learn how data plays a critical role in this Administration's priorities.

Procedures for Attendance and Public Comment

Register to attend the public meeting via the CDO Council website at *https://www.cdo.gov/public-meeting-2023/.* Attendees must register by 5 p.m. ET, on Tuesday, February 7, 2023. (GSA will be unable to provide technical assistance to attendees during the meeting.)

Accommodations

This meeting will include American Sign Language (ASL) interpretation as well as captioning services. Meeting materials will be posted to the meeting website in advance of the meeting. To request additional accommodations for a disability, please contact *cdocstaff@gsa.gov* at least seven (7) calendar days prior to the meeting to allow as much time as possible to process your request.

Background

The Chief Data Officers (CDO) Council was established in accordance with the requirements of the Foundations for Evidence-Based Policymaking Act of 2018 (Pub. L. 115–435). The Council's vision is to improve Government mission achievement and increase the benefits to the Nation through improvement in the management, use, protection, dissemination, and generation of data in Government decision-making and operations.

February 10, 2023 Meeting Agenda

- Call to Order and Logistics
- Welcome and CDO Council Accomplishments from the Chief Data Officers (CDO) Council Chair
- CDO Council, CDOs and Implementation of the Evidence Act
- Federal Data and the Evolving Role of the Federal CDO
- Panel Discussion: Driving Results for the People
- Public Comments and Questions
- Panel Discussion: Teamwork makes the Dream work—Collaboration Driving Success
- Panel Discussion: Supporting Operational Relevance
- The Power of Data for Improving Diversity, Equity, Inclusion, and Accessibility
- Closing Remarks

Ashley Jackson,

Senior Advisor CDO Council, Office of Shared Solutions and Performance Improvement, General Services Administration.

[FR Doc. 2023–00054 Filed 1–5–23; 8:45 am]

BILLING CODE 6820–14–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0545]

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 Product Deviations in Manufacturing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) 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: Submit written comments (including recommendations) on the collection of information by February 6, 2023.

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 0910–0458. 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, *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.

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 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 human cells, tissues, and cellular and tissue-based product (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 (21 CFR 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) (21 CFR 1271.350(b)), in brief, requires HCT/P establishments that manufacture non-

reproductive HCT/Ps described in § 1271.10 (21 CFR 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 (FY) 2021. 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 3 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 and 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 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 June 17, 2022 (87 FR 36512), we published a 60-day notice soliciting comment on the proposed collection of information. No comments were received.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section; activity	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	103	6.864	707	2	1,414
606.171; Reporting of product deviations by licensed manufacturers, unlicensed registered blood establishments, and transfusion services.	3486	2,008	6.883	13,821	2	27,642
1271.350(b); HCT/P deviations	3486	80	2.575	206	2	412
Web-based Addendum	[2] 3486A	66	6.69	442	0.25 (15 minutes)	110.5
Total				15,176		29,578.5

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Three percent of the number of respondents ((2,008 + 103 + 80) × 0.03 = 66) and total annual responses to CBER ((13,821 + 707 + 206) × 0.03 = 442).

Our estimated burden for the information collection reflects an overall decrease of approximately 65,014 hours and a corresponding decrease of 34,152 responses. We attribute this adjustment to a decrease in the number of deviation reports we received in FY 2021 from licensed manufacturers and unlicensed registered blood establishments under § 606.171. This is likely due to our issuance of the revised guidance document entitled ''Biological Product Deviation Reporting for Blood and Plasma Establishments'' (85 FR 14682, March 13, 2020), which provided blood and plasma establishments with revised recommendations related to BPD reporting. The revised guidance provided a less burdensome policy for reporting BPDs that is consistent with public health and eliminated the reporting of post donation information (PDI) events as BPD reports because these reports were no longer unexpected or unforeseeable. 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.

Dated: January 3, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–00013 Filed 1–5–23; 8:45 am]

BILLING CODE 4164–01–P