**SUPPLEMENTARY INFORMATION:**

*Agenda:* On April 16, 2020, the committee will discuss, make recommendations, and vote on information regarding the premarket approval application (PMA) for the TransMedics Organ Care System (OCS)—Heart, by TransMedics, Inc. The proposed Indication for Use for the TransMedics OCS—Heart, as stated in the PMA, is as follows:

The TransMedics Organ Care System (OCS) Heart System is a portable ex-vivo organ perfusion and monitoring system indicated for the resuscitation, preservation, and assessment of donor hearts with one or more of the following characteristics for transplantation into a potential recipient in a near-physiologic, normothermic, and beating state:

- Expected cross-clamp or ischemic time ≥4 hours due to donor or recipient characteristics (*e.g.,* donor-recipient geographical distance, expected recipient surgical time)
- Donor age ≥55 years
- Donors with history cardiac arrest and downtime ≥20 minutes
- Donor history of alcohol use
- Donor LV ejection fraction (LVEF) ≤50% but ≥40%
- Donor history of left ventricular hypertrophy (septal or posterior wall thickness of >12 ≤16 mm)

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 April 9, 2020. Oral presentations from the public will be scheduled on April 16, 2020, between approximately 1 p.m. and 2 p.m. 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 April 1, 2020. 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 April 2, 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 AnnMarie Williams at *Annmarie.Williams@fda.hhs.gov* or 301–796–5966 at least 7 days in advance of the meeting.

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: March 9, 2020.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

[FR Doc. 2020–05132 Filed 3–12–20; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2001–D–0007 (formerly Docket No. 2001D–0221)]**

### Biological Product Deviation Reporting for Blood and Plasma Establishments; Guidance for Industry; Availability

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

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA, Agency, or we) is announcing the availability of a revised final guidance entitled ''Biological Product Deviation Reporting for Blood and Plasma Establishments; Guidance for Industry.'' The final guidance document provides blood and plasma establishments with revised recommendations related to biological product deviation (BPD) reporting. The guidance is intended to assist blood and plasma establishments in determining when a report is required, who submits the report, what information to submit in the report, the timeframe for reporting, and how to submit the report. The revised guidance explains that we do not consider post donation information (PDI) events to require BPD reports. The revised guidance also contains other technical updates and editorial revisions to improve clarity and provide a more streamlined document. For the purposes of this guidance, ''blood and plasma establishment'' includes licensed manufacturers of blood and blood components, including Source Plasma, unlicensed registered blood establishments, and transfusion services. The guidance announced in this notice supersedes the document entitled ''Guidance for Industry: Biological Product Deviation Reporting for Blood and Plasma Establishments,'' dated October 2006.

**DATES:** 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. The announcement of the guidance is published in the **Federal Register** on March 13, 2020.

**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* 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–2001–D–0007 for ''Biological Product Deviation Reporting for Blood and Plasma Establishments; 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.

- 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.

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

Submit written requests for single copies of the final guidance to the Office of Communication, Outreach, and Development, Center for Biologics Evaluation and Research, 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 that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to guidance document.

**FOR FURTHER INFORMATION CONTACT:** Tami Belouin, 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 revised document entitled ''Biological Product Deviation Reporting for Blood and Plasma Establishments; Guidance for Industry.'' The final guidance document provides blood and plasma establishments with revised recommendations related to BPD reporting. The guidance is intended to assist blood and plasma establishments in determining when a report is required, who submits the report, what information to submit in the report, the timeframe for reporting, and how to submit the report. The revised guidance explains that we do not consider PDI events to require BPD reports. The revised guidance also contains other technical updates and editorial revisions to improve clarity and provide a more streamlined document. For the purposes of this guidance, ''blood and plasma establishment'' includes licensed manufacturers of blood and blood components, including Source Plasma, unlicensed registered blood establishments, and transfusion services. The guidance announced in this notice supersedes the document entitled ''Guidance for Industry: Biological Product Deviation Reporting for Blood and Plasma Establishments,'' dated October 2006.

FDA is also announcing the withdrawal of two obsolete memoranda to blood establishments entitled ''Responsibilities of Blood Establishments Related to Errors and Accidents in the Manufacture of Blood and Blood Components,'' issued March 20, 1991, and ''Guidance Regarding Post Donation Information Reports,'' issued December 10, 1993.

The revised guidance explains that we do not consider PDI events to require BPD reports under § 606.171 (21 CFR 606.171) because these events are no longer unexpected or unforeseeable based on 18 years of data, which show that more than 18,000 reports of PDI events have been submitted to FDA each fiscal year (FY) for the past 18 years.

Every year, the Center for Biologics Evaluation and Research (CBER) receives thousands of BPD reports of events associated with manufacturing, to include testing, processing, packing, labeling, or storage, or with the holding or distribution of both licensed and unlicensed blood or blood components, including Source Plasma. Such an event is reportable under § 606.171 if certain criteria are met, including that the event either: (1) Represents a deviation from current good manufacturing practice (CGMP), applicable regulations, applicable standards, or established specification that may affect the safety, purity, or potency of the product; or (2) represents an unexpected or unforeseeable event that may affect the safety, purity, or potency of the product. The Agency's BPD reporting program is one of the post-market surveillance tools that CBER uses to monitor blood manufacturing and to detect potential blood safety issues.

One type of BPD report received by FDA from blood establishments involves PDI events. PDI includes information that a donor, or other reliable source, provides to a blood establishment following a donation (*e.g.,* at a subsequent donation) that would have resulted in donor deferral had it been known by the establishment at the time of donation. In these situations, the relevant donor screening questions were asked at the original donation, but the donor did not provide the information at that time.

In the **Federal Register** of November 7, 2000 (65 FR 66635), FDA issued a final rule to amend the regulations for biological product deviation reporting. In the October 2006 guidance, ''Biological Product Deviation Reporting for Blood and Plasma Establishments,'' FDA explained that it considered PDI events to be ''unexpected or

unforeseeable'' events for purposes of BPD reporting (see § 606.171(b)(1)(ii)). Accordingly, establishments have been submitting BPD reports regarding PDI that may affect the safety, purity, or potency of a distributed product. PDI events continue to be reported, and the numbers have increased over time. Reports of PDI events have consistently been the highest number of reports received from blood establishments, representing a significant burden to industry and FDA. For example, from FYs 2000 through 2017, FDA has received approximately 18,000 to 40,000 PDI reports each year. The total number of PDI reports submitted by blood establishments in FY 2017 was 37,265 of 51,434 total BPD reports, representing approximately 72 percent of all BPD reports submitted by blood establishments. In reviewing the data for the past 18 years, based on the extraordinarily high number of PDI reports, FDA has concluded that PDI events are no longer ''unexpected or unforeseeable,'' and will likely continue to occur. Because PDI events are no longer ''unexpected or unforeseeable,'' and also do not represent deviations from CGMP, applicable regulations, applicable standards, or established specifications, such events are not reportable under § 606.171.

FDA is issuing this guidance for immediate implementation in accordance with § 10.115(g)(3) (21 CFR 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)). Specifically, we made this determination because this guidance presents a less burdensome policy for reporting BPDs that is consistent with public health. It eliminates the reporting of PDI events as BPD reports because these reports are no longer unexpected or unforeseeable based on PDI data for the past 18 years, without compromising public health protections.

This guidance is expected to significantly reduce the BPD reporting burden on industry and the burden on FDA to review these reports. Based on the above FY 2017 PDI data, FDA expects that the elimination of PDI reports will result in a 72 percent reduction in total BPD reports received (elimination of 37,265 of 51,434 total reports in FY 2017). FDA anticipates that this will substantially and proportionally reduce the blood industry's estimated annual reporting burden under § 606.171, which FDA recently estimated to be 92,384 total annual hours (84 FR 70979 at 70981; December 26, 2019). The revised recommendations are also consistent with public health.

Given the substantial number of PDI reports FDA has received, the Agency is aware that these events occur, and the submission of additional PDI reports to FDA is unlikely to facilitate the identification of manufacturing or safety issues. PDI events are not associated with deviations from CGMP or other requirements, and blood establishments generally have no control over information provided by donors or third parties subsequent to a donation. Eliminating PDI reports will enable blood establishments and FDA to prioritize resources on BPD reports that are more likely to inform corrective actions to protect the public health. Additionally, blood establishments are required to comply with applicable regulations regarding, among other things, establishing, maintaining, and following standard operating procedures (SOPs) (see § 606.100(b) (21 CFR 606.100(b)) and maintaining records (see § 606.160 (21 CFR 606.160)). FDA will continue to assess SOPs and records associated with PDI events during routine inspections of blood establishments. Thus, this revised guidance presents a less burdensome policy for reporting PDI events that is consistent with public health.

This guidance is being issued consistent with FDA's good guidance practices regulation (§ 10.115). 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. The guidance represents the current thinking of FDA on biological product deviation reporting for blood and plasma establishments. 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 FDA collections of information. 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. 3501–3521). The collections of information under §§ 600.14 and 606.171 were approved under OMB control number 0910–0458; the collections of information under §§ 606.100 and 606.160 were approved under OMB control number 0910–0116; the collections of information under 21 CFR 211.192 and 211.198 were approved under OMB control number 0910–0139; and the collections of information under 21 CFR 601.12 were approved under OMB control number 0910–0338.

## 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* or *https://www.regulations.gov.*

Dated: March 9, 2020.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

[FR Doc. 2020–05103 Filed 3–12–20; 8:45 am]

**BILLING CODE 4164–01–P**

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2018–D–4711]**

### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Nonbinding Feedback After Certain Food and Drug Administration Inspections of Device Establishments

**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 (PRA).

**DATES:** Fax written comments on the collection of information by April 13, 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 *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–NEW and title ''Nonbinding Feedback After Certain FDA Inspections of Device Establishments.'' Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Amber Sanford, Office of Operations,