FEDERAL COMMUNICATIONS COMMISSION

FEDERAL ADVISORY COMMITTEE ACT; DOWNLOADABLE SECURITY TECHNOLOGY ADVISORY COMMITTEE

AGENCY: Federal Communications Commission.

ACTION: Notice.

SUMMARY: In accordance with the Federal Advisory Committee Act, this notice advises interested persons that the Federal Communications Commission’s (FCC or Commission) Downloadable Security Technology Advisory Committee (DSTAC) will hold a meeting on March 24, 2015. At the meeting, the current Commercial Requirements Working Group and the Technology and Preferred Architectures Working Group will present their findings, the Advisory Committee will consider establishing more working groups, and the committee will discuss any other topics related to the DSTAC’s work that may arise.

DATES: March 24, 2015.


FOR FURTHER INFORMATION CONTACT: For additional information on this proceeding, contact Brendan Murray, Brendan.Murray@fcc.gov, of the Media Bureau, Policy Division, (202) 418–1573 or Nancy Murphy, Nancy.Murphy@fcc.gov, of the Media Bureau, (202) 418–1043.

SUPPLEMENTARY INFORMATION: The meeting will be held on March 24, 2015, from 10:00 a.m. to 4:00 p.m. in the Commission Meeting Room of the Federal Communications Commission, Room TW–C305, 445 12th Street SW., Washington, DC 20554.

The DSTAC is a Federal Advisory Committee that will “identify, report, and recommend performance objectives, technical capabilities, and technical standards of a not unduly burdensome, uniform, and technology- and platform-neutral software-based downloadable security system.”

The meeting on March 24, 2015, will be the second meeting of the DSTAC. The FCC will attempt to accommodate as many attendees as possible; however, admittance will be limited to seating availability. The Commission will provide audio and/or video coverage of the meeting over the Internet from the FCC’s Web page at http://www.fcc.gov/live. The public may submit written comments before the meeting to Brendan Murray, DSTAC Designated Federal Officer, by email to DSTAC@fcc.gov or by U.S. Postal Service Mail to 445 12th Street SW., Room 4–A726, Washington, DC 20554.

Open captioning will be provided for this event. Other reasonable accommodations for people with disabilities are available upon request. Requests for such accommodations should be submitted via email to fcc504@fcc.gov or by calling the Consumer & Governmental Affairs Bureau at (202) 418–0530 (voice), (202) 418–0432 (tty). Such requests should include a detailed description of the accommodation needed. In addition, please include a way the FCC can contact you if it needs more information. Please allow at least five days’ advance notice; last-minute requests will be accepted, but may be impossible to fill.

Federal Communications Commission.

Marlene H. Dortch, Secretary.

[FR Doc. 2015–05077 Filed 3–4–15; 8:45 am]
BILLING CODE 6712–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[DOCKET NO. FDA–2011–D–0147]

Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance for Industry and Food and Drug Administration Staff; Section 905(j) Reports: Demonstrating Substantial Equivalence for Tobacco Products and Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the Federal Register concerning each proposed collection of information, including each proposed...
extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collections in the guidelines for industry and FDA staff entitled “Guidance for Industry and Food and Drug Administration Staff on Section 905(j) Reports: Demonstrating Substantial Equivalence for Tobacco Products” and “Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions.”

**DATES:** Submit either electronic or written comments on the collection of information by May 4, 2015.

**ADDRESSES:** Submit electronic comments on the collection of information to http://www.regulations.gov. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, PRAStaff@fda.hhs.gov.

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. “Collection of information” is defined in 21 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA’s functions, including whether the information will have practical utility; (2) the accuracy of FDA’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

**Guidance for Industry and Food and Drug Administration Staff on Section 905(j) Reports: Demonstrating Substantial Equivalence for Tobacco Products—(OMB Control Number 0910–0673) (Extension)**

On June 22, 2009, the President signed the Family Smoking Prevention and Tobacco Control Act (the Tobacco Control Act) (Pub. L. 111–31) into law. The Tobacco Control Act amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act) by adding a new chapter granting FDA authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health generally and to reduce tobacco use by minors.

Section 905(j) of the FD&C Act (21 U.S.C. 387(j)) authorizes FDA to establish the form for the submission of information related to substantial equivalence (SE). In guidance documents issued under the Good Guidance Practices regulation (21 CFR 10.115), FDA provides recommendations intended to assist persons submitting reports under section 905(j) of the FD&C Act and explains, among other things, FDA’s interpretation of the statutory sections related to substantial equivalence.

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

<table>
<thead>
<tr>
<th>Activity</th>
<th>Number of respondents</th>
<th>Number of responses per respondent</th>
<th>Total annual responses</th>
<th>Average burden per response</th>
<th>Total hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>Full SE 905(j)(1)(A)(i) and 910(a)</td>
<td>75</td>
<td>1</td>
<td>75</td>
<td>300</td>
<td>22,500</td>
</tr>
<tr>
<td>Product Quantity Change SE Report</td>
<td>125</td>
<td>1</td>
<td>125</td>
<td>87</td>
<td>10,875</td>
</tr>
<tr>
<td>Same characteristics SE Report</td>
<td>100</td>
<td>1</td>
<td>100</td>
<td>47</td>
<td>4,700</td>
</tr>
<tr>
<td><strong>Totals</strong></td>
<td><strong>.................................</strong></td>
<td><strong>.................................</strong></td>
<td><strong>.................................</strong></td>
<td><strong>.................................</strong></td>
<td><strong>38,075</strong></td>
</tr>
</tbody>
</table>

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

FDA has based these estimates on information it now has available from interactions with the industry, information related to other regulated products, and FDA’s expectations regarding the tobacco industry’s use of the section 905(j) pathway to market their products. Table 1 describes the annual reporting burden as a result of the implementation of the SE requirements of sections 905(j) and 910(a) of the FD&C Act (21 U.S.C. 387(a)). Based on current information, FDA now estimates that it will receive 300 section 905(j) reports each year. Of these 300 reports, FDA estimates that 75 of these reports will be “full” SE reports that take a manufacturer approximately 300 hours to prepare. Under the newly issued guidance entitled, “Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions,” FDA is recommending that certain modifications might be addressed in either a “Same Characteristics SE Report” or “Product Quantity Change Report.” FDA estimates that it will receive 100 Same Characteristics SE Reports and that it will take a manufacturer approximately 47 hours to prepare this report. FDA estimates that it will receive 125 Product Quantity Change SE Reports and that it will take a manufacturer approximately 87 hours to prepare this report. Therefore, FDA estimates the burden for submission of SE information will be 38,075 hours.

Dated: February 27, 2015.

Leslie Kux, Associate Commissioner for Policy.

[FR Doc. 2015–05024 Filed 3–4–15; 8:45 am]

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