

MD 20993–0002. Information about becoming a member on an FDA advisory committee can also be obtained by visiting FDA's website at <https://www.fda.gov/AdvisoryCommittees/default.htm>.

**FOR FURTHER INFORMATION CONTACT:**

Regarding all nomination questions for membership, the primary contact is: Yvette Waples, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002; 301–796–9001, Fax: 301–847–8533, email: [PCAC@fda.hhs.gov](mailto:PCAC@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** FDA seeks to include the views of women and men, members of all racial and ethnic groups, and individuals with and without disabilities on its advisory committees and, therefore, encourages nominations of appropriately qualified candidates from these groups.

FDA is requesting nominations for voting members on the Pharmacy Compounding Advisory Committee.

**I. General Description of the Committee's Duties**

The Committee provides advice on scientific, technical, and medical issues concerning human drug compounding under sections 503A and 503B of the FD&C Act (21 U.S.C 353a and 353b), and, as required, any other product for which FDA has regulatory responsibility, and makes appropriate recommendations to the Commissioner of Food and Drugs.

In implementing sections 503A and section 503B of the FD&C Act, the Agency may consult the Committee on: (1) Drug products for inclusion on a list of drug products that have been withdrawn or removed from the market because such drug products or components of such drug products have been found to be unsafe or not effective, and therefore cannot be compounded; (2) bulk drug substances for inclusion on lists of bulk drug substances that may be used in compounding; and (3) drug products for inclusion on a list of drug products that present demonstrable difficulties for compounding.

Meetings are held approximately one to two times a year, announced in the **Federal Register**, and are open to the public except as determined otherwise by the Commissioner or designee in accordance with the Government in the Sunshine Act (5 U.S.C. 552b(c)) and the Federal Advisory Committee Act (Pub. L. 92–463). Notice of all meetings shall be given to the public.

**II. Criteria for Voting Members**

The Committee consists of a core of 12 voting members including the Chair. Members and the Chair are selected by the Commissioner or designee from among authorities knowledgeable in the fields of pharmaceutical compounding, pharmaceutical manufacturing, pharmacy, medicine, and related specialties. These members will include representatives from the National Association of Boards of Pharmacy, the U.S. Pharmacopeia, pharmacists with current experience and expertise in compounding, physicians with background and knowledge in compounding, and patient and public health advocacy organizations. Almost all non-Federal members of this committee serve as Special Government Employees. Members will be invited to serve for terms of up to 4 years.

**III. Nomination Procedures**

Any interested person may nominate one or more qualified individuals for membership on the advisory committee. Self-nominations are also accepted. Nominations must include a current, complete résumé or curriculum vitae for each nominee, including current business address and/or home address, telephone number, and email address if available, and a signed copy of the Acknowledgement and Consent form available at the FDA Advisory Committee Nomination Portal (see **ADDRESSES**). Nominations must also specify the advisory committee for which the nominee is recommended. Nominations must also acknowledge that the nominee is aware of the nomination unless self-nominated. FDA will ask potential candidates to provide detailed information concerning such matters related to financial holdings, employment, and research grants and/or contracts to permit evaluation of possible sources of conflicts of interest.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: June 11, 2020.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

[FR Doc. 2020–13042 Filed 6–16–20; 8:45 am]

**BILLING CODE 4164–01–P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA–2015–D–1211]

**Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products; Guidance for Industry; Availability**

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

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance entitled “Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products; Guidance for Industry.” The revised guidance provides blood establishments that collect blood or blood components, including Source Plasma, with FDA's revised donor deferral recommendations for individuals with increased risk for transmitting human immunodeficiency virus (HIV) infection. FDA is also recommending that these blood establishments make corresponding revisions to their donor educational materials, donor history questionnaires, and accompanying materials, along with revisions to donor requalification and product management procedures. The guidance also incorporates certain other recommendations related to donor educational materials. The guidance announced in this notice supersedes the guidance of the same title dated December 2015.

**DATES:** The announcement of the guidance is published in the **Federal Register** on June 17, 2020.

The Agency is soliciting public comment, but is implementing this guidance immediately, because the Agency has determined that prior public participation is not feasible or appropriate. Submit either electronic or written comments on Agency guidances at any time.

**ADDRESSES:** You may submit either electronic or written comments on Agency guidances at any time 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](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 <https://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):* 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-2015-D-1211 for "Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products; Guidance for Industry." Received comments 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, 240-402-7500.

- **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 <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. 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: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

**Docket:** For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://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 Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115 (§ 10.115(g)(5))).

Submit written requests for single copies of the guidance to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 240-402-8010. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

#### **FOR FURTHER INFORMATION CONTACT:**

Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993-0002, 240-402-7911.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

FDA is announcing the availability of a document entitled "Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products; Guidance for Industry." This document was posted on FDA's website

on April 2, 2020 (see section III for electronic access to the guidance). The revised guidance provides blood establishments that collect blood or blood components, including Source Plasma, with FDA's revised donor deferral recommendations for individuals with increased risk for transmitting HIV infection. FDA is also recommending that these blood establishments make corresponding revisions to their donor educational materials, donor history questionnaires, and accompanying materials, along with revisions to donor requalification and product management procedures. The guidance also incorporates certain other recommendations related to donor educational materials. FDA expects implementation of these revised recommendations will not be associated with any adverse effect on the safety of the blood supply. Furthermore, implementation of the recommendations in this guidance may help to address significant blood shortages that are occurring as a result of a current and ongoing Coronavirus Disease 2019 (COVID-19) public health emergency. The guidance announced in this notice supersedes the guidance of the same title dated December 2015.

In light of the COVID-19 public health emergency, FDA is issuing this guidance for immediate implementation in accordance with § 10.115(g)(3) without initially seeking prior comment because the Agency has determined that prior public participation is not feasible or appropriate (see § 10.115(g)(2) and section 701(h)(1)(C)(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371(h)(1)(C)(i))). FDA expects that the revised recommendations will increase the availability of blood and blood components while maintaining the safety of blood and blood components.

This guidance is being issued consistent with FDA's good guidance practices regulation (§ 10.115(g)(2)). The guidance represents the current thinking of FDA on "Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products." It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

##### **II. Paperwork Reduction Act of 1995**

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–

3520). The collections of information in 21 CFR part 601 have been approved under OMB control number 0910–0338; the collections of information in 21 CFR parts 610, 630, and 640 have been approved under OMB control number 0910–0116; and the collections of information for consignee notification have been approved under OMB control number 0910–0681.

### III. Electronic Access

Persons with access to the internet may obtain the guidance at either <https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances>, <https://www.fda.gov/emergency-preparedness-and-response/mcm-issues/covid-19-related-guidance-documents-industry-fda-staff-and-other-stakeholders>, or <https://www.regulations.gov>.

Dated: June 12, 2020.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

[FR Doc. 2020–13051 Filed 6–16–20; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2014–N–0086]

#### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Potential Tobacco Product Violations Reporting Form

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or the Agency) 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 (PRA).

**DATES:** Submit written comments (including recommendations) on the collection of information by July 17, 2020.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to <https://www.reginfo.gov/public/do/PRAMain>. Find this particular information collection by selecting “Currently under Review—Open for Public Comments” or by using the search function. The OMB control number for this information

collection is 0910–0716. Also include the FDA docket number found in brackets in the heading of this document.

#### FOR FURTHER INFORMATION CONTACT:

JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794, [PRAStaff@fda.hhs.gov](mailto:PRAStaff@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.

#### Potential Tobacco Product Violations Reporting

*OMB Control Number 0910–0716—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 section 201 *et seq.* of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 321 *et seq.*) by adding a new chapter granting FDA important new authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health generally and to reduce tobacco use by minors. FDA is requesting an extension of OMB approval for the collection of information to accept consumer and other stakeholder feedback and notification of potential violations of the FD&C Act, as amended by the Tobacco Control Act.

The public is crucial in helping FDA enforce tobacco regulations to protect America’s youth. FDA created the Tobacco Call Center (with a toll-free number: 1–877–CTP–1373) to assist the public with reporting potential violations of the Tobacco Control Act. FDA will evaluate any information reported and may conduct followup investigations if necessary. When callers report a violation, the caller will be asked to provide as much certain information as they can recall, including: The date the potential violation occurred; product type (e.g., cigarette, smokeless, roll-your-own, cigar, e-cigarette, hookah, pipe tobacco); tobacco brand; potential violation type; type of potentially violative promotional materials; who potentially violated, including the name, address, phone number, and email address of the potential violator. The caller will also be asked to list the potential violator’s website (if available), describe the potential violation, and provide any

additional files or information pertinent to the potential violation.

FDA currently provides a form that may be used to solicit this information from the public (Form FDA 3779, Potential Tobacco Product Violations Report) and seeks renewal of Form FDA 3779. The public and interested stakeholders are able to report information regarding possible violations of the Tobacco Control Act by submitting information online, via email, postal mail, or by calling FDA’s Tobacco Call Center. Instructions on how to report possible violations of the Tobacco Control Act can be found at (<https://www.fda.gov/tobacco-products/compliance-enforcement-training/report-potential-tobacco-product-violation>).

In the **Federal Register** of October 15, 2019 (84 FR 55161), FDA published a 60-day notice requesting public comment on the proposed collection of information. Two PRA related comments were received.

(Comment 1) FDA received a comment urging the Agency to publicize the availability of the Potential Tobacco Product Violations Report (PTVR) form more broadly. The comment further urged that if FDA does not already have a dissemination plan for this information collection actively, it must create one because it is important that consumers, retailers, and other stakeholders are aware of this form in order to be most helpful. The comment indicated that it is important that FDA disseminate the violations reporting form more broadly to the public so people are aware of how they can report the various types of violations.

(Response) There are multiple options available for industry and the public to report potential violations of the Tobacco Control Act, and FDA has publicized the form on multiple occasions, including when the FDA Commissioner issued public statements regarding the youth vaping epidemic and potential electronic nicotine delivery systems-related seizures. FDA’s website (<https://www.fda.gov/tobacco-products/compliance-enforcement-training/report-potential-tobacco-product-violation>) has a link to submit the online PTVR form (<https://www.accessdata.fda.gov/scripts/ptvr/index.cfm>).

As referenced previously in this notice, there are many additional options for submission, which can be found at <https://www.fda.gov/tobacco-products/compliance-enforcement-training/report-potential-tobacco-product-violation>.

(Comment 2) FDA received a comment which stated that the original