Dated: November 18, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2020–26050 Filed 11–24–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0380]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Product Jurisdiction and Combination Products

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 (PRA) of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by December 28, 2020.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0523. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794, *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.

Product Jurisdiction and Combination Products—21 CFR Part 3

OMB Control Number 0910–0523—Revision

This information collection supports implementation of section 503(g) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 353(g)), as amended by the 21st Century Cures Act (Pub. L. 114–255) (Cures Act), section 563 of the FD&C Act (21 U.S.C 360bbb–2) added to the FD&C Act by the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105–115), and Agency regulations in 21 CFR part 3. Section 503(g) of the FD&C Act expressly provides for the regulation of combination products, including how primary Agency responsibility shall be designated for such products and how certain submissions regarding such products may be made to the Agency. Section 563 of the FD&C Act requires FDA to classify products as biological products, devices, drugs, or combination products and to assign products to an Agency component for regulation, in response to requests for designation (RFDs) submitted by product sponsors. We updated our regulations in 21 CFR part 3 in 2005 to clarify the meaning of the statutory term ''primary mode of action,'' which determines the FDA component to which a combination product is assigned. We proposed to update these regulations further on May 15, 2018 (83 FR 22428), intending to: (1) Clarify the scope of our regulations; (2) streamline and clarify the appeals process; (3) align the regulations with more recent legislative and regulatory measures; (4) update advisory content; and (5) clarify Agency policies and practices.

We are revising the information collection to include changes to these existing procedures and current statutory and legislative mandates. Specifically, as amended by the Cures Act, section 503(g) of the FD&C Act includes provisions exclusive to FDA's Office of Combination Products (OCP) and/or to provide for combination product-specific submission types, including provisions addressing engagement between OCP and combination product sponsors and Combination Product Agreement Meetings (CPAMs) for sponsors to engage with FDA. In addition, FDA has developed an associated jurisdictional process to the RFD process, the pre-RFD process, for sponsors to obtain feedback regarding medical product classification and assignment.

To assist respondents with format and content elements related to the information collection for RFDs and pre-RFDs, we have developed proposed Forms FDA 5003, 5004, and 5005 (pre-request and request for designation). To support RFD and pre-RFD submissions, FDA has also made information technology improvements, enabling sponsors to use preferred submission methods, including automated, electronic, mechanical, and other technological collection techniques. We expect the use of improved technology to enhance sponsors' user experience with submissions.

We have also developed Agency guidance consistent with sections 503(g) and 563 of the FD&C Act and with our Good Guidance Practice regulations in 21 CFR 10.115 (approved under OMB control number 0910–0191).

The guidance entitled ''How to Write a Request for Designation'' (issued April 2011), provides instruction regarding the information that needs to be submitted to OCP in a RFD as described in 21 CFR 3.7. The guidance is available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/how-write-request-designation-rfd.* In the **Federal Register** of July 17, 2019 (84 FR 34188), we published a notice requesting public comment on the proposed collection of information associated with 21 CFR part 3; no comments were received.

The guidance entitled ''How to Prepare a Pre-Request for Designation,'' was developed to assist sponsors in obtaining a preliminary, nonbinding assessment from OCP through the pre-RFD process. The guidance explains the pre-RFD process and helps a sponsor understand the type of information to provide in a pre-RFD submission. The guidance is available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/how-prepare-pre-request-designation-pre-rfd.* In the **Federal Register** of January 13, 2017 (82 FR 4351), we published a notice announcing the availability of the draft guidance that included an analysis under the PRA and solicited public comment on the recommended information collection. In consideration of comments, we made minor edits to the guidance, including clarifying our pledge of confidentiality for information submitted and clarifying that OCP may be contacted at any time to discuss questions. No comments suggested revision to the information collection, and therefore we made no adjustment in our burden estimate.

The guidance entitled ''Requesting FDA Feedback on Combination Products,'' was developed to discuss ways in which combination product sponsors can obtain feedback from FDA on scientific and regulatory questions

and to describe best practices for FDA and sponsors when interacting on these topics. The guidance is available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/requesting-fda-feedback-combination-products.* In the **Federal Register** of December 26, 2019 (84 FR 70976), we published a notice announcing the availability of the draft guidance that included an analysis under the PRA and solicited public comment on the proposed collection of information for CPAMs. One comment was received in support of the collection but suggested no change in FDA's burden estimate.

Respondents to the information collection are sponsors of medical products, including combination products. We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section; activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (hours)	Total hours
3.7; request for designation	53	1	53	24	1,272
Pre-RFD submissions	83	1	83	24	1,992
CPAMs requests	3	1	3	25	75
Total					3339

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

For RFDs and pre-RFDs, our estimate is based on the number of submissions received from October 1, 2018, to September 30, 2019. We assume 1 submission per respondent, for an annual average of 53 RFD submissions, and 83 pre-RFD submissions and assume that each submission requires an average of 24 hours to prepare and submit to FDA.

Our estimate for CPAM requests is based on future activity in light of the minimal use of CPAMs to date; FDA has received two CPAM requests since the enactment of the Cures Act in December 2016. We estimate one CPAM request will be received per year by each medical product center (Center for Biologics Evaluation and Research, Center for Drug Evaluation and Research, and Center for Devices and Radiological Health). We assume it will take sponsors approximately 25 hours to compile and submit the recommended information. Because we expect burden associated with application submissions is already captured by approved information collection requests for drug, biologic, and medical device applications, respectively (approved under OMB control numbers 0910–0001, 0910–0338, and 0910–0231), we do not include burden associated with application submissions captured by these programs in this information collection request.

Dated: November 18, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2020–26062 Filed 11–24–20; 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: Findings of research misconduct have been made against Dr. David J. Panka (Respondent), former Harvard Medical School (HMS) Instructor of Medicine, and former HMS Associate Professor of Medicine at Beth Israel Deaconess Medical Center (BIDMC). Dr. Panka engaged in research misconduct in research supported by U.S. Public Health Service (PHS) funds, specifically National Cancer Institute (NCI), National Institutes of Health (NIH), grants P50 CA093683 and P50 CA101942. The administrative actions, including supervision for a period of three (3) years, were implemented beginning on November 9, 2020, and are detailed below.

FOR FURTHER INFORMATION CONTACT: Elisabeth A. Handley, Director, Office of Research Integrity, 1101 Wootton Parkway, Suite 240, Rockville, MD 20852, (240) 453–8200.

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

Dr. David J. Panka, Harvard Medical School and Beth Israel Deaconess Medical Center: Based on the report of an inquiry conducted by BIDMC and HMS and additional analysis conducted by ORI in its oversight review, ORI found that Dr. Panka, former HMS Instructor of Medicine, and former HMS Associate Professor of Medicine at BIDMC, engaged in research misconduct in research supported by PHS funds, specifically NCI, NIH, grants P50 CA093683 and P50 CA101942.

ORI found that Respondent engaged in research misconduct by intentionally, knowingly, and/or recklessly falsifying and/or fabricating Western blot images by selectively cutting, flipping, reordering, and reusing the same source images or non-correlated images to represent different results in the following three (3) published papers and one (1) conference presentation:

- The Raf inhibitor BAY 43–9006 (Sorafenib) induces caspase-independent apoptosis in melanoma cells. *Cancer Res.* 2006 Feb 1; 66(3):1611–9 (hereafter referred to as ''*Cancer Res.* 2006''). Retraction in: *Cancer Res.* 2019 Oct 15;79(20):5459.
- Differential modulatory effects of GSK–3b and HDM2 on sorafenib-induced AIF nuclear translocation (programmed necrosis) in melanoma. *Mol Cancer* 2011 Sep 19;10:115 (hereafter referred as to ''*Mol Cancer* 2011'').
- Effects of HDM2 antagonism on sunitinib resistance, p53 activation, SDF–1 induction, and tumor infiltration by CD11b+/Gr-1+ myeloid derived suppressor cells. *Mol Cancer* 2013 Mar 5;12:17 (hereafter referred to as ''*Mol Cancer* 2013'').
- Presentation #5328, ''BAY 43–9006 induces apoptosis in melanoma cell lines'', presented during Cellular and Molecular Biology session #63 '' ('Apoptosis 4: Chemotherapeutic Agents II')'' on April 20, 2005, at the 96th Annual American Association for Cancer Research (AACR) meeting, held in Anaheim, California (hereafter referred to as the ''2005 AACR Presentation'').