

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

### III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either <https://www.fda.gov/comboination-products/guidance-regulatory-information/comboination-products-guidance-documents> or <https://www.regulations.gov>.

Dated: December 18, 2019.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

[FR Doc. 2019-27799 Filed 12-23-19; 8:45 am]

**BILLING CODE 4164-01-P**

## 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: [TPSAC@fda.hhs.gov](mailto:TPSAC@fda.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: VLN™ King
- MR0000160: VLN™ Menthol King

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the 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).

Dated: December 19, 2019.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

[FR Doc. 2019-27774 Filed 12-23-19; 8:45 am]

**BILLING CODE 4164-01-P**

## 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.

**DATES:** Fax written comments on the collection of information by January 27, 2020.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202-395-7285, or emailed to [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910-0458. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-5733, [PRASStaff@fda.hhs.gov](mailto:PRASStaff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

**Biological Products: Reporting of Biological Product Deviations and Human Cells, Tissues, and Cellular and Tissue-Based Product Deviations in Manufacturing; Forms FDA 3486 and 3486A**

*OMB Control Number 0910-0458—Extension*

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 licensed 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 (parts 211, 606, and 820 (21 CFR parts 211, 606, and 820)) and current good tissue practice (CGTP) regulations (part 1271

(21 CFR part 1271)) as appropriate. FDA regards biological product deviation (BPD) reporting and HCT/P deviation reporting to be an essential tool in its directive to protect public health by establishing and maintaining surveillance programs that provide timely and useful information.

Section 600.14 (21 CFR 600.14), in brief, requires the manufacturer who holds the biological product license, for other than human blood and blood components, and who had control over a distributed product when the deviation occurred, to report to the Center for Biologics Evaluation and Research (CBER) or to the Center for Drug Evaluation and Research (CDER) as soon as possible but at a date not to exceed 45 calendar days after acquiring information reasonably suggesting that a reportable event has occurred. Section 606.171, in brief, requires licensed manufacturers of human blood and blood components, including Source Plasma, unlicensed registered blood establishments, and transfusion services, who had control over a distributed product when the deviation occurred, to report to CBER as soon as possible but at a date not to exceed 45 calendar days after acquiring information reasonably suggesting that a reportable event has occurred. Similarly, § 1271.350(b), in brief, requires HCT/P establishments that manufacture non-reproductive HCT/Ps described in § 1271.10 to investigate and report to CBER all HCT/P deviations relating to a distributed HCT/P that relates to the core CGTP requirements, if the deviation occurred in the establishment's facility or in a facility that performed a manufacturing step for the establishment under contract, agreement or other arrangement. Form FDA 3486 is used to submit BPD reports and HCT/P deviation reports.

Respondents to this collection of information are: (1) Licensed manufacturers of biological products other than human blood and blood components, (2) licensed manufacturers of blood and blood components including Source Plasma, (3) unlicensed registered blood establishments, (4) transfusion services, and (5) establishments that manufacture non-reproductive HCT/Ps regulated solely under section 361 of the PHS Act as described in § 1271.10. The number of respondents and total annual responses are based on the BPD reports and HCT/P deviation reports FDA received in fiscal year 2018. The number of licensed manufacturers and total annual responses under § 600.14 include the estimates for BPD reports submitted to

both CBER and CDER. Based on the information from industry, the estimated average time to complete a deviation report is 2 hours, which includes a minimal one-time burden to create a user account for those reports submitted electronically. The availability of the standardized report form, Form FDA 3486, and the ability to submit this report electronically to CBER (CDER does not currently accept electronic filings) further streamlines the report submission process.

CBER has developed a Web-based addendum to Form FDA 3486 (Form FDA 3486A) to provide additional information when a BPD report has been reviewed by FDA and evaluated as a possible recall. The additional information requested includes information not contained in the Form FDA 3486 such as: (1) Distribution pattern; (2) method of consignee notification; (3) consignee(s) of products for further manufacture; (4) additional product information; (5) updated product disposition; and (6) industry recall contacts. This information is requested by CBER through email notification to the submitter of the BPD report. This information is used by CBER for recall classification purposes. CBER estimates that 5 percent of the total BPD reports submitted to CBER would need additional information submitted in the addendum. CBER further estimates that it would take between 10 to 20 minutes to complete the addendum. For calculation purposes, CBER is using 15 minutes.

Activities such as investigating, changing standard operating procedures or processes, and followup are currently required under 21 CFR parts 211 (approved under OMB control number 0910-0139), 606 (approved under OMB control number 0910-0116), 820 (approved under OMB control number 0910-0073), and 1271 (approved under OMB control number 0910-0543) and, therefore, are not included in the burden calculation for the separate requirement of submitting a deviation report to FDA.

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:

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

21 CFR section	FDA form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
600.14; Reporting of product deviations by licensed manufacturers .....	3486	93	6.14	571	2.0	1,142
606.171; Reporting of product deviations by licensed manufacturers, unlicensed registered blood establishments, and transfusion services .....	3486	1,937	23.847	46,192	2.0	92,384
1271.350(b); Reporting requirements (human cells, tissues, and cellular and tissue-based products) .....	3486	93	2.61	243	2.0	486
1271.350(b) (CBER addendum report) .....	<sup>2</sup> 3486A	102	22.76	2,322	0.25	580.5
Total .....				49,328		94,592.5

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

<sup>2</sup> 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).

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.

Dated: December 10, 2019.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

[FR Doc. 2019-27791 Filed 12-23-19; 8:45 am]

**BILLING CODE 4164-01-P**

**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.

**DATES:** Comments on the ICR must be received on or before January 27, 2020.

**ADDRESSES:** Submit your comments to *OIRA\_submission@omb.eop.gov* or via facsimile to (202) 395-5806.

**FOR FURTHER INFORMATION CONTACT:** Sherrette Funn, *Sherrette.Funn@hhs.gov* or (202) 795-7714. When submitting comments or requesting information, please include the document identifier 0990-New-30D and project title for reference.

**SUPPLEMENTARY INFORMATION:** Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

*Title of the Collection:* Medical Countermeasures.gov.

*Type of Collection:* OMB No. 0990-0323—Extension—

*Abstract:* The Office of the Assistant Secretary for Preparedness and Response (ASPR), Office of the Biomedical Advanced Research and Development Authority (BARDA), is requesting an approval on an extension by OMB on a currently approved information collection.

The purpose of this collection is, in order to route product developers to the most appropriate personnel within the Department of Health and Human Services (HHS), HHS collects some basic information about the company's product through *Medical Countermeasures.gov*. Using this information and a routing system that has been developed with input from participating agencies within HHS, including the Office of the Assistant Secretary for Preparedness and Response (ASPR), the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), and the National Institutes of Health (NIH), *Medical Countermeasures.gov* routes the meeting request to the appropriate person within HHS. ASPR is requesting an extension by OMB for a three-year clearance.

*Type of respondent:* Developers of medical countermeasures to naturally occurring and intentional public health threats visit the site on a monthly basis.

**ANNUALIZED BURDEN HOUR TABLE**

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

**Terry Clark,**

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

[FR Doc. 2019-27753 Filed 12-23-19; 8:45 am]

**BILLING CODE 4150-04-P**