

manufacturing plant; (5) name, telephone number, and email address of the contact person; (6) list of products divided into three categories: Presently shipped, ready to ship, and available for shipment in the next 3 years; (7) identities of agencies that inspected the plant; (8) date of last inspection, plant number, and copy of last inspection notice; and (9) if other than an FDA inspection, copy of last inspection report.

We request that this information be updated every 2 years.

We use the information submitted by firms to determine their eligibility for placement on the export lists, which are

published on our Web site. The purpose of the lists is to help foreign governments in their determinations of which U.S. milk product manufacturers and processors are eligible to export to their respective countries.

FDA has recently developed an electronic registry system (Form FDA 3972) that allows milk product manufacturers and processors to electronically send a request to FDA to be included on the export lists. Manufacturers and processors that prefer to submit a paper request in a format of their own choosing will still have the option to do so. Electronic Form FDA 3972 collects the same

information as is currently collected via the existing paper-based process. Draft screenshots of Form FDA 3972 and instructions are available at <http://www.fda.gov/Food/GuidanceRegulation/ImportsExports/Exporting/ucm496929.htm> and is entitled "Dairy Listing Module."

**Description of Respondents:** Respondents to this collection of information include U.S. milk product manufacturers/processors subject to FDA jurisdiction that wish to export to certain foreign countries that require inclusion on export lists.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
New requests to be placed on the lists .....	2,000	1	2,000	1 .....	2,000
Biennial update .....	2,000	1	2,000	0.5 (30 minutes) .....	1,000
Occasional updates .....	200	1	200	0.5 (30 minutes) .....	100
<b>Total .....</b>					<b>3,100</b>

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA bases its estimate on the number of manufacturers/processors that have submitted new written requests, biennial updates, and occasional updates over the past 10 years. The estimate of the number of burden hours it will take a manufacturer/processor to gather the information needed to be placed on the list or update its information is based on FDA's experience with manufacturers/processors submitting similar requests. FDA believes that the information to be submitted will be readily available to manufacturers/processors. This collection is also incorporating information collected to maintain lists of eligible exporters of dairy products who wish to export to the EU from OMB control number 0910-0320, "Request for Information from U.S. Processors that Export to the European Community."

FDA estimates that 2,000 firms will average 60 minutes (1 hour) to submit new requests for inclusion on the list, 2,000 firms will average 30 minutes (0.5 hour) to update their information every 2 years, and 200 firms will average 30 minutes (0.5 hour) to occasionally update their information in this system. We also believe that submission via the electronic registry system will not affect the burden estimates. An electronic registry will enhance the ability of firms to more efficiently request inclusion on export lists. FDA calculates, therefore, that the total burden for this collection

is 3,100 hours ((2,000 × 1) plus (2,000 × 0.5) plus (200 × 0.5)).

Dated: June 9, 2017.

**Anna K. Abram,**  
*Deputy Commissioner for Policy, Planning, Legislation, and Analysis.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2017-D-3001]

**Modified Risk Tobacco Product Applications: 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.; Availability**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing the availability for public comment of modified risk tobacco product applications (MRTPAs) 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.

**DATES:** Submit either electronic or written comments on the application by December 12, 2017.

**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):* Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Division of Dockets Management, 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: 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 will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Division of Dockets Management 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 Division of Dockets Management. 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 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 Division of Dockets Management, 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 20993-0002, 1-877-287-1373, email: [AskCTP@fda.hhs.gov](mailto:AskCTP@fda.hhs.gov).

### SUPPLEMENTARY INFORMATION:

#### I. Background

Section 911 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 387k) addresses the marketing and distribution of modified risk tobacco products (MRTPs). MRTPs are tobacco products that are sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products. Section 911(a) of the FD&C Act prohibits the introduction or delivery for introduction into interstate commerce of any MRTP unless an order issued by FDA under section 911(g) of the FD&C Act is effective with respect to such product.

Section 911(d) of the FD&C Act describes the information that must be included in an MRTPA, which must be filed and evaluated by FDA before an applicant can receive an order from FDA. FDA is required by section 911(e) of the 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.

Section 911(g) of the FD&C Act describes the demonstrations applicants must make to obtain an order from FDA under either section 911(g)(1) or (g)(2). A person seeking an order under section 911(g)(1) of the FD&C Act must show

that the tobacco product, as it is actually used by consumers, will significantly reduce harm and the risk of tobacco-related disease to individual tobacco users and will benefit the health of the population as a whole taking into account both users of tobacco products and persons who do not currently use tobacco products. Section 911(g)(4) of the FD&C Act describes factors that FDA must take into account in evaluating whether a tobacco product benefits the health of individuals and the population as a whole.

FDA may issue an order under section 911(g)(2) of the FD&C Act with respect to a tobacco product that does not satisfy the section 911(g)(1) standard. A person seeking an order under section 911(g)(2) of the FD&C Act must show that:

- Such an order would be appropriate to promote the public health;
- Any aspect of the label, labeling, and advertising for the product that would cause the product to be an MRTP is limited to an explicit or implicit representation that the tobacco product or its smoke does not contain or is free of a substance or contains a reduced level of a substance, or presents a reduced exposure to a substance in tobacco smoke;
- Scientific evidence is not available and, using the best available scientific methods, cannot be made available without conducting long-term epidemiological studies for an application to meet the standards for obtaining an order under section 911(g)(1);
- The scientific evidence that is available without conducting long-term epidemiological studies demonstrates that a measurable and substantial reduction in morbidity or mortality among individual tobacco users is reasonably likely in subsequent studies;
- The magnitude of overall reductions in exposure to the substance or substances which are the subject of the application is substantial, such substance or substances are harmful, and the product as actually used exposes consumers to the specified reduced level of the substance or substances;
- The product as actually used by consumers will not expose them to higher levels of other harmful substances compared to the similar types of tobacco products then on the market unless such increases are minimal and the reasonably likely overall impact of use of the product remains a substantial and measurable reduction in overall morbidity and mortality among individual tobacco users;

- Testing of actual consumer perception shows that, as the applicant proposes to label and market the product, consumers will not be misled into believing that the product is or has been demonstrated to be less harmful or presents or has been demonstrated to present less of a risk of disease than one or more other commercially marketed tobacco products; and

- Issuance of the exposure modification order is expected to benefit the health of the population as a whole taking into account both users of tobacco products and persons who do not currently use tobacco products.

Section 911(g)(4) of the FD&C Act describes factors that FDA must take into account in evaluating whether a tobacco product satisfies the requirements in section 911(g)(2).

FDA is issuing this notice to inform the public that the following MRTPAs submitted by Philip Morris Products S.A. have been filed and are being made available for public comment:

- MR0000059: IQOS system with Marlboro Heatsticks
- MR0000060: IQOS system with Marlboro Smooth Menthol Heatsticks
- MR0000061: IQOS system with Marlboro Fresh Menthol Heatsticks

Due to the large size of these applications, FDA will post the application documents in batches on a rolling basis as they are redacted in accordance with applicable laws. In this document, FDA is announcing the availability of the first batch of application documents. FDA is making the applications available for public comment for 180 days from the posting of the first batch of application documents. In the event that fewer than 30 days remain in the comment period when the final batch is posted, FDA will issue a notice in the **Federal Register** extending the comment period to allow for at least 30 days of public comment from the day the final batch is posted. FDA believes that this comment period is appropriate given the volume and complexity of the applications being posted. 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 obtain the documents at <http://www.fda.gov/TobaccoProducts/Labeling/MarketingandAdvertising/ucm546281.htm>.

Dated: June 9, 2017.

**Anna K. Abram,**

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

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**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2011-N-0424]

#### Agency Information Collection Activities; Proposed Collection; Comment Request; Temporary Marketing Permit Applications

**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/reinstatement of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on reporting requirements contained in existing FDA regulations governing temporary marketing permit applications.

**DATES:** Submit either electronic or written comments on the collection of information by August 14, 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 14, 2017. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time at the end of August 14, 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-2011-N-0424 for "Temporary Marketing Permit Applications." 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