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

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C. UNIT / PRODUCT INFORMATION

Please check the type of product:

Blood ☐ (Continued on Page 5)

Non-Blood ☐ (Continued on Page 6)

Form Approved:
OMB No. 0910-0458
Expires: 2/29/2020

PSC Publishing Services (301) 443-6740 EF

See PRA Statement on Page 8.

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

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
Food and Drug Administration
Center for Biologics Evaluation and Research
Document Control Center
10903 New Hampshire Avenue
Building 71, Room G112
Silver Spring, MD 20993-0002

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."

General Instructions for Completing the Biological Product Deviation Report (BPDR) - Form FDA 3486

For use by biological product manufacturers to report biological product deviations (BPD) that may affect the safety, purity, or potency of a distributed product in accordance with 21 CFR, Part 600.14 or 606.171. Also for use by Human Cells, Tissues and Cellular and Tissue-Based Product (HCT/P) manufacturers to report HCT/P deviations in accordance with 21 CFR 1271.350(b).

General Instructions:

- Complete all sections that apply to your report.
- If exact dates are not known, make your best guess.
- Complete a separate form for each BPD. If a BPD involves more than one product, only one form needs to be completed listing all distributed products potentially affected.
- Only submit completed pages of the report. Do not submit blank pages (e.g., 2, 3, 4 and 7) if additional space is not needed.
- **DO NOT** include donor, patient, or employee personal identification information or other confidential information.
- **DO NOT** use this form to report fatalities that occur as a result of collection or transfusion of blood or blood products. Fatalities must be reported in accordance with 21 CFR 606.170.
- **DO NOT** use this form to report Adverse Experiences related to biological products other than blood or blood components or HCT/Ps. Adverse Experiences must be reported in accordance with 21 CFR 600.80 and, for HCT/Ps, 21 CFR 1271.350(a). Information regarding Adverse Experience Reporting is available at www.fda.gov/medwatch/ (/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program). Information regarding Adverse Experience Reporting for vaccine products is available on our VAERS page.
- Send amended or follow-up reports or information to CBER via regular mail or e-mail to bp_deviations@fda.hhs.gov (mailto:bp_deviations@fda.hhs.gov). For

amended or follow-up information to a HCT/P Deviation report, send an email to hctp_deviations@fda.hhs.gov (mailto:hctp_deviations@fda.hhs.gov). When submitting the amended or follow-up report via regular mail, please identify the report as an amended or follow-up report and highlight the changes and/or the additional information. Please include the establishment identification number, tracking number (if available), first listed unit or lot number, and the date the report was submitted.

- It is recommended that you print these instructions for reference when completing the report. In addition to these instructions, you should also print the listing of the Biological Product Deviation Codes (Deviation Codes), Product Codes for Blood (Blood Products) and Product Codes for Non-blood Products (Non-Blood Products, includes HCT/Ps) for quick reference. These codes need to be manually entered into the report.

A. Facility Information

The reporting establishment is the establishment who had control over the product at the time the BPD occurred.

For example:

- A BPD that occurs at a Source Plasma collection center should be reported by that center and not by the corporate office.
- A BPD that occurs at an auxiliary facility (e.g., donor center, distribution center) operating under a blood bank or blood center should be reported by the blood bank or blood center.
- A BPD that occurs at one of several locations of a licensed establishment, should be reported by the location who had control over the product, not by the headquarters location.
- A BPD that occurs at a contract manufacturing site (e.g., test laboratory, filling facility), should be reported by the license holder of the product.
- A HCT/P deviation that occurs at an establishment that makes the HCT/P available for distribution or in a facility that is under contract agreement or other arrangement should be reported by the establishment who determined that the HCT/P met all release criteria and made the HCT/P available for distribution.

1. Reporting Establishment Information

Enter the Reporting Establishment's name and address

Enter the following information in the event more information is needed and CBER needs to contact you:

Point of Contact: Name of the person who is the point of contact for the report

Telephone: Enter the telephone number of the person who is the point of contact

E-mail: Enter the e-mail address, if available, of the person who is the point of contact.

2. Reporting Establishment Identification Number

You must enter a valid registration number (Central File Number (CFN) or FDA Establishment Identification (FEI) Number), or CLIA number.

Registration Number - either a Central File Number (CFN), which is a 7 digit number or an FDA Establishment Identifier (FEI), which may be up to 10 digits assigned to your facility if you have completed an FDA Form #2830 for blood establishments, FDA Form #2656 for drug manufacturers or FDA Form #2891 for device manufacturers. If you have a license number you will also have a registration number.

CLIA Number - a 10 character number that is assigned by Center for Medicare and Medicaid Services (CMS - formerly HCFA) to facilities who are eligible for Medicare reimbursement. Only provide this number if you do not have a registration number.

You may contact your local FDA district office to obtain your registration number from the appropriate Registration Monitor (Blood, Device or Drug). Foreign establishments may contact the Office of Regional Operations, Division of Emergency and Investigational Operations (ORA/ORO/DEIO) at 301-827-5653. For a valid CLIA number contact your CLIA State Survey Agency. The State Agency telephone numbers and contact people are listed on CMS's web site.

3. If the BPD occurred somewhere other than the above facility, please complete this Section and Section A4, otherwise continue on to Section B1.

Enter the Establishment's name and address.

4. Establishment Identification Number: Enter the Establishment Identification - either Registration number or CLIA number.

B. Biological Product Deviation (BPD) Information

1. Establishment Tracking Number: - Your establishment's internal tracking number to identify individual reports. This number could consist of no more than 14 numbers and/or characters.

2. Date BPD Occurred - The date the deviation or unexpected event occurred. Please enter using the format mm/dd/yyy.

3. Date BPD Discovered - The date the deviation or unexpected event was discovered. The date discovered is the date you acquire information reasonably suggesting that a reportable event has occurred. If the event occurred at your contractor, the date of discovery is when the contractor learns about the deviation or unexpected event. Please enter using the format mm/dd/yyy.

4. Date BPD Reported - The date the report is completed. Please enter using the format mm/dd/yyyy.

5. Description of BPD - Describe the event in detail, including description of what happened and a summary of all relevant information (labeling, test results, reason for donor deferral, etc.). Do not include any confidential information, such as patient, donor, or employee names. Use page 2 for additional space.

6. Description of Contributing Factors or Root Cause - Describe all contributing factors or root causes of the deviation or unexpected event. Please indicate, if after investigation, a root cause cannot be determined. Use page 3 for additional space.

7. Follow-up - Describe the intended short term and long term follow-up action plans, if applicable. Any corrective actions identified do not have to be implemented at the time of filing this report. If consignee notification or product retrieval was performed, please include the date and method (letter, telephone, fax, etc.) of notification. Use page 4 for additional space.

8. Please Enter the 6 character BPD Code: Enter the code from the BPD Code Listing that best describes the BPD. Use the Blood Deviation Codes for the BPD's involving blood products. Use the Non-Blood Deviation Codes for the BPD's involving non-blood products. Use the HCT/P deviation codes for the deviations involving HCT/Ps. The BPD Code is made up of three levels. The first level (XX) identifies the system affected in which there was a breakdown or failure, which resulted in the distribution of an unsuitable product. Use the appropriate guidance document for determining the system affected.

BPD Code | XX | - | | - | |

Summary of Product Codes by Type of Product

For blood products the systems include:	For non-blood products the systems include:	For HCT/Ps the systems include:
PD - Post Donation Information	IM - Incoming Material Specifications	DE - Donor Eligibility
DS - Donor Screening	PC - Process Controls	DS - Donor Screening
DD - Donor Deferral	TE - Testing	DT - Donor Testing
BC - Blood Collection	LA - Labeling	FA - Facilities
CP - Component Preparation	PS - Product Specifications	EC - Environmental Controls and Monitoring
VT - Viral Testing	QC - Quality Control and Distribution	EQ - Equipment
RT - Routine Testing	MI - Miscellaneous	SR - Supplies and Reagents
LA - Labeling		RE - Recovery
QC - Quality Control and Distribution		PC - Processing and Process Controls
MI - Miscellaneous		LC - Labeling Controls
		ST - Storage
		SD - Receipt, Pre-Distribution, Shipment and Distribution

The second level (YY) of the code is a subset of the system affected. The third level (ZZ) contains more detailed information regarding the BPD. Select the code that most closely describes the deviation or unexpected event (see list of Deviation Codes). If you cannot determine the appropriate code, enter question marks. For example ??-??-?? or LA-??-??

BPD Code | | - | YY | - | ZZ |

C. Unit / Product Information

Check the type of product: Check either Blood or Non-Blood to identify the type of product potentially affected by the BPD.

Blood Product - includes products manufactured by blood and plasma establishments, such as whole blood, red blood cells, fresh frozen plasma, platelets, and plasma for further manufacture and Source Plasma.

Non-Blood Product - includes products manufactured by a facility other than blood establishments, such as vaccines, therapeutics, allergenics, in-vitro diagnostics, plasma derivatives, and HCT/Ps.

C1. Blood Products / Components

Total Number of Units: Enter the total number of units. For example, if one unit of whole blood was manufactured into Red Blood Cells, Fresh Frozen Plasma and Platelets, the total number of units is 1.

For each component provide the following:

Unit # - donor number or bleed number

Collection date - the date the unit was collected. If the collection date is not known, leave this field blank.

Expiration date - the date the component expires. If the expiration date is not applicable (e.g., for Recovered Plasma), leave this field blank.

Product Code - use the list of specific blood product codes (Blood Product Codes). Use the code YY01 for products for further manufacture, such as recovered plasma. Use the code DB00 for products not listed on the Blood Product Codes list, such as IVIG or albumin (if the blood establishment distributed it) and specify the product in the comments section.

Disposition - provide the disposition of the product using the following list - **DO NOT** list any products that were not distributed. Valid dispositions are:

Specify if the unit was distributed:

In-house (IH) - distributed from the blood bank within a hospital to another department, e.g., emergency room, surgery, nursing floor, etc.

To another facility (AF) - distributed from a blood center to a hospital, from one hospital to another, or from a blood or plasma establishment to a manufacturer of biological products other than blood and blood components.

Valid dispositions are:

No information - product distributed, information regarding final disposition not available at time of reporting

Corrected by consignee - product distributed and deviation corrected by consignee

Destroyed by consignee - product distributed and destroyed by consignee

Expired - product distributed and is now expired, no other information available

Returned and corrected - product distributed, returned to manufacturer and deviation corrected

Returned and destroyed - product distributed, returned to manufacturer and destroyed

Sent for further manufacturing - product distributed for further manufacture

Sent for further manufacturing of non-injectable products only - product distributed for further manufacture into non-injectable products only

Transfused - product distributed and transfused to a patient

Other - if other is selected, please explain in Additional Comments

Notification - provide either yes or no to identify whether consignee was notified. If the consignee notified you of the deviation or unexpected event, select RN for reverse notification.

The following are examples of how to report the disposition and notification information:

1. A unit of RBC's is distributed from the blood bank to the nursing floor. Prior to transfusion the nurse discovers a discrepancy in labeling. The nurse returns the unit to the blood bank and the blood bank corrects the label. The unit is reissued and transfused.

Disposition: IH, Returned and corrected - Notification: RN (reverse notification)

2. A unit of RBC's is distributed from a blood center to a hospital. The blood center discovers a deviation in testing the unit and notifies the hospital to return the unit. The unit was transfused prior to notification from the blood center.

Disposition: AF, Transfused - Notification: Y (yes)

D. Additional Comments - use this section to further explain any missing information or product information such as product code, product disposition, or notification. If multiple units have the same information (i.e., collection date, expiration date, product, disposition and notification) enter the information for the first unit number and list the additional unit numbers in this section. If more than 18 units were potentially affected, enter the product information for the first 18 units and enter the remaining unit numbers in this section.

The following are examples of ways to enter information when multiple units are involved:

Additional Comments page: Additional units - 1235, 1236, 1345, 1844, 2900 and 4344

1. Information for one component (unit number 1234) entered on the Blood Products/Components Information Page and there are additional units with the same information:
2. Information for 18 components entered on the Blood Products/Components Information Page, additional component information entered on the Additional Comments page (2 examples)
    A. Additional products - Transfused, No Notification - Product Code DB29: 01X1111, 01X0000, 01X2222, 01X3333, 01X4444. Product Code DB56: 01X5555, 01X6666, 01X77777, 01X8888, 01X9999.
    B. Additional products - Notification: Yes - 25 DB29 Distributed; 6 DB56 Distributed; 1 DB00 (pediatric aliquot) Distributed; 1 DB01 Distributed; 1 DB05 Distributed; 1 DB45 Transfused; 7 DB53 Distributed; 25 YY01 Sent for further manufacturing.

C2. Non-Blood Products

Total Number of Lots: Enter the total number of lots

For each lot provide the following:

Lot # - lot number of the product

Expiration Date - the date the product expires

Product Type - major category of products:

Allergenics
Derivatives
In-Vitro Diagnostics
Therapeutics
Vaccines
"361" HCT/Ps **
"351" HCT/Ps **

** "361" HCT/Ps - Human cells, tissues and cellular and tissue-based products (HCT/Ps) that are regulated solely under section 361 of the Public Health Service Act because they meet all of the criteria in 21 CFR 1271.10(a).

** "351" HCT/Ps - Human cells, tissues and cellular and tissue-based products (HCT/Ps) that are regulated as biological products under section 351 of the Public Health Service Act and the Food, Drug, and Cosmetic Act because they do not meet the criteria in 21 CFR 1271.10(a).

Product Code- Use the list of specific non-blood product codes (Non-Blood Product Codes)

Disposition - provide the disposition of the product using the following list - **DO NOT** list any products that were not distributed. Valid dispositions are:

Destroyed by consignee - product distributed and destroyed by consignee

Distributed - product distributed, information regarding final disposition not available at time of reporting

Expired - product distributed and is now expired, no other information available

Returned and destroyed - product distributed, returned to manufacturer and destroyed

Returned and reworked - product distributed, returned to manufacturer and reworked according to an appropriate procedure

Sent to distributor - product distributed to a facility outside of your control for further distribution

Other - if other is selected, please explain in Additional Comments

(361 HCT/P) Distributed In-house/transplanted or infused

(351 or 361 HCT/P) Distributed to another facility/transplanted or infused

(361 HCT/P) Distributed In-house/expired

(361 HCT/P) Distributed to another facility/expired

(361 HCT/P) Distributed In-house/destroyed

(361 HCT/P) Distributed to another facility/destroyed

(361 HCT/P) Distributed In-house/returned

(361 HCT/P) Distributed to another facility/returned

Notification - provide either yes or no to identify whether consignee was notified.

D. Additional Comments - use this section to further explain any missing information or product information, such as product code, product disposition, or notification. If multiple lots have the same information (i.e., expiration date, product code, disposition and notification) enter the information for the first lot number and list the additional lot numbers in this section. If more than 18 lots were potentially affected, enter the product information for the first 18 units and enter the remaining unit numbers in this section.

The following are examples of ways to enter information when multiple lots are involved:

Additional products - Distributed, No Notification - Product Code GR65: X0111, X0022, X2244, Product Code GS22: S5555, S6666, S7777, Product Code: GS34: T8888, T9999.

1. Information for one lot entered, additional lots with same information entered in the Comments Section:

   Additional lots- 1235, 1236, 1345A, 1345B

2. Product information entered for 18 lots, additional lot information entered in Comments Section:

Mail report to:

Food and Drug Administration
Center for Biologics Evaluation and Research
Document Control Center
10903 New Hampshire Avenue
WO71-G112
Silver Spring, MD 20993-0002

Reports involving biological therapeutic products that have been transferred to the Center for Drug Evaluation and Research (CDER):

Food and Drug Administration, CDER
Office of Compliance
Division of Compliance Risk Management and Surveillance
10903 New Hampshire Ave. Bldg. 51, Rm 4207
Silver Spring, MD 20993-0002

Problems?

If you need assistance you may contact CBER at 240-402-9160 or by email at bp_deviations@fda.hhs.gov (mailto:bp_deviations@cber.fda.gov)or hctp_deviations@fda.hhs.gov (mailto:hctp_deviations@cber.fda.gov) for questions specific to HCT/P deviation reporting.

Related Information

- Privacy Act (/regulatory-information/freedom-information/privacy-act)