

WEB FORM ADDENDUM TO FORM 3486
COLLECTION OF INFORMATION FOR RECALL CLASSIFICATION

The collection of additional information associated with a BPD for the purpose of recall classification will be requested through an e-mail notification to the submitter of the BPD and a web-based form to provide the information.

E-mail

Subject: BPD confirmation #_____, Establishment Tracking #_____
Reporting Establishment ID # _____

Thank you for the electronic submission of the Biologic Product Deviation Report (BPDR) referenced below. The Center for Biologics Evaluation and Research (CBER) has completed initial review of this BPDR. Additional information is necessary to complete our review for possible recall classification purposes.

The web form to provide CBER the additional information is available at <https://www.accessdata.fda.gov/scripts/cber/CFApps/Login/Index.cfm>

Access to the form requires the BPDR submitter's username and password. Upon login, access the electronic BPDR system (eBPDR) and select "Unfinished Reports."

FEI <FEI #>
BPD Confirmation # <Confirmation #>
BPD Submitted Date <BPD Received Date>
Establishment Tracking # <Establishment Tracking #>

Thank You,

CBER Recall Coordinator
Food and Drug Administration
Office of Compliance and Biologics Quality

Web Form

FORM 3486A – BPDR SUPPLEMENTAL INFORMATION

Reporting Establishment ID # _____

Establishment Tracking # _____

BPD Confirmation # _____

(The above items will be pre-populated by the system.)

1. Distribution Pattern

Provide the States (for products distributed within the United States) and/or the Countries (for products distributed outside the United States) where the products were distributed.

Provide counts related to the distribution pattern.

Consignee	#	Consignee	#
Foreign <i>(total)</i>		Manufacturers	
Domestic <i>(total)</i>		Veterans Admin.	
Distributors		Dept. of Defense	
Medical Facilities		Other	

If you distributed products to Canada, a U.S. federal government and/or DoD facility, please provide the consignee name and address in the comments field below.

Comments:

Notes: Selectable list of States and Countries will be displayed. Selections will populate the text field.

2. Notification

Provide method(s) and date(s) of consignee notification. If your method of notification is not one of the available choices, select "other" and describe the notification method in the comments field. Provide the Recall Completion date.

Initial Notification: Method Date mm/dd/yyyy

Further Notifications: Method Date

Method Date

Recall Completion Date:

Comments:

*Notes: Allow for up to 2 initial notification and 3 further notification entries.
Method fields will be selected from a pick list.*

3. Updated Product Disposition

Provide the following additional information for products distributed to another facility. Provide dates of distribution, verify consignee(s) were notified, and if notified, provide final disposition(s).

Unit Number	Product Code	Date Distributed	Verify Consignee Notified	Final Disposition
<prefilled>	<prefilled>	Enter mm/dd/yyyy	<prefilled & Select Value>	<Select Value>

If you chose a non-specific product code on your BPDR (e.g., DB00), provide the name of the product(s) in the comments field. You may skip this step if you included this information on your BPDR.

Comments:

*Notes: Only products needing additional information will display.
Unit number and Product code will be pre-filled and not editable.
Date Distributed will be editable.
Verify Consignee Notified will be pre-filled and editable.
Final Disposition will be selected from a pick list.
Comments field was previously located in section 6 "Name of Products"*

4. Industry Recall Contacts

Provide Official's Name and Contact Information for the Most Responsible Individual and Recall Contact.

Most Responsible Individual

Official's Name
Title
Firm Name
Street Address Line 1
Street Address Line 2
City
State/Province Postal Code
Country
Telephone Facsimile
E-mail

Recall Contact

Official's Name
Title
Firm Name
Street Address Line 1
Street Address Line 2
City
State/Province Postal Code
Country
Telephone Facsimile
E-mail

Notes: State/Province and Country will be selected from a pick list.