

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:	* Zip Code:
Country:	
* 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:	Zip Code:
* Country:	
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: <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/>	
C. Unit/Product Information	
Please check the type of product:	Blood <input type="checkbox"/> (Continued on Page 5) Non-Blood <input type="checkbox"/> (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)

[Empty text area for description of contributing factors or root cause]

Biological Product Deviation Report

B7. Follow-Up (Continued)

Biological Product Deviation Report

C1. Blood Products/Components

Total Number of Units: _____

** RN = Reverse Notification

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