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
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* Indicates required information		BI B No.			
A. FACILITY INFORMATION		B. BIOLOGICAL PRODUCT DEVIATION (BPD) INFORMATION			
1. Reporting Establishment Information		Establishment Tracking #			
* Reporting Establishment Name		Date BPD Occurred			
* Street Address Line 1		3. * Date BPD Discovered			
Street Address Line 2		4. * Date BPD Reported			
		5. * Description of BPD (use Page 2 for additional space)			
* City	* State				
Country	* Zip Code				
* Point of Contact	l e				
* Telephone #		* Description of Contributing Factors or Root Cause (use Page 3 for additional space)			
E-mail					
2. * Reporting Establishmen	nt Identification Number				
FDA Registration #					
CLIA#		7. * Follow-Up (use Page 4 for additional space)			
If the BPD occurred some facility, please complete otherwise, continue on to	this Section and Section A4;				
* Establishment Name					
Street Address Line 1					
Street Address Line 2		8. * Please Enter the 6 Character BPD Code			
* City	* State				
* Country	Zip Code	C. UNIT / PRODUCT INFORMATION			
4. Establishment Identification Number		Please check the type Blood (Continued on Page 5)			
FDA Registration #		of product: Non-Blood (Continued on Page 6)			
CLIA#					
FORM FDA 3486 (10/12)	Form Approved:	Page 1 of 8 PSC Publishing Services (301) 443-6740 E			

OMB No. 0910-0458 Expires: 1/31/2014

B5.	DESCRIPTION OF BPD (continued)

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

B7.	FOLLOW-UP (continued)

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.)					
FORM FDA 3486 (10/12)					

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.)					

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 (HFM-600) Center for Biologics Evaluation and Research Food and Drug Administration 1401 Rockville Pike, Suite 200N Rockville, MD 20852-1448

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."

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