S.A.'' Received comments, those filed in a timely manner (see DATES), 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: Paul Hart, Center for Tobacco Products, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. G335, Silver Spring, MD 20993, 1–877–CTP–1373, *AskCTP@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of June 15, 2017 (82 FR 27487), FDA published a notice of availability for MRTPAs submitted by Philip Morris Products S.A. for its IQOS products and gave the public 180 days to comment on the applications. FDA issued a subsequent notice in the **Federal Register** of November 22, 2017 (82 FR 55616), extending the period for public comment and announcing its intent to issue a notice in a future edition of the **Federal Register** announcing when the comment period will close. FDA recently received amendments to the MRTPAs and has made them available for public comment. In this notice, FDA is announcing that the period for public comment on these MRTPAs, including amendments, will close on February 11, 2019.

FDA is required by section 911(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 387k) (FD&C Act) to make an MRTPA available to the public (except for matters in the application that are trade secrets or otherwise confidential commercial information) and to request comments by interested persons on the information contained in the application and on the label, labeling, and advertising accompanying the application. The determination of whether an order is appropriate under section 911(g) of the FD&C Act is based on the scientific information submitted by the applicant as well as the scientific evidence and other information that is made available to the Agency, including through public comments.

In the event FDA receives additional amendments or otherwise needs to modify the comment period closing date, FDA will notify the public via the Agency's web page for the MRTPAs (see section II) and by other means of public communication, such as by email to individuals who have signed up to receive email alerts. FDA does not intend to issue additional notices in the **Federal Register** regarding amendments or the comment period for these MRTPAs. To receive email alerts, visit FDA's email subscription service management website (*http://go.fda.gov/subscriptionmanagement*), provide an email address, scroll down to the ''Tobacco'' heading, select ''Modified Risk Tobacco Product Application Updates'', and click ''Submit''. To encourage public participation consistent with section 911(e) of the FD&C Act, FDA is making the redacted MRTPAs that are the subject of this notice available electronically (see section II).

II. Electronic Access

Persons with access to the internet may access the application documents at: *https://www.fda.gov/TobaccoProducts/Labeling/MarketingandAdvertising/ucm546281.htm.*

Dated: December 18, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–27807 Filed 12–21–18; 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 Uthra Rajamani, Ph.D. (Respondent), former project scientist in the Induced Pluripotent Stem Cell Core Facility, Cedars-Sinai Medical Center (CSMC). Dr. Rajamani engaged in research misconduct in research supported by National Center for Advancing Translational Science (NCATS), National Institutes of Health (NIH), grant UL1 TR000124. The administrative actions, including supervision for a period of one (1) year, were implemented beginning on November 27, 2018, and are detailed below.

FOR FURTHER INFORMATION CONTACT: Wanda K. Jones, Dr.P.H., Interim Director, Office of Research Integrity, 1101 Wootton Parkway, Suite 750, 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:

Uthra Rajamani, Ph.D., Cedars-Sinai Medical Center: Based on the report of an inquiry conducted by CSMC, the Respondent's admission, and additional analysis conducted by ORI in its oversight review, ORI found that Dr. Uthra Rajamani, former project scientist in the Induced Pluripotent Stem Cell Core Facility, CSMC, engaged in research misconduct in research supported by NCATS, NIH, grant UL1 TR000124.

ORI found that Respondent engaged in research misconduct by falsifying data that were included in the following paper: *Nature Communications* 8(219):1–15, 2017 (hereafter referred to as ''*Nature Communications* 2017'').

ORI found that Respondent knowingly and intentionally falsified western blot images in *Nature Communications* 2017 by using the same western blot panel to represent the

expression of different proteins from whole cell lysates exposed to different endocrine disrupting chemical (EDC) treatments. Specifically, Respondent:

• Digitally altered the original image to darken the western blot panel for COX IV expression in Figure 4b in *Nature Communications* 2017 and represented the blot as the expression of:

—pNF-kB p65 Figure 4b in *Nature Communications* 2017
—NF-kB p65 Figure 4b in *Nature Communications* 2017
—p50 Figure 4b in *Nature Communications* 2017
—p105 Figure 4b in *Nature Communications* 2017
—p100 Figure 4b *Nature Communications* 2017

• Digitally altered the original image by superimposing a darker band over the original bands in lanes 2 and 4 of the western blot panel for COX IV expression in whole cell lysates exposed to different endocrine disrupting chemical (EDC) treatments in Figure 4b in *Nature Communications* 2017 and represented the falsified blot in Figure 6a in *Nature Communications* 2017 as expression of:

— P-p65 Figure 6a in *Nature Communications* 2017
— p50 Figure 6a in *Nature Communications* 2017
— p105 Figure 6a in *Nature Communications* 2017
— p52 Figure 6a in *Nature Communications* 2017

• Reused and relabeled the blot from Figure 3d in *Cell Stem Cell* 22:698–712, 2018 to falsely represent BiP expression under different experimental conditions in Figure 3d in *Nature Communications* 2017.

As a result of its inquiry, CSMC recommended that *Nature Communications* 2017 be retracted.

Dr. Rajamani entered into a Voluntary Settlement Agreement (Agreement) and voluntarily agreed:

(1) To have her research supervised for a period of one (1) year beginning on November 27, 2018; Respondent agrees that prior to 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 ensure the scientific integrity of Respondent's research contribution; Respondent agrees that she shall not participate in any PHS-supported research until such a supervision plan is submitted to and approved by ORI; Respondent agrees to maintain responsibility for compliance with the agreed upon supervision plan;

(2) that for a period of one (1) year beginning on November 27, 2018, any institution employing her shall submit, in conjunction with each application for PHS funds, or report, manuscript, or abstract involving PHS-supported research in which Respondent is involved, a certification to ORI that the data provided by Respondent are based on actual experiments or are otherwise legitimately derived and that the data, procedures, and methodology are accurately reported in the application, report, manuscript, or abstract;

(3) that if no supervisory plan is provided to ORI, Respondent will provide certification to ORI at the conclusion of the supervision period that she has not engaged in, applied for, or had her name included on any application, proposal, or other request for PHS funds without prior notification to ORI;

(4) to exclude herself from serving in any advisory capacity to PHS including, but not limited to, service on any PHS advisory committee, board, and/or peer review committee, or as a consultant for a period of one (1) year beginning on November 27, 2018; and

(5) that as a condition of the Agreement, Respondent will request that *Nature Communications* 8(219):1–15, 2017 be retracted.

Wanda K. Jones,

Interim Director, Office of Research Integrity.

[FR Doc. 2018–27874 Filed 12–21–18; 8:45 am]

BILLING CODE 4150–31–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Organization, Functions, and Delegations of Authority; Part G; Indian Health Service

Part G, of the Statement of Organization, Functions, and Delegations of Authority of the Department of Health and Human Services (HHS), as amended at 70 FR 24087, May 6, 2005, as amended at 75 FR 38112, July 1, 2010, and most recently as amended at 79 FR 65671, November 5, 2014, is hereby amended to reflect a reorganization of the Indian Health Service (IHS) Headquarters (HQ).

The IHS proposes a reorganization at IHS HQ to strengthen operations and oversight responsibilities to ensure quality health care by establishing an Office of Quality.

Delete the functional statements for the IHS HQ Office of the Director, Office of Clinical and Preventive Services, and Office of Management Services, and replace with the following revised statements, which includes a new Office of Quality:

Chapter GA—Office of the Director

Section GA–10, Indian Health Service—Organization

The IHS is an Operating Division within the Department of Health and Human Services (HHS) and is under the leadership and direction of a Director who is directly responsible to the Secretary of Health and Human Services. The IHS Headquarters is proposing to reorganize the following major components: Office of the Director (GA), Office of Clinical and Preventive Services (GAF), Office of Management Services (GAL), and the Office of Quality (OQ).

Section GA–20, Indian Health Service—Functions

Office of the Director (OD) (GA)

Provides overall direction and leadership for the IHS: (1) Establishes goals and objectives for the IHS consistent with the mission of the IHS and ensures agency performance is managed through goals/objectives, achievements, and/or improved outcomes; (2) provides for the full participation of Indian tribes in the programs and services provided by the Federal Government; (3) develops health care policy; (4) ensures the delivery of quality comprehensive health services; (5) advocates for the health needs and concerns of American Indians/Alaska Natives (AI/AN); (6) promotes the IHS programs at the local, state, national, and international levels; (7) develops and demonstrates alternative methods and techniques of health services management and delivery with maximum participation by Indian tribes and Indian organizations; (8) supports the development of individual and tribal capacities to participate in Indian health programs through means and modalities that they deem appropriate to their needs and circumstances; (9) the IHS will carry out the responsibilities of the United States to Indian tribes and individual Indians; (10) affords Indian people an opportunity to enter a career in the IHS by applying Indian preference; (11) ensures full application of the principles of Equal Employment Opportunity laws and the Civil Rights Act in managing the human resources of