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)

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

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, gathering 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
Office of Chief Information Officer
1350 Piccard Drive, Room 400
Rockville, MD 20850

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.