provisions in 21 CFR part 601 are approved under OMB control number 0910–0338.

III. Electronic Access


Dated: December 18, 2019.

Lowell J. Schiller,
Principal Associate Commissioner for Policy.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–0001]

The Tobacco Products Scientific Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Tobacco Products Scientific Advisory Committee (TPSAC, the Committee). 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 February 14, 2020, from 8:30 a.m. to 5 p.m.

ADDRESSES: FDA White Oak Campus, 10903 New Hampshire Ave., Building 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.

For those unable to attend in person, the meeting will also be webcast and will be available at the following link: https://collaboration.fda.gov/tpsac021420/.

FOR FURTHER INFORMATION CONTACT: Serina Hunter-Thomas, Office of Science, Center for Tobacco Products, Food and Drug Administration, Document Control Center, Bldg. 71, Rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 1–877–287–1373, email: TPSAC02fda.hhs.gov, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the Federal Register about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency’s website at https://www.fda.gov/AdvisoryCommittees/default.htm and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: On February 14, 2020, the Center for Tobacco Product’s TPSAC will convene for one open session, during which the Committee will discuss the modified risk tobacco product applications, submitted by 22nd Century Group Inc. for the following combusted filtered cigarette tobacco products:

- MR0000159: VLNTM King
- MR0000160: VLNTM Menthol King

FDA intends to make background material available to the public no later than 2 business days before the meeting. Background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA’s website after the meeting. Background material is available at https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm. Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before February 7, 2020. Oral presentations from the public will be scheduled between approximately 10:45 a.m. and 11:45 a.m. on February 14, 2020. Those individuals interested in making formal oral presentations should notify the contact person (see FOR FURTHER INFORMATION CONTACT) and submit a brief statement describing the general nature of the evidence or arguments they wish to present and the names and email addresses of proposed participants on or before January 30, 2020, by 5 p.m. Eastern Time. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by January 31, 2020.

Persons attending FDA’s advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets. FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Serina Hunter-Thomas at least 7 days in advance of the meeting (see FOR FURTHER INFORMATION CONTACT).

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).


Lowell J. Schiller,
Principal Associate Commissioner for Policy.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0579]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Biological Products: Reporting of Biological Product Deviations and Human Cells, Tissues, and Cellular and Tissue-Based Deviations in Manufacturing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

The document discusses the reporting requirements for biological product deviations (BPDs) and human cell, tissue, and cellular and tissue-based product deviations in manufacturing. It mentions the Federal Register Notice and the Office of Management and Budget (OMB) control number 0910–0458 extension for this collection of information.

Under section 351 of the Public Health Service Act (PHS Act) (42 U.S.C. 262), all biological products, including human blood and blood components, offered for sale in interstate commerce must be labeled and meet standards, including those prescribed in the FDA regulations, designed to ensure the continued safety, purity, and potency of such products. In addition, under section 361 of the PHS Act (42 U.S.C. 264), FDA may issue and enforce regulations necessary to prevent the introduction, transmission, or spread of communicable diseases between the States or possessions or from foreign countries into the States or possessions. Further, the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 351) provides that drugs and devices (including human blood and blood components) are adulterated if they do not conform with current good manufacturing practice (CGMP) assuring that they meet the requirements of the FD&C Act. Establishments manufacturing biological products, including human blood and blood components, must comply with the applicable CGMP regulations.

In the Federal Register of July 31, 2019 (84 FR 37321), we published a 60-day notice requesting public comment on the proposed collection of information. One comment offering general support for the information collection was received.

We estimate the burden of this collection of information as follows:
Our estimated burden for the information collection reflects an overall increase of 739 hours and a corresponding increase of 398 responses. We attribute this adjustment to an increase in the number of submissions we received over the last few years.


Lowell J. Schiller,
Principal Associate Commissioner for Policy.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–0990–0323]

Agency Information Collection Request; 30-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN

<table>
<thead>
<tr>
<th>21 CFR section</th>
<th>FDA form No.</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>600.14; Reporting of product deviations by licensed manufacturers ..........................................................</td>
<td>3486</td>
<td>93</td>
<td>6.14</td>
<td>571</td>
<td>2.0</td>
<td>1,142</td>
</tr>
<tr>
<td>606.171; Reporting of product deviations by licensed manufacturers, unlicensed registered blood establishments, and transfusion services ..........................................................</td>
<td>3486</td>
<td>1,937</td>
<td>23.847</td>
<td>46,192</td>
<td>2.0</td>
<td>92,384</td>
</tr>
<tr>
<td>1271.350(b); Reporting requirements (human cells, tissues, and cellular and tissue-based products) ..........................................................</td>
<td>3486</td>
<td>93</td>
<td>2.61</td>
<td>243</td>
<td>2.0</td>
<td>486</td>
</tr>
<tr>
<td>1271.350(b) (CBER addendum report) ..........................................................</td>
<td>3486A</td>
<td>102</td>
<td>22.76</td>
<td>2,322</td>
<td>0.25</td>
<td>580.5</td>
</tr>
<tr>
<td>Total ..........................................................</td>
<td>........................</td>
<td>........................</td>
<td>........................</td>
<td>........................</td>
<td>........................</td>
<td>........................</td>
</tr>
</tbody>
</table>

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

2 Five percent of the number of respondents ((1,937 + 93) × 0.05 = 102) and total annual responses to CBER ((46,192 + 243) × 0.05 = 2,322).

Annualized Burden Hour Table

<table>
<thead>
<tr>
<th>Forms (if necessary)</th>
<th>Respondents (if necessary)</th>
<th>Number of respondents</th>
<th>Number of responses per respondent</th>
<th>Average burden per response</th>
<th>Total burden hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>Meeting Request ........</td>
<td>Developers of medical countermeasures to naturally occurring and intentional public health threats.</td>
<td>245</td>
<td>1</td>
<td>10/60</td>
<td>41</td>
</tr>
<tr>
<td>Total .................</td>
<td>..................................</td>
<td>........................</td>
<td>........................</td>
<td>........................</td>
<td>41</td>
</tr>
</tbody>
</table>


Terry Clark,
Office of the Secretary, Asst. Paperwork Reduction Act Reports Clearance Officer.

BILLING CODE 4150–04–P