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

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 #_____

Thank you for the electronic submission of the above referenced Biologic Product Deviation Report (BPDR). The Center for Biologics Evaluation and Research has completed initial review of the BPDR. Additional information is necessary to complete the review. The form to provide the additional information is available at (hyperlink). Access to the form requires a username and password to the eBPDR system.

Web Form

FORM 3486A – BPDR SUPPLEMENTAL INFORMATION

Reporting Establishment ID #_____

Establishment Tracking #_____

BPD Confirmation #_____

(The items above will be filled in by the system, not the user)

Please provide the following additional information related to the above referenced BPDR. Only provide the requested information for products that were distributed to another facility (disposition code AF) and that the consignees were notified.

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.

Notes: Text field, same number of characters as RES field (think about 4000 characters
Map to RES-Event Details-Distribution Pattern

2. **Notification**

Provide the methods and dates of consignee notification. If the notification method used was not one of the available choices, select "other" and describe the notification in the comment field.

				mm/dd/yyyy
Initial Notification:	Method		Date	
Further Notifications:	Method		Date	
	Method		Date	

Comments:

Notes: Allow for up to 10 further notification entries
Method will be picklist from RES-Start Recall-Initial Firm Notification field
Comments field is a text field, 1000 characters should be sufficient
Initial Notification Method maps to RES-Start Recall-Initial Firm Notification
Initial Notification Date maps to RES-Start Recall-Recall Initial Date; Date Distribution Chain Notified, and Voluntary/Mandated Date
All methods and dates map to RES-Event Details-Recall Strategy, display as "method, date; method, date…"

3. **Consignees of Products for Further Manufacture**

If any of the products were distributed for further manufacture (e.g., Recovered Plasma or Source Plasma), provide the names and addresses of the consignees. If products were distributed to more than one consignee, provide the unit/lot numbers that each consignee received.

Consignee Name
Street Address Line 1
Street Address Line 2
City
State/Province Postal Code
Country

Unit/lot numbers received by this consignee

Notes: Unit/lot numbers received is a large text field
Allow for entry of up to 10 consignees
Map consignee names to RES-Event Details-List of Consignees or Comments
Do not map specific unit/lot numbers – will need to be done manually

4. **Additional Product Information**

If you provided product information (e.g., there were more than 18 products) in either the Additional Information section on the Blood Product/Components Information page or the Comments Section page, provide the unit/lot numbers, product codes, and disposition of each product below. This information is only needed for products distributed to another facility and for which the consignee was notified.

Note: If you provided the additional product information on the BPDR in a manner that clearly relates this information for each additional product, you may skip this step.

Notes: Large text field
No mapping

5. **Updated Product Disposition**

Provide any available updated product disposition information for products on the BPDR with the dispositions of: 1) no information, 2) distributed, 3) other, 4) sent for further manufacturing, or 5) sent for further manufacturing of non-injectable products only.

N

Map to RES-Event Details-Recall Strategy and (maybe) RES-Summary and Termination-Product Disposition

6. **Name of Products**

If you used a non-specific product code on the BPDR (e.g., DB00), provide the name of the products. If you provided this information in either the Additional Information section on the Blood Product/Components Information page or the Comments Section page, you may skip this step.

Notes: Large text field
No mapping

Not sure what buttons will be needed, maybe:

Submit Save Cancel