

to disclose an actual or potential violation of section 1877 of the Act was posted on the CMS Web site. The most recent approval of this information collection request ("ICR") was issued by the Office of Management and Budget on August 26, 2014.

We are now seeking approval to revise the currently approved ICR. Under the currently approved collection, a party must provide a financial analysis of overpayments arising from actual or potential violations of section 1877 of the Act based on a 4-year lookback period. On February 12, 2016, CMS published a final rule on the reporting and returning of overpayments. See CMS-6037-F, Medicare Program; Reporting and Returning of Overpayments, 81 FR 7654 (Feb. 12, 2016) (the "final overpayment rule"). The final overpayment rule establishes a 6-year lookback period for reporting and returning overpayments. We are revising the information collection for the SRDP to reflect the 6-year lookback period established by the final overpayment rule. The revision is necessary to ensure that parties submitting self-disclosures to the SRDP report overpayments for the entire 6-year lookback period. The 6-year lookback period applies *only* to submissions to the SRDP received *on or after* March 14, 2016, the effective date of the final overpayment rule; parties submitting self-disclosures to the SRDP prior to March 14, 2016 need only provide a financial analysis of potential overpayments based on a 4-year lookback period.

We are also taking the opportunity to streamline and simplify the SRDP by issuing a required form for SRDP submissions. The SRDP Form will reduce the burden on disclosing parties by reducing the amount of information that is required for submissions to the SRDP and providing a streamlined and standardized format for the presentation of the required information. *Form Number:* CMS-10328 (OMB control number: 0938-1106); *Frequency:* Annually and semi-annually; *Affected Public:* Private sector (Business or other for-profits and Not-for-profits); *Number of Respondents:* 200; *Total Annual Responses:* 200; *Total Annual Hours:* 5,000. (For policy questions regarding this collection contact Matt Edgar at 410-786-0698).

Dated: September 2, 2016.

**William N. Parham, III,**

*Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2016-N-0001]

#### Blood Products Advisory Committee 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 Blood Products Advisory 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 November 17, 2016, from 8 a.m. to 5:30 p.m. and on November 18, 2016, from 8:30 a.m. to 1 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: <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm>.

#### FOR FURTHER INFORMATION CONTACT:

LCDR Bryan Emery or Joanne Lipkind, Division of Scientific Advisors and Consultants, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, Bldg. 71, Rm. 6132, at 240-402-8054, [bryan.emery@fda.hhs.gov](mailto:bryan.emery@fda.hhs.gov) and 240-402-8106, [joanne.lipkind@fda.hhs.gov](mailto:joanne.lipkind@fda.hhs.gov), respectively, 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 Web site at <http://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. For those unable to attend in person, the meeting will also be

available via Webcast. The Webcast will be available at the following link for both days: <https://collaboration.fda.gov/bpac1116/>.

#### SUPPLEMENTARY INFORMATION:

**Agenda:** On the morning of November 17, 2016, the Committee will meet in open session to discuss strategies to manage iron deficiency associated with blood donation. The Committee will also discuss proposed procedures for assuring donor safety for collections of blood from female donors with hemoglobin values of 12.0–12.4g/dL or a hematocrit value between 36 and 38. In the afternoon, the Committee will meet in open session to discuss adverse reactions related to blood donation in teenage (16 to 18 years) donors, and the effectiveness of several mitigation measures. On November 18, 2016, the Committee will meet in open session to hear an informational session on Zika virus and blood safety in the United States. Following the informational session, the Committee will hear presentations on the following topics: (1) The Transfusion Transmissible Infections Monitoring System; (2) a summary of the FDA workshop on new methods to predict the immunogenicity of therapeutic coagulation proteins; and (3) a summary of the FDA workshop on preclinical evaluation of red blood cells for transfusion.

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 Web site 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 Web site after the meeting. Background material is available at <http://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 November 4, 2016. Oral presentations from the public will be scheduled between approximately 11 a.m. to 11:45 a.m. and 4 p.m. to 4:30 p.m. on November 17, 2016. Oral presentations from the public will also be scheduled between approximately 10:30 a.m. and 11 a.m. and 12:30 p.m. to 1 p.m. on November 18, 2016. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief

statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before October 27, 2016. 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 October 28, 2016.

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 Bryan Emery or Joanne Lipkind at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://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: September 2, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2009-D-0600]

#### Health Document Submission Requirements for Tobacco Products; Revised Draft Guidance for Industry; Availability

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

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA or we) is announcing the availability of a revised draft guidance for industry entitled

“Health Document Submission Requirements for Tobacco Products.” The revised draft guidance is intended to assist persons making certain document submissions to FDA as required by the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act).

**DATES:** Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment of this revised draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by October 11, 2016.

**ADDRESSES:** You may submit comments as follows:

#### *Electronic Submissions*

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://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 <http://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-2009-D-0600 for “Health Document Submission Requirements for Tobacco Products.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <http://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 <http://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: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://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.

Submit written requests for single copies of the revised draft guidance to the Center for Tobacco Products, Food and Drug Administration, Document Control Center, Bldg. 71, Rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993-2000. Send two self-addressed adhesive labels to assist that office in processing your requests. See