her research supervised for a period of three (3) years beginning on May 17, 2017; Respondent agreed to ensure that prior to the submission of an application for U.S. Public Health Service (PHS) support for a research project on which Respondent's participation is proposed and prior to Respondent's participation in any capacity on PHS-supported research, Respondent shall ensure that a plan for supervision of Respondent's duties is submitted to ORI for approval; the supervision plan must be designed to