UNITED STATES FOOD & DRUG ADMINISTRATION

Reporting of Biological Product Deviations and Human Cells, Tissues, and Cellular and Tissue-Based Product Deviations in Manufacturing

OMB Control No. 0910-0458 – Reinstatement without change

SUPPORTING STATEMENT **Part A – Justification**:

1. Circumstances Making the Collection of Information Necessary

This information collection supports certain biological product reporting. The FDA has established implementing regulations in 21 CFR parts 211, 606, and 820, as well as current good tissue practice (CGTP) regulations in 21 CFR part 1271, that prescribe certain reporting requirements. Specifically, manufacturers who hold a biological product license and have control over a product when a deviation or unexpected event associated with its manufacturing occurs must submit Biological Product Deviation Reports (BPDRs) to FDA within a prescribed time schedule and in accordance with established criteria. We maintain resource information on our website, including the guidance document entitled, "Biological Product Deviation Reporting for Licensed Manufacturers of Biological Products Other than Blood and Blood Components" (October 2006), to help respondents understand the applicable statutory and regulatory requirements. We have also developed Forms FDA 3486 and 3486A (*Biological Product Deviation* Report and a web-based Addendum) for submitting the data elements required under the applicable regulations. The forms are completed and submitted electronically, although paper-based forms may be utilized in certain circumstances.

We therefore request an extension of approval for the information collection provisions discussed in this supporting statement and found in applicable Forms FDA 3486 and FDA 3486A.

2. Purpose and Use of the Information Collection

Establishments manufacturing biological products must comply with applicable CGMP regulations or may be subject to regulatory action. Reporting of BPDs and HCT/P deviations also enables FDA to identify areas in which further regulation or guidance is needed to assist in decreasing the occurrence of these events.

3. Use of Improved Information Technology and Burden Reduction

To facilitate prompt processing of all incoming BPDRs, we recommend using FDA Form 3486. We provide general instructions on our website at General Recommendations for Completing CDER-Regulated Biological Product Deviation Report (BPDR) and General Instructions for Form FDA 3486. Though the electronic form is strongly encouraged, we also communicate that the form can be mailed to:

Food and Drug Administration, CDER
Office of Pharmaceutical Quality
Office of Quality Surveillance
Attn: CDER DQRS Reports – BPDR Assessment
10903 New Hampshire Ave. Bldg. 75, Rm 6654
Silver Spring, MD 20993-0002

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection. Although FDA has established information collection requests supporting regulations in part 211 (21 CFR 211 currently approved under OMB Control No. 0910-0139); part 600 (21 CFR 600, currently approved under OMB Control No. 0910-0308); and part 1271 (21 CFR 1271, currently approved under OMB Control No. 0910-0453); this information collection specifically supports reporting associated with biological product deviations as described in the applicable regulations and included in our burden analysis at Question 12.

5. Impact on Small Businesses or Other Small Entities

The information collection poses no undue burden on small entities.

6. Consequences of Collecting the Information Less Frequently

The information collection schedule is consistent with statutory and regulatory requirements. There are no technical or legal obstacles to reducing the burden.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

Reporting may occur more frequently than quarterly, as necessary to comply with statutory requirements governing the protection of the public health as it pertains to certain biological products..

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

In accordance with 5 CFR 1320.8(d), FDA published a 60-day notice for public comment in the *Federal Register* of February 25, 2026 (91 FR 9287), FDA published a 60-day notice requesting public comment on the proposed collection of information. One comment raised concerns about the long-term safety of amniotic membrane-based products and whether additional toxicological information, including long-term carcinogenicity, should be considered, as discussed in related agency guidance. No adjustments were made upon considering the comment.

9. Explanation of Any Payment or Gift to Respondents

No payment or gift is provided to respondents.

10. Assurance of Confidentiality Provided to Respondents

The Privacy Act of 1974

In preparing this supporting statement, we consulted with our Privacy Office to ensure appropriate handling of information collected. The ICR collects personally identifiable information (PII), the PII in the context of the subject individuals' professional capacity and the FDA-related work performed for their employer (e.g., point of contact at a regulated entity). The PII submitted via Form FDA 3486 (Biological Product Deviation Report) is name, telephone number, and email. The PII submitted via Form FDA 3486A (Addendum) is name, address, telephone number, and email. Both forms are accessed using FDA Unified Registration and Listing System (FURLS) which collects account ID/username, password, name, address, mailing address, telephone number, fax number, email address for account set up. We have determined that, although PII is collected, the collection is not subject to the Privacy Act of 1974 and the particular notice and other requirements of the Privacy Act do not apply. Specifically, FDA does not use name or any other personal identifier to retrieve records from the information collected. Through appropriate form design, FDA limits submission fields and minimizes the PII collected to protect the privacy of the individuals.

The Freedom of Information Act

Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), the public has broad access to government documents. However, FOIA provides certain exemptions from mandatory public disclosure of government records (5 U.S.C. 552(b)(1-9)). FDA will make the fullest possible disclosure of records to the public, consistent with the rights of individuals to privacy, the property rights of persons in trade and confidential commercial or financial information

11. Justification for Sensitive Questions

No questions of a sensitive nature are included in the information collection.

12. Estimates of Annualized Burden Hours and Costs

12a. Annualized Hour Burden Estimate

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) 2024. 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.

Estimated Annual Reporting Burden[1]

21 CFR Section	Form Number	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
600.14 Reporting of product deviations by licensed manufacturers	3486	70	7.186	503	2.0	1,006
606.171 Reporting of product deviations by licensed manufacturers, unlicensed registered blood establishments and transfusion services	3486	2,455	6.630	16,277	2.0	32,554
1271.350(b) Reporting requirements (human cells tissues and cellular and tissue-based products)	3486	86	2.465	212	2.0	424
1271.350(b) CBER addendum report	3486A[2]	127	6.50	826	0.25	207
Total				17,818		34,191

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Five percent of the number of respondents ((2,455 + 86) × 0.05 = 127).

Activities such as investigating, changing standard operating procedures or processes, and follow up 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. To determine reports submitted using Form FDA 3486A, we calculate three percent (3%) of the number of respondents (2,008+103+80) x 0.03 = 66) and assume 15 minutes is required for each submission.

12b. Annualized Cost Burden Estimate

We estimate an annualized cost to respondents of $1,478,925, as reflected below:

Activity	Total Burden Hours	Hourly Wage Rate	Total Cost
Reporting	34,191	$50	$1,709,550

Out estimated cost assumes a pay rate of $50 per hour for a mid-level professional who has the training and skills to handle the various reporting requirements. This salary estimate includes benefits but no overhead costs. There should not be any additional costs of investigating BPDs

and HCT/P deviations or keeping records of them, since these activities are already required under other sections in 21 CFR Parts 211, 606, 820, and 1271.

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/Capital Costs

There are no capital costs or operating and maintenance costs associated with this collection of information.

14. Annualized Cost to the Federal Government

We estimate an annualized cost to FDA of $285,460.56. Using the total number of annual submissions (15,176), and assuming 20 minutes per submission for reviewing, assessing, and recording information, we factored these figures by an average hourly pay rate of $57.00, representing pay for an employee at the GS/13-5 level in the Washington DC/Metro Area.

15. Explanation for Program Changes or Adjustments

16. Plans for Tabulation and Publication and Project Time Schedule

Information collected will not be tabulated or published.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

Display of OMB expiration date is appropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.