CBER's DRC Program

Laura Hieronymus

Office of Compliance and Biologics Quality
Center for Biologics Evaluation and Research
Food and Drug Administration

U.S. Department of Health and Human Services
Food and Drug Administration

FDA-Industry IVD Roundtable Meeting
November 29, 2012

DRC – Non Blood Products

- Expand DRC product area to include:
  - Allergenics
  - Blood Derivatives
  - In-vitro Diagnostics (IVD)
  - Vaccines
  - HCT/Ps

DRC – Non Blood Products

- BPD Report Received
- Report Reviewed
  - Deviation?
  - Consignees Notified ?
  - Electronic Submission
  - 100 or fewer Lots / Units
- DRC Record Created
- Additional Information (AI) Request Sent

From: CBER_RecallAlerts@fda.hhs.gov
To:
Subject: BPD Additional Information (AI)- Conf # 211754, Facility # 1234567890

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

The web form used to provide CBER this 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#	: 1234567890
BPD Confirmation#	: 211754
BPD Submitted Date	: 02/11/2009
Establishment Tracking#	: BPD1234

Note: To provide BPD Additional Information (AI) access to multiple authorized representatives, you may create a single user account to submit future BPD reports.

Thank You,
CBER Recall Coordinator
Food and Drug Administration

BPD AI – Updated Product Disposition

Product Disposition	Notification	Distribution	Contact Info	Preview Report

Reporting FEI: 1234567890
BPD Confirmation # 298424
Reporting Establishment Name: FDA Testing facility for development

Establishment Tracking # 0012012
Todays Date: 11/28/2012

BPD AI - Updated Product Disposition

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

* Required
** Conditionally Required (see instructions)

Row #	Unit or Lot #	Product Code	* Verify Consignee Notified	** Date Distributed (mm/dd/yyyy)	** Final Disposition
Row 1	123	FB02	Yes	10/01/2012	Destroyed by Consignee
Row 2	456	FB03	Yes	10/01/2012	Destroyed by Consignee

If "Other" is selected as a final disposition, provide further details in the Comments field.

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.

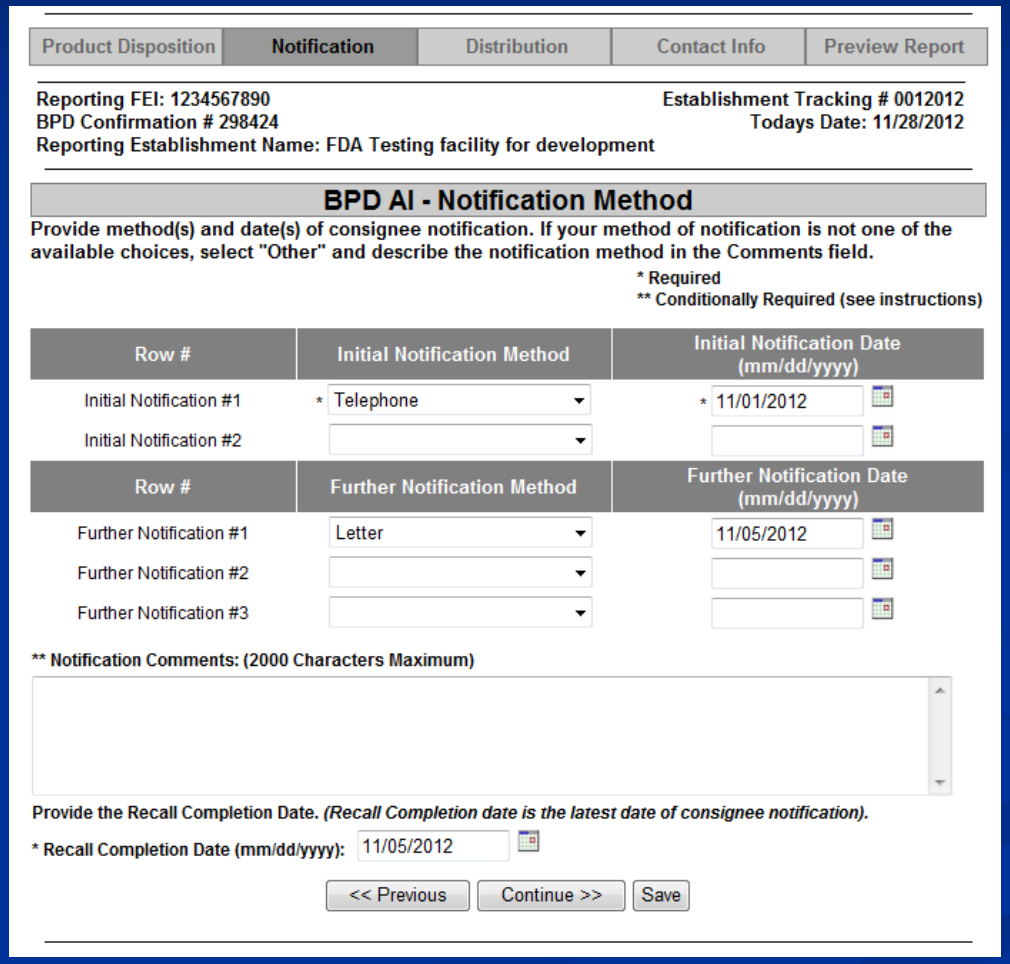
**** Product Information Comments: (2000 Characters Maximum)**

Provide Total Quantity Distributed:

2 Lots

Continue >> Save

BPD AI – Notification Method



Product Disposition | Notification | Distribution | Contact Info | Preview Report

Reporting FEI: 1234567890
BPD Confirmation # 298424
Reporting Establishment Name: FDA Testing facility for development

Establishment Tracking # 0012012
Todays Date: 11/28/2012

BPD AI - Notification Method

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.

* Required
** Conditionally Required (see instructions)

Row #	Initial Notification Method	Initial Notification Date (mm/dd/yyyy)
Initial Notification #1	* Telephone	* 11/01/2012
Initial Notification #2		

Row #	Further Notification Method	Further Notification Date (mm/dd/yyyy)
Further Notification #1	Letter	11/05/2012
Further Notification #2		
Further Notification #3		

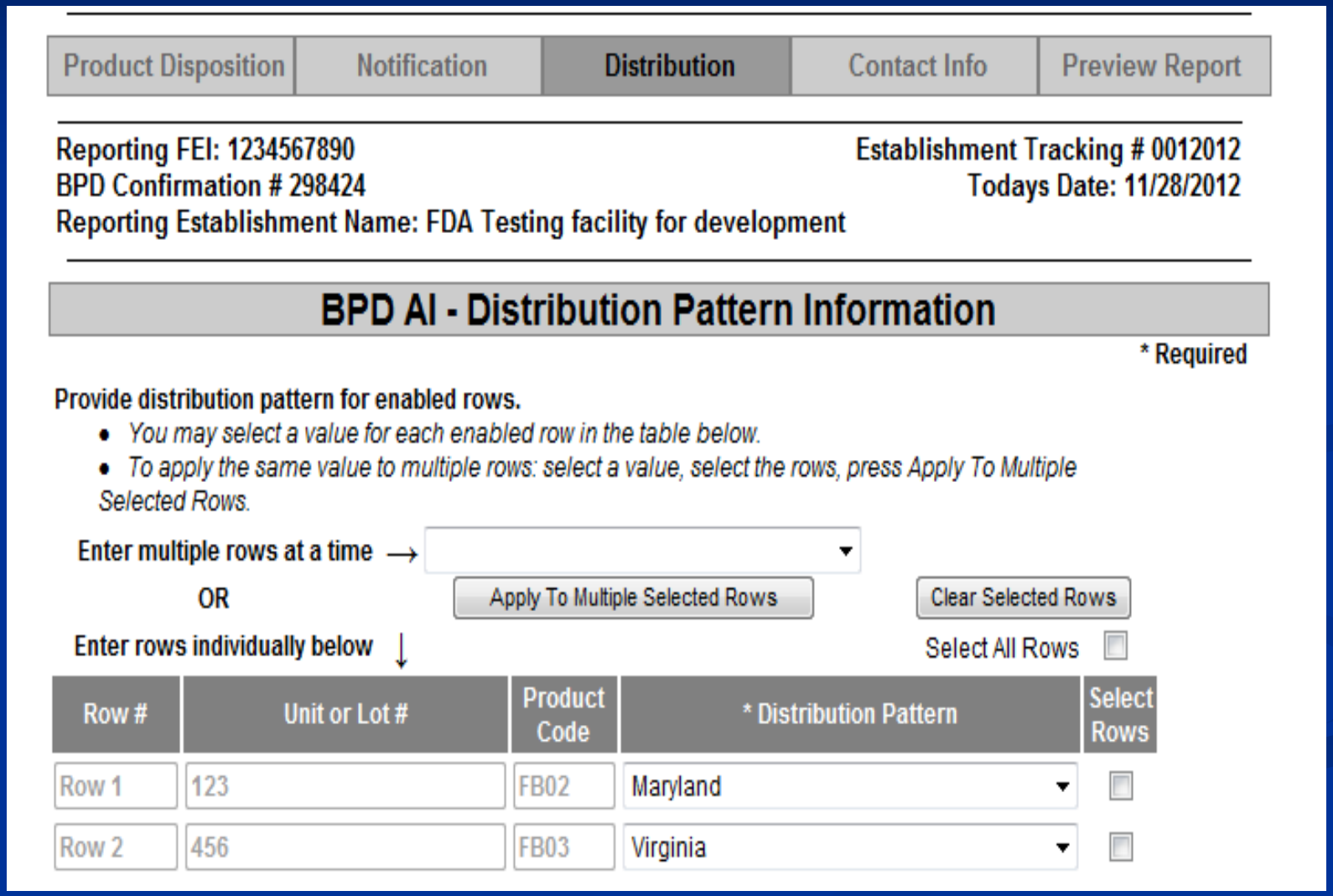
** Notification Comments: (2000 Characters Maximum)

Provide the Recall Completion Date. *(Recall Completion date is the latest date of consignee notification).*

* Recall Completion Date (mm/dd/yyyy): 11/05/2012

<< Previous | Continue >> | Save

BPD AI – Distribution Pattern Information



Product Disposition | Notification | **Distribution** | Contact Info | Preview Report

Reporting FEI: 1234567890
BPD Confirmation # 298424
Reporting Establishment Name: FDA Testing facility for development

Establishment Tracking # 0012012
Todays Date: 11/28/2012

BPD AI - Distribution Pattern Information

* Required

Provide distribution pattern for enabled rows.

- *You may select a value for each enabled row in the table below.*
- *To apply the same value to multiple rows: select a value, select the rows, press Apply To Multiple Selected Rows.*

Enter multiple rows at a time →

OR

Apply To Multiple Selected Rows | Clear Selected Rows

Enter rows individually below ↓

Select All Rows

Row #	Unit or Lot #	Product Code	* Distribution Pattern	Select Rows
Row 1	123	FB02	Maryland	
Row 2	456	FB03	Virginia	

BPD-AI Distribution Pattern Information

Provide counts related to the distribution pattern.

* Domestic Consignees (total)	2
* Foreign Consignees (total)	0
# of Consignees Responding to Notification (total)	2
# of Distributors	
# of Manufacturers	
# of Medical Facilities	2
# of Dept. Of Defense	
# of Veterans Admin	
# of Other U.S. Federal Government	

If you selected the distribution pattern value 'Multiple U.S. States' or 'Multiple Countries', provide the specific distribution pattern for each lot in the Comments field below. Not applicable for HCT/P or blood products.

Distribution Pattern Comments: (2000 Characters Maximum)

<< Previous | Continue >> | Save

BPD AI – Industry Recall Contacts

Product Disposition	Notification	Distribution	Contact Info	Preview Report

Reporting FEI: 1234567890 — **Establishment Tracking # 0012012**
BPD Confirmation # 298424 — **Todays Date: 11/28/2012**
Reporting Establishment Name: FDA Testing facility for development

BPD AI - Industry Recall Contacts

Provide contact information for the Recalling Firm's Most Responsible Individual and Recall Contact

*** Required**
**** Conditionally Required (see instructions)**

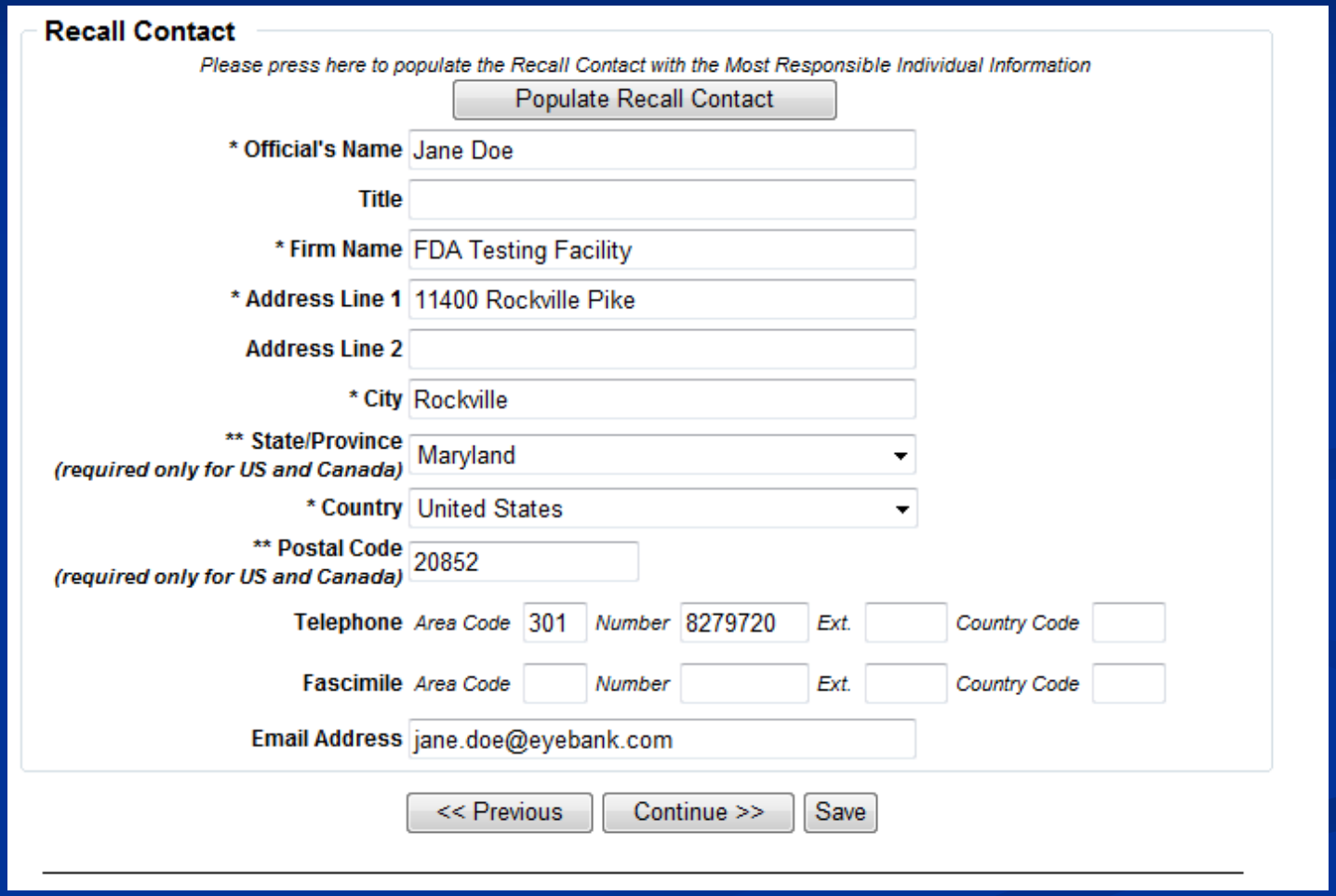
Most Responsible Individual

*** Official's Name**	Sally Jones
Title	
*** Firm Name**	FDA Testing Facility
*** Address Line 1**	11400 Rockville Pike
Address Line 2	
*** City**	Rockville
**** State/Province** *(required only for US and Canada)*	Maryland
*** Country**	United States
**** Postal Code** *(required only for US and Canada)*	20852

Telephone	*Area Code*	301	*Number*	8279720	*Ext.*		*Country Code*	
Facsimile	*Area Code*		*Number*		*Ext.*		*Country Code*	

Email Address	sally.jones@eyebank.com

BPD AI – Industry Recall Contacts



BPD AI – Preview Report

Product Disposition	Notification	Distribution	Contact Info	Preview Report

Reporting FEI: 1234567890 **Establishment Tracking # 0012012**
BPD Confirmation # 298424 **Todays Date: 11/28/2012**
Reporting Establishment Name: FDA Testing facility for development

BPD AI - Preview Report

This Report Has Not Been Submitted To FDA

Please review the following information for accuracy. If any information is inaccurate please navigate to the appropriate page, make corrections, and then submit the report.

BPD AI - Updated Product Disposition and Distribution Pattern

Row #	Unit or Lot #	Product Code	Verify Consignee Notified	Date Distributed	Final Disposition	Distribution Pattern
1	123	FB02	Yes	10/01/2012	Destroyed by Consignee	Maryland
2	456	FB03	Yes	10/01/2012	Destroyed by Consignee	Virginia

Total Quantity Distributed
2 Corneas

BPD AI - Notification Method

Row #	Initial Notification Method	Initial Notification Date
Initial Notification #1	Telephone	11/01/2012
Row #	**Further Notification Method**	**Further Notification Date**
Further Notification #1	Letter	11/05/2012

Recall Completion Date 11/05/2012

Enforcement Report Publication

- Select Non-Blood Product DRC Recalls
  - IVDs, Vaccines, Derivatives
    - Extensive Effectiveness Check Efforts
  - Two Enforcement Report Publications
    - On-Going
      - Soon after Consignee Notifications Initiated
    - Completed / Terminated
      - Once Notification Attempts Completed

CENTER FOR BIOLOGICS EVALUATION AND RESEARCH

FDA Home Page | Contact eBPDR Technical Support | Log Out

Product Disposition | **Notification** | Distribution | Contact Info | Preview Report

Reporting FEI: 1472204
BPD Confirmation # 298163
Reporting Establishment Name: LifeSource

Establishment Tracking # 50884
Todays Date: 05/11/2012

BPD AI - Notification Method

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.

*** Required**
**** Conditionally Required (see instructions)**

Row #	Initial Notification Method	Initial Notification Date (mm/dd/yyyy)
Initial Notification #1	*	*
Initial Notification #2		

Row #	Further Notification Method	Further Notification Date (mm/dd/yyyy)
Further Notification #1		
Further Notification #2		
Further Notification #3		

**** Notification Comments: (2000 Characters Maximum)**

Provide the Recall Completion Date. ***(Recall Completion date is the latest date of consignee notification).***

*** Recall Completion Date (mm/dd/yyyy):**

<< Previous | Continue >> | Save

Enforcement Report Event Detail

Event ID	12345
Product Type	In-Vitro Diagnostic
Status	On-Going
Recalling Firm	IVD Manufacturer, Inc.
City	Rockville
State	Maryland
Country	US
Voluntary/Mandated	Voluntary; Firm Initiated
Recall Initiation Date	11-01-2012
Initial Firm Notification	Letter
Distribution Pattern	Maryland, Virginia

www.fda.gov/Savety/Recalls/EnforcementReports/default.htm

Enforcement Report Product Detail

Product Description	Code Information	Classification	Reason for Recall	Product Quantity	Recall Number
IVD	Lot 12345	Class III	IVD, mislabeled with an extended expiration date, was distributed	1 Lot	B-0123-12

www.fda.gov/Savety/Recalls/EnforcementReports/default.htm

Direct Recall Classification Non-Blood

- Recall Efforts Completed
  - Additional Information Request Submitted

FDA U.S. Food and Drug Administration — Department of Health and Human Services

CENTER FOR BIOLOGICS EVALUATION AND RESEARCH

FDA Home Page | Contact eBPDR Technical Support | Log Out

Product Disposition	Notification	Distribution	Contact Info	Preview Report

Reporting FEI: 1234567890
BPD Confirmation # 298424
Reporting Establishment Name: FDA Testing facility for development

Establishment Tracking # 0012012
Todays Date: 11/28/2012

BPD AI - Submitted Report

This BPD Additional Information report was submitted to FDA on 11/28/2012
Please print a copy of this report for your records

BPD AI - Updated Product Disposition and Distribution Pattern

Row #	Unit or Lot #	Product Code	Verify Consignee Notified	Date Distributed	Final Disposition	Distribution Pattern
1	123	FB02	Yes	10/01/2012	Destroyed by Consignee	Maryland
2	456	FB03	Yes	10/01/2012	Destroyed by Consignee	Virginia

Total Quantity Distributed
2 Corneas

BPD AI - Notification Method

Row #	Initial Notification Method	Initial Notification Date
Initial Notification #1	Telephone	11/01/2012
Row #	**Further Notification Method**	**Further Notification Date**
Further Notification #1	Letter	11/05/2012

Recall Completion Date 11/05/2012

Enforcement Report Event Detail

Event ID	12345
Product Type	In-Vitro Diagnostic
Status	Completed
Recalling Firm	IVD Manufacturer, Inc.
City	Rockville
State	Maryland
Country	US
Voluntary/Mandated	Voluntary; Firm Initiated
Recall Initiation Date	11-01-2012
Initial Firm Notification	Letter
Distribution Pattern	Maryland, Virginia

www.fda.gov/Savety/Recalls/EnforcementReports/default.htm

Enforcement Report Product Detail

Product Description	Code Information	Classification	Reason for Recall	Product Quantity	Recall Number
IVD	Lot 12345	Class III	IVD, mislabeled with an extended expiration date, was distributed	1 Lot	B-0123-12

www.fda.gov/Savety/Recalls/EnforcementReports/default.htm

CBER's DRC Program

- hugely successful in reducing overall resource investment on the part of the agency and industry
- contributes to the agency's public health mission