Beaumont

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Blood Product Deviation (BPD) Reporting - Dearborn Blood Bank

Document Type: Procedure

I. PURPOSE AND OBJECTIVE:

This document will provide the Dearborn Blood Bank (BB) staff with guidance and policies for a timely reporting of an event/occurrence to the Food and Drug Administration (FDA) once it has been determined that the event has affected the safety, purity or potency of a biologic product which was under the control of Beaumont Health, Dearborn Blood Bank facility, and the product was released for transfusion or shipped to another facility within Beaumont Health.

II. DEFINITIONS/ACRONYM:

A. Deviation: An unexpected event; departure from a standard or norm.

B. BPD: Blood Product Deviation

III. POLICY:

A. The FDA requires that any event/occurrence associated with the manufacturing of a blood component be reported if the safety, purity, or potency of the product may be affected. This includes testing, processing, packing, labeling, or storage of a blood component.

B. The Blood Bank department is required to submit a Blood Product Deviation (BPD) report to the Center for Biologics Evaluation and Research (CBER), Office of Compliance and Biologics Quality (OCBQ) as soon as possible, but not to exceed 45 calendar days from the date of discovery.

IV. PROCEDURE:

A. To facilitate reporting, FDA has developed a standardized reporting format that may be used to submit electronically or in paper form by mail, and has provided key resources to assist with the submission of the BPD reports. The BPD report is primarily submitted electronically, password required and protected.

B. Once it has been determined that an unexpected event/occurrence is reportable to the FDA the report will be submitted by using the following:

1. The BPD report can be found on the FDA website at:
www.fda.gov > Vaccines, Blood & Biologics > Safety & Availability (Biologics) > Report a Problem to

the Center for Biologics Evaluation & Research > Biological Product Deviations > Electronic Submission of Biological Product Deviation Reports (eBPDR)

2. Start the submission by clicking on the CBER login screen link from the Key Resources section,
   a. Enter the account name **bea96307** and password.
   b. For general instructions click on Instructions for Using the eBPDR System link from the Forms & Instructions section. There are additional links under the **Forms & Instructions** and **Deviation Codes** sections to provide additional assistance.
3. Continue the submission by opening a new report from the main menu and entering all required information as prompted and self-guided by the system.
4. Print a hard copy of the completed electronic BPD report receipt confirmation, attach ALL supporting documents and file appropriately, in the FDA reports section of the Transfusion Services Inspection Readiness binder located in the blood bank Supervisor office.
5. If for any reason, on rare occasion, the on-line system can not be utilized, the Form FDA3486 may be submitted manually.
   a. Download Form FDA 3486 from the Forms & Instructions section of the FDA website (www.FDA.gov) if copy is not already available. See note section below
   b. Complete the form by following the General Instructions for Completing the BPDR From FDA 3486, save it, print it out and return it to the following address:
   Food and Drug Administration
   Center for Biologics Evaluation and Research
   Document Control Center
   10903 New Hampshire Avenue
   WO71-G112
   Silver Spring, MD 20993-0002

V. NOTES:

A. For any other assistance contact CBER at 240-402-9160 or by email at: bp_deviations@fda.hhs.gov
B. Do NOT include donor, patient, or employee personal identification information or other confidential information when submitting a report to the FDA.
C. Hard copies of the documents and/or forms below can be accessed on the FDA website; www.FDA.gov:
   1. Guidance for Industry (BPD Reporting)
   2. BPD Codes
   3. FDA Blood Product Codes
   4. Downtime BPDR Form FDA 3486
   5. General Instructions for Completing the BPDR Form FDA 3486

VI. REFERENCES:

1. AABB, *Standards for Blood Banks and Transfusion Services*, Current Edition
2. College of American Pathologists (CAP) Standards, Current Edition
3. FDA: 21 Code of Federal Regulations (CFR) Part 600.14 or 606.171

Attachments

No Attachments

Approval Signatures

Step Description	Approver	Date
	Jeremy Powers: Chief, Pathology	11/15/2021
Policy and Forms Steering Committe (if needed)	Gail Juleff: Project Mgr Policy	11/2/2021
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	Kelly Sartor: Supv, Laboratory	11/2/2021
	Kelly Sartor: Supv, Laboratory	11/2/2021

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