DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

BIOLOGICAL PRODUCT DEVIATION REPORT

FDA USE ONLY
Date Received:
Date Reviewed:
BPD ID:
BPD No.

* Indicates required information

A. FACILITY INFORMATION

1. Reporting Establishment Information

* Reporting Establishment Name

***** Street Address Line 1

Street Address Line 2

***** City | * State

Country | ***** Zip Code

***** Point of Contact

***** Telephone #

E-mail

2. * Reporting Establishment Identification Number

FDA Registration #

CLIA #

3. If the BPD occurred somewhere other than the above facility, please complete this Section and Section A4; otherwise, continue on to Section B1.

* Establishment Name

Street Address Line 1

Street Address Line 2

***** City | * State

* Country | Zip Code

4. Establishment Identification Number

FDA Registration #

CLIA #

B. BIOLOGICAL PRODUCT DEVIATION (BPD) INFORMATION

1. Establishment Tracking #
2. Date BPD Occurred
3. ***** Date BPD Discovered
4. ***** Date BPD Reported
5. * Description of BPD *(use Page 2 for additional space)*
6. * Description of Contributing Factors or Root Cause *(use Page 3 for additional space)*
7. * Follow-Up *(use Page 4 for additional space)*
8. * Please Enter the 6 Character BPD Code

☐☐ ☐☐ ☐☐

C. UNIT / PRODUCT INFORMATION

Please check the type of product:

Blood ☐ (Continued on Page 5)

Non-Blood ☐ (Continued on Page 6)

Form Approved:
OMB No. 0910-0458
Expires: 2/28/2026

PSC Publishing Services (301) 443-6740 EF

See PRA Statement on Page 8.

Biological Product Deviation Report

B5. DESCRIPTION OF BPD *(continued)*

Biological Product Deviation Report

B6. DESCRIPTION OF CONTRIBUTING FACTORS OR ROOT CAUSE *(continued)*

Biological Product Deviation Report

B7. FOLLOW-UP *(continued)*

Biological Product Deviation Report

C1. BLOOD PRODUCTS / COMPONENTS

TOTAL NUMBER OF UNITS: _____

	Unit #	Collection Date *(MM/DD/YYYY)*	Expiration Date *(MM/DD/YYYY)*	Product Code	Disposition	Notification *(Y,N,RN)*
1.)						
2.)						
3.)						
4.)						
5.)						
6.)						
7.)						
8.)						
9.)						
10.)						
11.)						
12.)						
13.)						
14.)						
15.)						
16.)						
17.)						
18.)						

Biological Product Deviation Report

C2. NON-BLOOD PRODUCTS

TOTAL NUMBER OF LOTS: _____

	Lot #	Expiration Date *(MM/DD/YYYY)*	Product Type	Product Code	Disposition	Notification *(Y,N)*
1.)						
2.)						
3.)						
4.)						
5.)						
6.)						
7.)						
8.)						
9.)						
10.)						
11.)						
12.)						
13.)						
14.)						
15.)						
16.)						
17.)						
18.)						

Biological Product Deviation Report

D. ADDITIONAL COMMENTS

Biological product deviation reports required by 21 CFR 600.14, 21 CFR 606.171, or 21 CFR 1271.350(b), involving products regulated by the Center for Biologics Evaluation and Research (CBER), mail to:

Director, Office of Compliance and Biologics Quality
Food and Drug Administration
Center for Biologics Evaluation and Research
Document Control Center
10903 New Hampshire Avenue
Building 71, Room G112
Silver Spring, MD 20993-0002

Biological product deviation reports required by 21 CFR 600.14, involving licensed biological products regulated by the Center for Drug Evaluation and Research (CDER), mail to:

Division of Compliance Risk Management and Surveillance
Office of Compliance
Center for Drug Evaluation and Research
Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993-0002

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 2 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."