Biological Product Deviation Reporting for CBER Licensed In Vitro Diagnostic (IVD) Devices

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Perspective on IVD Devices Regulated by the OBRR/CBER; Public Workshop

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Reporting of Product Deviations

21 CFR 600.14 – Reporting of biological product deviations by licensed manufacturers

Guidance for Industry

“Biological Product Deviation Reporting For Licensed Manufacturers of Biological Products Other than Blood and Blood Components”

Available on the Internet at:

https://www.fda.gov/media/76309/download

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What Do I Report?

21 CFR 600.14(b) "You must report any event, and information relevant to the event, associated with the manufacturing… of a licensed biological product, if that event meets all the following criteria:

(1) Either:

(i) Represents a deviation from current good manufacturing practice, applicable regulations, applicable standards, or established specifications that may affect the safety, purity, or potency of that product; or

(ii) Represents an unexpected or unforeseeable event that may affect the safety, purity, or potency of that product; and

(2) Occurs in your facility or another facility under contract with you; and

(3) Involves distributed biological product."

REPORTABLE????

- Was the event associated with the manufacturing?
- Was there a deviation or unexpected event that may affect safety, purity, or potency of the product?
- Did it occur in your facility or at your contract facility?
- Did you have control over the product when the deviation occurred?
- Was product distributed?

Control

21 CFR 600.3(ii): "*Control* means having responsibility for maintaining the continued safety, purity, and potency and for compliance with applicable product and establishment standards, and for compliance with current good manufacturing practices."

Distribution

21 CFR 600.3(hh): *"Distributed* means:

The biological product has left the control of the licensed manufacturer."

When Do I Report

21 CFR 600.14(c): “You should report a biological product deviation as soon as possible, but you must report at a date not to exceed 45-calendar days from the date you… acquire information reasonably suggesting that a reportable event has occurred.”

Contract Manufacturing When Do I Report?

21 CFR 600.14 (a): "…You must establish, maintain, and follow a procedure for receiving information from that person on all deviations, complaints, and adverse events concerning the affected product."

If you contract with a facility to perform a manufacturing step and a reportable event occurred at the contractor, the time period will start when your contractor learns about the deviation or unexpected event.

How Do I Report?

21 CFR 600.14(d): "You must report on Form FDA-3486."

Biological Product Deviation Report Form

Where Do I Report?

21 CFR 600.14(e): "You must send the completed Form FDA-3486 to the CBER Document Control Center or submit electronically…"

Electronically through the CBER Web site:

https://www.fda.gov/vaccines-blood-biologics/report-problem-center-biologics-evaluation-research/electronic-submission-biological-product-deviation-reports-ebpdr

By mail:

CBER
Document Control Center
10903 New Hampshire Avenue
WO71-G112
Silver Spring, MD 20993-0002

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)

Form Approved:
OMB No. 0910-0458
Expires: 3/29/2020

See PRA Statement on Page 8.

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.)						

FORM FDA 3486 (6/17)

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FDA Home Page | Contact CBER On-Line Technical Support

CBER On-Line - Login Screen

AS OF 03/15/2019 FDA'S SECURITY POLICY REQUIRES YOU TO RESET YOUR PASSWORD TO RETAIN ACCESS EVERY 60 DAYS

Use the CBER On-line system to make these electronic submissions online:
Blood Establishment Registration
Tissue Establishment Registration
Biological Product Deviation Reporting (Form FDA 3486)

New CBER On-Line Users
New users must first create an account. Create a New Account.

Existing account holders may login by entering your user name and password below.

Create New Account
See Instructions
Contact Support

*User Name:
*Password:
Forgot your User Name or Password?
*Application: CBER On-Line - Main Menu

REMINDER: User Names and Passwords are CASE SENSITIVE

FDA Home Page | Contact CBER On-Line Technical Support | Log Out

CBER On-Line - Main Menu

Production Applications	Welcome to the CBER On-Line
Biological Product Deviation Reporting (eBPDR)	
Blood Establishment Registration (eBER)	
HCT/P Establishment Registration (eHCTERS)	

Exit CBER On-Line Application | Edit Current Account | Change Password

CBER On-Line Version 1.13.00
Page Updated 03/15/2019

Contact CBER On-Line Technical Support | Help | Release Notes | Log Out

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Contact CBER On-Line Technical Support

FDA / Center for Biologics Evaluation and Research

FDA Home Page | Contact eBPDR Technical Support | Log Out

Electronic Biological Product Deviation Report (eBPDR) - Select Establishment

To create a new BPD report, please do the following:

- Select your establishment from the list below
- Press "Create New Report"
- If your establishment is not listed, press "My Establishments" to add it to the list.

Add an establishment My Establishments

Select Your Establishment:

(To add your establishment to this list, press the My Establishments button)

Create New Report for the selected establishment Create New Report

Edit an Unfinished Report **P#** Edit Report

View a listing of your Unfinished Reports - ***1 report(s)*** Unfinished Reports

BPDRs Submitted Within the Past 90 Days Submitted Reports

List of Active Users | eBPDR User Guide | CBER On-Line Main Menu

Biological Product Deviations

https://www.fda.gov/vaccines-blood-biologics/report-problem-center-biologics-evaluation-research/biological-product-deviations

- Federal Register - 21 CFR 600.14, 606.171
- FDA Form 3486 - PDF format
- Electronic Form
- Instructions for completing forms
- Deviation Codes *(updated each fiscal year)*
  - Blood Biological Product Deviation Codes
  - ***Licensed Non-Blood Biological Product Deviation Codes***
  - Human Cells, Tissues, and Cellular and Tissue-Based product Deviation Codes
- Product Codes
  - Blood
  - ***Non-Blood***
- Guidance Documents
- Annual Summary Reports

Contact Information

Office of Compliance and Biologics Quality
Division of Inspections and Surveillance
Program Surveillance Branch

Sharon O'Callaghan, CSO
Beth Rogerson, CSO

Telephone: 240-402-9160
Email: bp_deviations@fda.hhs.gov