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 onto 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)

# 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 LOTS: _____

| 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.) | | | | | |
| 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.) | | | | | |
| 10.) | | | | | |
| 11.) | | | | | |
| 12.) | | | | | |
| 13.) | | | | | |
| 14.) | | | | | |
| 15.) | | | | | |
| 16.) | | | | | |
| 17.) | | | | | |
| 18.) | | | | | |

# Biological Product Deviation Report

**D. ADDITIONAL COMMENTS**

Public reporting burden for this collection of information is estimated to average 2 hours per response, including the time for reviewing instructions, searching existing data sources, adhering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Center for Biologics Evaluation and Research
Office of Compliance and Biologics Quality
1401 Rockville Pike, Suite 200N, HFM-600
Rockville, MD 20852-1148

An agency may not initiate a collection activity without first obtaining OMB approval. The approved collection instrument should display a current and valid OMB control number, expiration date, public protection provision, and a burden statement on the approved collection instrument.