under section 904(c)(1) of the FD&C Act at least 90 days prior to delivery for introduction into interstate commerce for all new products, to report their company information to FDA through the use of the electronic portal or paper forms.

The company information reported includes: Company name; mailing address; telephone and Fax numbers; FDA Establishment Identifier number; Data Universal Numbering System number; and point of contact name, mailing address, and telephone and Fax numbers, as applicable. It also addresses the time required for manufacturers and importers to report their product information by entering certain testing information into the electronic or paper forms.

The product information includes: Brand and subbrand name; unique product identification number; type of product identification number; product category and subcategory; and mean weight and standard deviation of tobacco in product.

We estimate that the burden to enter both the company and product information is no more than 1.82 hours for cigarettes, 0.43 hours for RYO, and 0.63 hours for smokeless tobacco products regardless of whether the paper or electronic Form FDA series 3787 is used. The time to report per tobacco product type varies because the number of HPHCs varies by tobacco product category.

The estimated number of responses under section 904(c)(1) is based on FDA’s experience and the past 3 years’ actual responses to FDA under this provision of the FD&C Act for statutorily regulated products.

Section 2 of table 1 estimates that 88 respondents (46 cigarette filler and RYO tobacco manufacturers and importers and 42 smokeless manufacturers) will test quantities of HPHCs in an average of 24.5 products annually. This section addresses the time required for manufacturers and importers (or their agents) who must test HPHC quantities in products. The burden estimates include the burden to test the tobacco products, draft testing reports, and submit the report to FDA. The total expected burden for this section is 291 hours.

Section 3 of table 1 addresses the time required for manufacturers and importers to test quantities for HPHCs in cigarette smoke. The burden estimates include: The burden to test the number of replicate measurements; test date range; manufacture date range; extraction method; separation method; detection method; and mean quantity and standard deviation of HPHCs and includes the burden to test the tobacco products, draft testing reports, and submit the report to FDA. The annual burden reflects our estimate of the time it takes to test the tobacco products (i.e., carry out laboratory work). The burden estimate assumes that manufacturers and importers report HPHC quantities in cigarette mainstream smoke according to the two smoking regimens. The total expected burden is 2,128 hours for this section.

The total estimated burden for this information collection is 2,516 hours and 139 responses.

Our estimated burden for the information collection reflects an overall decrease of 2,125 hours and a corresponding decrease of 142 responses. We attribute this decrease to updated information on the number of submissions we received over the last few years.

Dated: January 11, 2019.

Leslie Kux,
Associate Commissioner for Policy.
[FR Doc. 2019–00448 Filed 1–30–19; 8:45 am]
BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
[Docket No. FDA–2019–N–0070]

Microbiology Devices Panel Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing a forthcoming public advisory committee meeting of the Microbiology Devices Panel. The general function of the committee is to provide advice and recommendations to the Agency on FDA’s regulatory issues. The meeting will be open to the public.

DATES: The meeting will be held on March 8, 2019, from 8 a.m. to 5 p.m.

ADDITIONAL INFORMATION:

ATTENTION: For further information, including information about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice, and the committee will discuss potential changes to the HR HPV device indications for use generated since the approval of the first High Risk (HR) HPV screening device in 2003 as well as the effects of HPV vaccination on clinical studies of devices for HPV detection. Topics to be addressed at the meeting include clinical study design and comparator methods. Additionally, the committee will discuss potential changes to the clinical study design and evaluation of devices detecting Human Papillomavirus (HPV) nucleic acid. These approaches will take into consideration scientific data generated since the approval of the first High Risk (HR) HPV screening device in 2003 as well as the effects of HPV vaccination on clinical studies of devices for HPV detection. 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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[DOCKET NO. FDA–2019–N–0218]

Pulmonary-Allergy Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Pulmonary-Allergy Drugs Advisory Committee. The general function of the committee is to provide advice and recommendations to FDA on regulatory issues. The meeting will be open to the public. FDA is establishing a docket for public comment on this document.

DATES: The meeting will be held on March 27, 2019, from 8 a.m. to 5 p.m.

ADDRESSES: FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993–0002. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.

FDA is establishing a docket for public comment on this meeting. The docket number is FDA–2019–N–0218. The docket will close on March 26, 2019. Submit either electronic or written comments on this public meeting by March 26, 2019. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before March 26, 2019. The https://www.regulations.gov electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of March 26, 2019. 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.

Comments received on or before March 13, 2019, will be provided to the committee. Comments received after that date will be taken into consideration by FDA.

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 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–2019–N–0218 for “Pulmonary-Allergy Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments.” 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