TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

| 21 CFR section and activity | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response | Total hours |
|---|---|---|---|---|---|
| Filing a Request for a Hearing on Medicated Feed Mill License (515.30(c)). | 1 | 1 | 1 | 4 | 4 |
| Total | | | | | 29 |

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

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

| 21 CFR section and activity | Number of recordkeepers | Number of records per recordkeeper | Total annual records | Average burden per recordkeeping | Total hours |
|---|---|---|---|---|---|
| Maintenance of Records for Approved Labeling for Each "Type B" and "Type C" Feed (510.305). | 837 | 1 | 837 | 0.03 (2 minutes). | 25 |

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

These estimates are based on our experience with medicated feed mill license applications. We estimate that we will receive 14 medicated feed mill license applications, 54 supplemental applications, 29 requests for voluntary revocation, and that these submissions will take approximately 15 minutes per response, as shown in table 1, rows 1 through 3. We estimate that preparing a request for a hearing under § 515.30(c) takes approximately 4 hours, as shown in table 1, row 4. In table 2, we estimate that 837 licensees will keep the records required by 21 CFR 510.305 expending a total of 25 hours annually.

Our estimated burden for the information collection reflects an overall decrease of 2 hours and a corresponding decrease of 56 responses/records. We attribute this adjustment to a net decrease in the number of submissions we received over the last few years.

Dated: December 18, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2018–27812 Filed 12–21–18; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2017–D–3001]**

### Modified Risk Tobacco Product Applications for IQOS System With Marlboro Heatsticks, IQOS System With Marlboro Smooth Menthol Heatsticks, and IQOS System With Marlboro Fresh Menthol Heatsticks Submitted by Philip Morris Products S.A.; Closing of Comment Period

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; closing of comment period.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing a closing date for the period for public comment on modified risk tobacco product applications (MRTPAs) submitted by Philip Morris Products S.A. for its IQOS system products. FDA recently received amendments to these MRTPAs and has made them available for public comment.

**DATES:** Submit either electronic or written comments by February 11, 2019 to ensure FDA considers your comment before completing its review of the applications.

**ADDRESSES:** You may submit comments as follows:

*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–2017–D–3001 for "Modified Risk Tobacco Product Applications for IQOS system with Marlboro Heatsticks, IQOS system with Marlboro Smooth Menthol Heatsticks, and IQOS system with Marlboro Fresh Menthol Heatsticks submitted by Philip Morris Products

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