

BIOLOGICAL PRODUCT DEVIATION REPORT

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

* Indicates required information

A. FACILITY INFORMATION		B. BIOLOGICAL PRODUCT DEVIATION (BPD) INFORMATION							
1. Reporting Establishment Information		1. Establishment Tracking #							
* Reporting Establishment Name		2. Date BPD Occurred							
* Street Address Line 1		3. * Date BPD Discovered							
Street Address Line 2		4. * Date BPD Reported							
* City	* State	5. * Description of BPD (use Page 2 for additional space)							
Country	*Zip Code								
* Point of Contact									
* Telephone # ()									
E-mail									
2. *Reporting Establishment Identification Number		6. * Description of Contributing Factors or Root Cause (use Page 3 for additional space)							
FDA Registration #		7. * Follow-Up (use Page 4 for additional space)							
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		8. * Please Enter the 6 Character BPD Code							
* City	* State	<table border="1" style="margin-left: auto; margin-right: auto;"> <tr> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> </tr> </table>							
* Country	* Zip Code	C. UNIT / PRODUCT INFORMATION Please check the type of product: <table style="margin-left: 20px;"> <tr> <td>Blood</td> <td><input type="checkbox"/></td> <td>(Continued on Page 5)</td> </tr> <tr> <td>Non-Blood</td> <td><input type="checkbox"/></td> <td>(Continued on Page 6)</td> </tr> </table>		Blood	<input type="checkbox"/>	(Continued on Page 5)	Non-Blood	<input type="checkbox"/>	(Continued on Page 6)
Blood	<input type="checkbox"/>			(Continued on Page 5)					
Non-Blood	<input type="checkbox"/>			(Continued on Page 6)					
4. Establishment Identification Number:									
FDA Registration #									
CLIA #									

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B5. DESCRIPTION OF BPD *(continued)*

Empty box for description of BPD.

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

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B7. FOLLOW-UP *(continued)*

Empty space for follow-up details.

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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.)					

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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.)					

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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.