Biological Product and HCT/P Deviation Reports –

Annual Summary for Fiscal Year 2006

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I. Executive Summary:

Licensed manufacturers of blood and blood components, including Source Plasma; unlicensed registered blood establishments; and transfusion services who had control over the product when the deviation occurred must submit Biological Product Deviation (BPD) reports to the Center for Biologics Evaluation and Research (CBER) (21 CFR 606.171). Manufacturers of licensed biological products other than blood and blood components (non-blood) who hold the biological product license for and had control over the product when the deviation occurred are also required to submit BPD reports (21 CFR 600.14). In addition, manufacturers of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/P) regulated under section 361 of the Public Health Service Act are required to submit deviation reports (21 CFR Part 1271.350(b)). Detailed information concerning deviation reporting is available at www.fda.gov/cber/biodev/biodev.htm.

From October 1, 2005 through September 30, 2006 (Fiscal Year 2006 or FY06), CBER's Office of Compliance and Biologics Quality/Division of Inspections and Surveillance entered 38,618 deviation reports into the BPD database:

- We received more than 38,618 reports, but did not capture data for reports that did not meet the reporting threshold. We notified the reporter that a report was not required.
- The total number of reports we received in FY06 was approximately the same as the number received in the previous year (FY05 – 38,757, FY06 – 38,618) *{Table #2}*.
- The number of reporting establishments increased by 4% (1,409 establishments in FY05 and 1,481 establishments in FY06) *{Table #2}*. There were 80 additional HCT/P establishments reporting in FY06 that did not submit reports in FY05.
    - Unregistered transfusion services typically report few BPDs (68% of those reporting in FY06 submitted 1 or 2 reports) and may file no reports in a given year. Only 15% of the transfusion services submitted more than 5 reports during FY06.
    - There was an increase of 6 percentage points in the number of establishments reporting electronically (FY05 – 69% {974/1,409}; FY06 – 75% {1118/1481}). We continue to encourage electronic reporting.
- The number of reports submitted electronically increased by 10 percentage points (FY05 – 62%, FY06 – 72%) *{Table #7}*. There was an increase in the number of reports submitted electronically from licensed blood establishments (FY05 – 51%, FY06 – 79%), plasma centers (FY05 – 52%, FY06 – 61%), derivative manufacturers (FY05 – 30%, FY06 – 51 %), and in vitro diagnostic manufacturers (FY05 – 53%, FY06 – 68%).
- Reports of post-donation information (PDI) continue to represent the largest subset of BPD reports submitted by blood and plasma establishments (72%) *{Table #8}*. Most often (90%), the blood collector becomes aware of disqualifying information during a subsequent donation interview *{Table 10}*. In 90% of the PDI reports the donor was aware of the information, but the donor screening process failed to elicit the information *{Table #11}*. It is unclear why blood establishments are unable to elicit information during the first donor interview, but successfully elicit the information during a subsequent interview. It is clear that the most common PDI relates to travel (45%).

Eliciting proper information regarding a donor candidate's travel history is apparently the most problematic part of the donor qualification process.

- 2,046 (5.3%) of the reports received by CBER were sent to FDA District Offices for follow-up/evaluation as potential recall situations *{Table #1}*.
    - Of the 1,982 reports submitted by blood and plasma establishments, deviations and unexpected events that occur during the donor screening process continue to be the leading cause of potential recall situations (41%) *{Table #9}*.
    - There was an 18% decrease from the previous year in the number of reports submitted by licensed blood establishments involving donor screening that were potential recall situations.
        - ❖ The number of reports in which a donor provided disqualifying information regarding travel to a malarial endemic area or vCJD risk area and was inappropriately accepted decreased by 23% from the previous year.

Reports Submitted by Licensed Blood Establishments

	FY04	FY05	FY06
Donor Screening	666	577	472
Travel to malarial endemic area	399	333	251
Travel to vCJD risk area	82	87	73

- There was a 23% increase, from the previous year, in the number of reports submitted by blood and plasma establishments in which they distributed a unit collected from a donor who subsequently tested confirmed positive for a viral marker. The majority of this increase in reports involved donors who subsequently tested confirmed positive for Hepatitis B or Hepatitis C. Based on the number of questions we received regarding the requirement to report this event and discussions at public meetings, we believe the increase over the past two years was most likely due to under reporting of this type of event in the previous years, rather than an increase in the number of donors who subsequently tested confirmed positive for any viral marker.

Reports submitted by Blood and Plasma Establishments

	FY04			**FY05**			**FY06**		
	Blood	Plasma	*Total*	Blood	Plasma	*Total*	Blood	Plasma	*Total*
Lookback; Subsequent unit confirmed positive	340	10	*350*	431	6	*495*	510	98	*608*
HIV	70	2	*72*	84	2	*92*	87	12	*99*
HBV	28	3	*31*	34	2	*50*	67	23	*90*
HCV	239	5	*244*	293	2	*333*	309	63	*372*

- There was a 20% increase, from the previous year, in the number of reports submitted by plasma centers involving post donation information related to behavior or history.
    - There was a 34% increase in the number of post donation information reports in which the donor had a history of piercing.

- There was a 29% increase in the number of post donation information reports in which the donor had a history of receiving a tattoo.

Reports submitted by Plasma Centers

	FY04	FY05	FY06
Post Donation Information	4,304	3,998	4,826
Donor received tattoo	1,593	1,579	2,045
Donor received ear piercing	245	158	196
Donor received body piercing	667	630	857

- There was a 26% decrease, from the previous year, in the number of reports submitted by blood establishments involving collection.
  - There was a 25% decrease in the number of reports in which a distributed product was found to be clotted, but was not identified prior to distribution.
  - The number of reports in which a product was found to be hemolyzed, but was not identified prior to distribution decreased by 35 reports.

Reports submitted by Blood Establishments

	FY04	FY05	FY06
Blood Collection	851	972	718
Product contained clots	546	674	506
Product hemolyzed	80	51	16

- FY06 was the first full year since the implementation of the deviation reporting requirement for HCT/Ps. We included data on HCT/P deviation reporting, for the first time, in this annual summary. We categorized the HCT/P deviation reports as either Cellular, which includes peripheral and cord stem cells or Tissue, which includes all other HCT/Ps, such as bone, skin, cornea, etc.
- Manufacturers must submit deviation reports within 45 calendar days of the date of discovery of the reportable event. In FY06, manufacturers submitted 90% of the blood BPD reports, 77% of the non-blood BPD reports, and 69% of the HCT/P deviation reports within 45 days *{Tables #26, #29, and #31}.* FDA investigators review reporting practices during establishment inspections, and we continue to publicize reporting requirements through professional meetings and publications.

FDA published two final guidance documents October 18, 2006 to assist industry in determining what events are reportable[1,2].

[1] Guidance for Industry - Biological Product Deviation Reporting for Blood and Plasma Establishments 10/18/2006

[2] Guidance for Industry - Biological Product Deviation Reporting for Licensed Manufacturers of Biological Products Other than Blood and Blood Components 10/18/2006

You may submit questions concerning this summary to:
FDA/Center for Biologics Evaluation and Research
Office of Compliance and Biologics Quality
Division of Inspections and Surveillance (HFM-650)
1401 Rockville Pike, Suite 200 North
Rockville, Maryland 20852-1448

You may also contact us by email at bp_deviations@fda.hhs.gov, hctp_deviations@fda.hhs.gov, or sharon.ocallaghan@fda.hhs.gov (Sharon O'Callaghan) or by phone at 301-827-6220.

Total Deviation Reports
FY06

Table 1

	Number Of Reporting Establishments	Total Reports Received	*Potential* Recalls	
Blood/Plasma Manufacturers				
Licensed Blood Establishments	231(119*)	27,393	1,706	6.2%
Unlicensed Blood Establishments[1]	384	3,926	78	2.0%
Transfusion Services[2]	460	1,510	0	0%
Plasma Centers	287(54*)	5,359	198	3.7%
Sub-Total	*1,362*	*38,188*	*1,982*	*5.2%*
Non-Blood Manufacturers				
Allergenic	7	149	5	3.4%
Blood Derivative	13	35	1	2.9%
In Vitro Diagnostic	9	60	7	11.7%
Vaccine	10	41	1	2.4%
351 HCT/P	1	1	1	100%
Sub-Total	*40*	*286*	*15*	*5.2%*
361 HCT/P Manufacturers				
Cellular HCT/P	41	74	5	6.8%
Non-Cellular HCT/P	38	70	44	62.9%
Sub-Total	*79*	*144*	*49*	*34.3%*
Total	**1,481**	**38,618**	**2,046**	**5.3%**

[1]Unlicensed Blood Establishments – unlicensed blood establishments performing manufacturing of blood and blood components that require registration with FDA

[2]Transfusion Services – blood banks that perform limited blood and blood component manufacturing (e.g. pooling, thawing, compatibility testing), may or may not register with FDA.

*****Number of license holders; one or more establishments operate under one biologics license.

Total Deviation Reports
FY04 - FY06

Table 2

	Number Of Reporting Establishments			Total Reports Received			*Potential* Recalls		
Blood/Plasma Manufacturers	**FY04**	**FY05**	**FY06**	**FY04**	**FY05**	**FY06**	**FY04**	**FY05**	**FY06**
Licensed Blood Establishments	237(117*)	230(115*)	231(119*)	27,621	28,153	27,393	2,170	1,925	1,705
Unlicensed Blood Establishments	371	392	384	3,502	3,897	3,926	58	44	78
Transfusion Services	468	457	460	1,592	1,517	1,510	0	0	0
Plasma Centers	357(55*)	286(53*)	287(54*)	5,115	4,805	5,359	377	269	198
Sub-Total	1,433	1,365	1,362	37,830	38,372	38,188	2,605	2,238	1,982
Non-Blood Manufacturers									
Allergenic	9	8	7	158	200	149	5	13	5
Blood Derivative	17	14	13	44	47	35	4	2	1
In Vitro Diagnostic	10	11	9	86	100	60	8	18	7
Vaccine	9	11	10	42	37	41	1	1	1
351 HCT/P	1	1	1	2	1	1	0	0	1
Sub-Total	47	45	40	334	385	286	18	33	15
361 HCT/P Manufacturers									
Cellular HCT/P	NA	5†	41	NA	7†	74	NA	2†	5
Non-Cellular HCT/P	NA	4†	38	NA	6†	70	NA	5†	44
Sub-Total	NA	9†	79	NA	13†	144	NA	7†	49
Total	**1,480**	**1,419**	**1,481**	**38,164**	**38,757**	**38,618**	**2,623**	**2,271**	**2,046**

*Number of license holders; one or more establishments operate under one biologics license.
†Reports of events involving products manufactured on or after 5/25/05 {implementation of 21 CFR 1271.350(b)}

Blood & Plasma BPD Reports By Manufacturing System
FY04 - FY06

Table 3

MANUFACTURING SYSTEM	FY04		FY05		FY06	
DONOR SUITABILITY	28,952	76.5%	29,148	76.0%	29,067	76.1%
POST DONATION INFORMATION	*26,854*	*71.0%*	*27,452*	*71.5%*	*27,427*	*71.8%*
DONOR SCREENING	*2,007*	*5.3%*	*1,628*	*4.2%*	*1,548*	*4.1%*
DONOR DEFERRAL	*91*	*0.2%*	*68*	*0.2%*	*92*	*0.2%*
QC & DISTRIBUTION	3,740	9.9%	3,934	10.3%	4,134	10.8%
LABELING	2,415	6.4%	2,405	6.3%	2,199	5.8%
LABORATORY TESTING	1,122	3.0%	981	2.6%	1,013	2.7%
ROUTINE TESTING	*1,027*	*2.7%*	*912*	*2.4%*	*945*	*2.5%*
VIRAL TESTING	*95*	*0.3%*	*69*	*0.2%*	*66*	*0.2%*
COLLECTION	851	2.2%	972	2.5%	718	1.9%
COMPONENT PREPARATION	368	1.0%	407	1.1%	401	1.0%
MISCELLANEOUS	382	1.0%	525	1.4%	658	1.7%
TOTAL	**37,830**	**100%**	**38,372**	**100%**	38,188	100%

Non-Blood Deviation Reports By Manufacturing System
FY04 - FY06

Licensed Biological Products Other Than Blood and Blood Components
Table 4

Manufacturing System	Allergenic			Derivative			In Vitro Diagnostic		
	FY04	*FY05*	*FY06*	*FY04*	*FY05*	*FY06*	*FY04*	*FY05*	*FY06*
Incoming Material	2	0	0	9	9	2	5	4	2
Process Controls	2	1	9	9	5	5	20	18	10
Testing	0	0	6	0	3	2	14	17	5
Labeling	8	22	7	3	15	2	16	24	16
Product Specifications	146	177	125	15	11	20	23	30	18
Quality Control & Distribution	0	0	2	7	4	3	6	7	9
Miscellaneous	0	0	0	1	0	1	2	0	0
TOTAL	**158**	**200**	**149**	**44**	**47**	**35**	**86**	**100**	**60**

Table 4 (con't)

Manufacturing System	Vaccine			351 HCT/P			Total		
	FY04	*FY05*	*FY06*	*FY04*	*FY05*	*FY06*	*FY04*	*FY05*	*FY06*
Incoming Material	1	1	1	0	1	0	17	15	5
Process Controls	7	4	2	1	0	0	38	28	26
Testing	4	1	5	0	0	0	18	21	18
Labeling	10	12	8	0	0	0	37	73	33
Product Specifications	17	17	17	0	0	1	201	235	181
Quality Control & Distribution	1	2	8	1	0	0	14	13	22
Miscellaneous	2	0	0	0	0	0	5	0	1
TOTAL	**42**	**37**	**41**	**2**	**1**	**1**	**332**	**385**	**286**

361 HCT/Ps
Table 5

Manufacturing System	Cellular HCT/Ps		Non-Cellular HCT/Ps		Total	
	FY05[†]	*FY06*	*FY05*[†]	*FY06*	*FY05*[†]	*FY06*
Donor Eligibility	3	2	5	30	8	32
Donor Screening	0	0	0	12	0	12
Donor Testing	0	27	0	8	0	35
Environmental Control	0	0	0	1	0	1
Supplies and Reagents	0	2	0	1	0	3
Recovery	0	2	0	0	0	2
Processing and Processing Controls	0	11	0	3	0	14
Labeling Controls	0	0	1	1	1	1
Storage	0	0	0	1	0	1
Receipt, Pre-Distrib., Shipment & Distrib.	4	30	0	13	4	43
TOTAL	**7**	**74**	**6**	**70**	**13**	**144**

[†]Reports of events involving products manufactured on or after 5/25/05 (implementation of 21 CFR 1271.350(b))

We implemented the on-line electronic deviation report form on June 18, 2001. The percentage of reports submitted electronically in FY06 increased by 9.8 percentage points from FY05 (from 61.9% to 71.7%). We continue to encourage all reporters to use the electronic reporting format.

Deviation Reports Submitted Electronically

Table 6

	Total Reports	# of eBPDR	% eBPDR
BLOOD/PLASMA MANUFACTURERS			
LICENSED BLOOD ESTABLISHMENTS	27,393	19,402	70.8%
UNLICENSED BLOOD ESTABLISHMENTS	3,926	3,541	90.2%
TRANSFUSION SERVICES	1,510	1,188	78.7%
PLASMA CENTERS	5,359	3,275	61.1%
SUB-TOTAL	38,188	27,406	71.8%
NON-BLOOD MANUFACTURERS			
ALLERGENIC	149	132	88.6%
DERIVATIVE	35	18	51.4%
IN VITRO DIAGNOSTIC	60	41	68.3%
VACCINE	41	4	9.8%
351 HCT/P	1	0	0%
SUB-TOTAL	286	195	68.2%
361 HCT/P Manufacturers			
Cellular HCT/P	74	55	**74.3%**
Non-Cellular HCT/P	70	45	**64.3%**
SUB-TOTAL	144	100	**69.4%**
TOTAL	**38,618**	**27,701**	**71.7%**

Percent of Electronic Deviation Reports

Table 7

	FY03	FY04	FY05	FY06
BLOOD/PLASMA MANUFACTURERS				
LICENSED BLOOD ESTABLISHMENTS	41.8%	52.1%	58.6%	70.8%
UNLICENSED BLOOD ESTABLISHMENTS	84.2%	88.9%	90.8%	90.2%
TRANSFUSION SERVICES	75.5%	81.9%	79.9%	78.8%
PLASMA CENTERS	28.3%	49.6%	51.7%	61.1%
SUB-TOTAL	*43.7%*	*56.4%*	*61.8%*	*71.8%*
NON-BLOOD MANUFACTURERS				
ALLERGENIC	60.0%	81.6%	93.5%	88.6%
DERIVATIVE	19.3%	50.0%	29.8%	51.4%
IN VITRO DIAGNOSTIC	72.7%	65.1%	53.0%	68.3%
VACCINE	8.9%	14.3%	5.4%	9.8%
351 HCT/P				0%
SUB-TOTAL	*45.9%*	*64.2%*	*66.5%*	*68.2%*
361 HCT/P Manufacturers				
Cellular HCT/P	NA	NA	100%†	74.3%
Non-Cellular HCT/P	NA	NA	33.3%†	64.3%
SUB-TOTAL	*NA*	*NA*	*69.2%†*	*69.4%*
TOTAL	**43.7%**	**56.5%**	**61.9%**	**71.7%**

†Reports of events involving products manufactured on or after 5/25/05 {implementation of 21 CFR 1271.350(b)}

II. BPD Reports Submitted By Blood And Plasma Establishments:

Total BPDRs By Manufacturing System

Table 8

Manufacturing System	Licensed Establishments	Unlicensed Establishments	Transfusion Services	Plasma Centers	Total	
DS-Post Donation Information	21,955	483	NA	4,989	27,427	71.8%
QC & Distribution	1,535	1,739	800	60	4,134	10.8%
Labeling	803	987	400	9	2,199	5.8%
DS-Donor Screening	1,189	186	NA	173	1,548	4.1%
LT-Routine Testing	257	386	302	0	945	2.6%
Blood Collection	693	22	NA	3	718	1.9%
Miscellaneous	556	3	0	99	658	1.7%
Component Preparation	299	94	8	0	401	1.1%
DS-Donor Deferral	47	19	NA	26	92	0.2%
LT-Viral Testing	59	7	NA	0	66	0.2%
TOTAL	27,393	3,926	1,510	5,359	38,188	100%

DS-Donor Suitability
LT-Laboratory Testing
NA-Not applicable: manufacturing not performed in transfusion service

Potential Recalls By Manufacturing System

Table 9

Manufacturing System	Licensed Establishments	Unlicensed Establishments	Transfusion Services	Plasma Centers	Total	
DS-Donor Screening	644	45	NA	128	817	41.2%
QC & Distribution	576	14	0	36	626	31.6%
Component Preparation	147	2	0	0	149	7.5%
Blood Collection	142	1	NA	0	143	7.2%
Labeling	56	9	0	1	66	3.3%
DS-Donor Deferral	33	5	NA	15	53	2.7%
DS-Post Donation Information	28	0	NA	18	46	2.3%
LT-Routine Testing	43	2	0	0	45	2.3%
LT-Viral Testing	36	0	NA	0	36	1.8%
Miscellaneous	1	0	0	0	1	0.1%
TOTAL	1,706	78	0	198	1,982	100%

DS-Donor Suitability
LT-Laboratory Testing
NA-Not applicable: manufacturing not performed in transfusion service

Post donation information (PDI) continues to be the most frequently reported event associated with the manufacturing of blood and plasma products. The most common PDI involved donors providing information concerning travel to malarial endemic areas and travel to an area at potential risk for vCJD. It is unclear why blood establishments are unable to elicit information during the first donor interview, but successfully elicit the information during a subsequent interview. Eliciting proper information regarding a donor candidate's travel history is apparently the most problematic part of the donor qualification process.

FY06 Reports of Post Donation Information (PDI)

Table 10

PDI OBTAINED THROUGH:	LICENSED ESTABLISHMENTS	UNLICENSED ESTABLISHMENTS	PLASMA CENTERS	TOTAL	
Subsequent Donation	20,002	436	4,150	24,588	89.6%
Telephone Call from Donor	1,322	34	19	1,375	5.0%
Third Party (e.g., doctor, family)	409	11	820	1,240	4.5%
Telerecruitment	222	2	0	224	0.8%
TOTAL	21,955	483	4,989	27,427	100%

Table 11

THE PDI WAS:	LICENSED ESTABLISHMENTS	UNLICENSED ESTABLISHMENTS	PLASMA CENTERS	TOTAL	
Known, but not Provided at Time of Donation*	19,950	422	4,482	24,854	90.6%
Not Known at Time of Donation**	2,005	61	507	2,573	9.4%
TOTAL	21,955	483	4,989	27,427	100%

* Known, e.g., travel outside of U.S., tattoo or body piercing, history of cancer, male to male sexual contact, medication

**Not known, e.g., post donation illness, cancer diagnosed post donation, sex partner participated in high risk behavior or tested positive

A. Reporting Issues

In an effort to provide practical and useful information regarding reporting deviations, this section addresses non-reportable events, deviation code selection and product information entry.

Non-Reportable Events

Blood establishments submitted most of the non-reportable reports. The reports did not meet the reporting threshold because the events were either not associated with manufacturing, did not affect the safety, purity or potency of the product, or did not involve distributed products. Examples of non-reportable events include:

- Establishment distributed product collected from a donor who provided post donation information of cold or flu symptoms.

- Establishment distributed product collected from a donor who did not meet suitability criteria related to donor safety only, such as donor's weight, age, donating within 56 days of last donation, or more than 24 pheresis donations within 12 months.

- Establishment distributed product labeled with a shortened expiration date. This includes associated labeling, such as crossmatch tag or transfusion record.

- Establishment distributed an otherwise unsuitable product, such as product with incomplete testing, through appropriate emergency release procedures.

- Hospital staff transfused the wrong patient or transfused the patient with the wrong product. This event is not associated with manufacturing.

- Establishment distributed an allogeneic product when an autologous product was available.

- Recipient had a transfusion reaction unrelated to an event in manufacturing, such as Transfusion Related Acute Lung Injury (TRALI).

- Establishment distributed products collected from a donor who tested negative. The donor returned and tested reactive or repeat reactive, but not confirmed positive for a viral marker (HIV, HBV or HCV) for which we require or recommend product quarantine or consignee notification (i.e., lookback).

- Establishment distributed plasma for further manufacture which was collected from a donor who provided a history of travel to a malarial endemic area.

Deviation Code (BPD Code) Selection

In some cases the establishment selected the incorrect deviation code to capture the event. The most common errors in coding were:

- Donor Screening (DS) vs. Post Donation Information (PD)

  - If the blood establishment does not know the disqualifying information at the time of donation, the correct code is post donation information. If the establishment knows the disqualifying information or the information is available, but does not appropriately defer the donor, the event is a donor screening deviation.
- Routine Testing (RT) vs. Quality Control & Distribution (QC).
  - A patient had a history of an antibody and the blood bank did not screen the unit for the corresponding antigen. The appropriate deviation code is QC9311 (Required testing not performed or documented for: antigen screen), not RT6106 (Testing performed, interpreted, or documented incorrectly for: antigen typing).
- Blood Collection (BC) vs. Quality Control & Distribution (QC)
  - A blood establishment distributed a unit that was subsequently found to be clotted. The appropriate deviation code is BC4305.
  - A blood establishment discovers a clotted component prior to distribution and discards the product. The appropriate deviation code is QC9405 if any associated products, such as FFP or Platelets, were distributed.
- Bacterial Detection Testing
  - All events associated with bacterial detection testing should be coded as QC & Distribution; Distribution of product that did not meet specifications; Product with unacceptable (e.g., positive), undocumented, or incomplete product QC (QC9404).

<u>Product Information</u>

When identifying the number of units and components, the number of units should equal the number of donations. For example if the event involved 2 donations and each donation was manufactured into red blood cells, platelets and plasma, the number of units would be 2 and the number of components would be 6. Some reports listed the number of units as 6 and the number of components as 6.

B. Most Frequent BPD Reports Submitted by Licensed Blood Establishments

Of the 27,393 reports submitted by licensed blood establishments, 21,955 (80.1%) reports involved post donation information.

- The number of these reports decreased by 2% (FY05 – 22,498).
- The number of reports in which a male donor subsequently provided information of a history of sex with another male increased by 18% (FY05 – 618).
- The number of reports in which a donor subsequently provided information regarding travel to a CJD risk area decreased by 16% (FY05 – 5,659).
- The number of reports in which a donor reported a subsequent diagnosis of cancer decreased by 23% (FY05 – 551).
- The number of reports in which a donor had a reactive test either prior to or post donation decreased by 48% (FY05 – 299). Most of these involved testing reactive post donation.

Most Frequent BPD Reports - Post Donation Information
From *Licensed Blood Establishments*

Table 12

POST DONATION INFORMATION (PD) 21,955	# Reports	% of Total (PD)
Behavior/History	***19,994***	***91.07%***
Travel to malaria endemic area/history of malaria	7,018	31.97%
Risk factors associated with Creutzfeldt-Jakob Disease (CJD) – travel	4,752	21.64%
History of cancer	1,258	5.73%
Donor received tattoo within 12 months of donation	870	3.96%
Male donor had sex with another man	732	3.33%
Received Proscar, Tegison or Accutane	557	2.54%
History of disease	462	2.10%
Donor received bone graft or transplant	436	1.99%
Illness	***1,705***	***7.77%***
Post donation illness (not hepatitis, HIV, HTLV-I, STD, or cold/flu related)	1,190	5.42%
Reaction at phlebotomy site	57	0.26%
Babesiosis	28	0.13%
Post donation diagnosis of cancer	423	1.93%
Testing *	***154***	***0.70%***
Tested reactive for HIV prior to donation	31	0.14%
Tested reactive for HIV post donation	24	0.11%
Tested reactive for Hepatitis C post donation	22	0.10%
Not specifically related to high risk behavior	***102***	***0.01%***
Donated to be tested or called back for test results	73	0.33%
Donor does not want their blood used	29	0.13%

*Includes: tested positive for viral marker either prior to or post donation

Of the 27,393 reports submitted by licensed blood establishments, 1,535 (5.6%) reports involved quality control and distribution deviations and unexpected events.

- The number of these reports increased by 3% (FY05 – 1,486).
- The number of reports involving the release of a product with unacceptable, undocumented, or incomplete product QC, specifically related to bacterial detection testing used as a quality control test, increased 16% (FY05 - 553). The industry implemented a standard for bacterial detection testing in March 2004.

Most Frequent BPD Reports - Quality Control & Distribution
From *Licensed Blood Establishments*
Table 13

QC & DISTRIBUTION (QC) 1,535	# Reports	% of Total (QC)
Distribution of product that did not meet specifications	***1,074***	***69.97%***
Product with unacceptable, undocumented, or incomplete product QC	644	41.95%
Bacterial Detection Testing	412	26.84%
Platelet count	101	6.58%
White Blood Cell count	43	2.80%
Product in which instrument QC or validation was unacceptable or not documented	124	8.08%
Product released prior to resolution of discrepancy	78	5.08%
Product identified as unsuitable due to a donor screening deviation or unexpected event	54	3.52%
Shipping and storage	***214***	***13.94%***
Product not packaged in accordance with specifications	51	3.32%
No documentation that product was shipped at appropriate temperature	44	2.87%
Shipped at incorrect temperature	42	2.74%
Distribution procedures not performed in accordance with blood bank transfusion service's specifications	***132***	***8.60%***
Product not documented as issued in computer	25	1.63%
Product not irradiated as required	25	1.63%
Product not leukoreduced as required	14	0.91%
Visual inspection not performed or documented	11	0.72%
Required testing incomplete, or positive	***36***	***2.35%***
Failure to quarantine unit due to medical history:	***44***	***2.87%***
Post donation illness	25	1.63%
Required testing not performed or documented	***35***	***2.28%***

Of the 27,393 reports submitted by licensed blood establishments, 1,189 (4.3%) reports involved donor screening deviations and unexpected events.

- The number of these reports decreased by 7% (FY05 - 1,272).
- There was a 21% decrease in reports involving donor records which were incomplete, incorrect or not reviewed (FY05 – 337). There was a 32% decrease in reports related to the donor history questions (FY05 – 268). Of the 182 reports related to donor history questions incomplete, incorrect or not reviewed, there were 5 reports related to the use of an abbreviated donor history questionnaire when the screener should have used a full-length questionnaire, compared to 22 reports in FY05.
- The number of reports involving a donor who provided disqualifying information, specifically related to travel to a malarial endemic area, and was not deferred decreased by 20% (FY05 – 362).
- There was a 29% increase in reports in which the screener used incorrect donor identification to check the deferral file or did not check the deferral file, i.e., deferral screening not done (FY05 – 160).

Most Frequent BPD Reports - Donor Screening
From *Licensed Blood Establishments*

Table 14

DONOR SCREENING (DS) 1,189	# Reports	% of Total (DS)
Donor gave history which warranted deferral and was not deferred	***607***	***51.05%***
Travel to malaria endemic area/history of malaria	288	24.22%
Risk factors associated with Creutzfeldt-Jakob Disease (vCJD) - travel	93	7.82%
Received medication or antibiotics	43	3.62%
History of cancer	33	2.78%
History of disease	19	1.60%
Donor record incomplete or incorrect	***265***	***22.29%***
Donor history questions	182	15.31%
Donor identification	23	1.93%
Donor signature missing	23	1.93%
Incorrect ID used during deferral search	***189***	***15.90%***
Donor not previously deferred	173	14.55%
Donor previously deferred due to testing	9	0.76%
Donor previously deferred due to history	7	0.59%
Donor did not meet acceptance criteria	***107***	***9.00%***
Hemoglobin or Hematocrit unacceptable or not documented	73	6.14%
Temperature unacceptable or not documented	25	2.10%
Deferral screening not done	***17***	***1.43%***
Donor previously deferred due to testing	6	0.50%
Donor not previously deferred	6	0.50%
Donor previously deferred due to history	5	0.42%

Of the 27,393 reports submitted by licensed blood establishments, 803 (2.9%) reports involved labeling deviations and unexpected events.

- The number of these reports decreased by 6% (FY05 – 854).
- The number of reports involving the labeling of the unit or product decreased by 18% (FY05 – 443).
- The number of reports involving the labeling of the crossmatch tag or tie tag increased by 7% (FY05 – 375).

Most Frequent BPD Reports - Labeling
From *Licensed Blood Establishments*

Table 15

LABELING (LA) 803	#Reports	% of Total (LA)
Crossmatch tag or tie tag labels incorrect or missing information	***401***	***49.94%***
Recipient identification missing or incorrect	252	31.38%
Autologous unit	113	14.07%
Crossmatch tag switched, both units intended for the same patient	27	3.36%
Unit, lot, or pool number incorrect or missing	23	2.86%
Antigen incorrect or missing	22	2.74%
Blood unit labels	***365***	***45.45%***
Volume incorrect or missing	65	8.09%
Extended expiration date or time	53	6.60%
Donor number or lot number incorrect or missing	46	5.73%
ABO and/or Rh incorrect	42	5.23%
Transfusion record (crossmatch slip) incorrect or missing information	***31***	***3.86%***
Recipient identification missing or incorrect	12	1.49%

Of the 27,393 reports submitted by licensed blood establishments, 693 (2.5%) reports involved blood collection deviations and unexpected events.

- The number of these reports decreased by 26% (FY05 - 931).
- The number of reports in which a clotted product was discovered after distribution decreased by 25% (FY05-647).

Most Frequent BPD Reports – Blood Collection
From *Licensed Blood Establishments*

Table 16

BLOOD COLLECTION (BC) 693	# Reports	% of Total (BC)
Collection Process	***551***	***79.51%***
Product contained clots, not discovered prior to distribution	490	70.71%
Donor sample tube mix-up or donor sample tube mislabeled	20	2.89%
Product hemolyzed, not discovered prior to distribution	16	2.31%
Sterility compromised	***85***	***12.26%***
Bacterial contamination	35	5.05%
Arm prep not performed or performed inappropriately	34	4.91%
Air contamination	13	1.88%
Collection Bag	***29***	***4.18%***
Apheresis collection device	***18***	***2.60%***

C. Most Frequent BPD Reports Submitted by Unlicensed Blood Establishments

Of the 3,926 reports submitted by unlicensed blood establishments, 1,739 (44.3%) involved quality control and distribution deviations and unexpected events.

- The number of these reports increased by 7% (FY05 - 1,618). This increase was associated with an increase by 20% in the number of reports in which a product was not documented as issued in the computer (FY05 – 434). This type of event is reportable if the blood establishment uses the computer system as the only documentation of the final checks of the issue process.
- The number of reports involving the release of a product in which testing was not performed or document increased by 34% (FY05 – 181). Specifically, the number of reports involving not performing or documenting compatibility testing increased from 36 in FY05 to 50 in FY06.

Most Frequent BPD Reports - Quality Control & Distribution
From *Unlicensed Blood Establishments*

Table 17

QC & Distribution (QC) *1,739*	# Reports	% of Total QC
Distribution procedures not performed in accordance with blood bank transfusion service's specifications	***1,229***	***70.67%***
Product not documented as issued in the computer	519	29.84%
Product not irradiated as required	189	10.87%
Improper ABO or Rh type selected for patient	93	5.35%
Procedure for issuing not performed or documented in accordance with specifications	68	3.91%
Improper product selected for patient	67	3.85%
Visual inspection not performed or documented	50	2.88%
Product not leukoreduced as required	44	2.53%
Required testing not performed or documented for:	***244***	***14.03%***
Antibody screen or identification	56	3.22%
Antigen screen	51	2.93%
Compatibility	50	2.88%
Distribution of product that did not meet specifications::	***175***	***10.06%***
Product with unacceptable, undocumented, or incomplete product QC	89	5.12%
Bacterial Detection Testing	61	3.51%
Outdated product	31	1.78%
Product in which instrument QC or validation unacceptable or not documented	23	1.32%
Required testing incomplete or positive:	***64***	***3.68%***
Antibody screen or identification	20	1.15%
Compatibility	15	0.86%
Shipping and storage	***21***	***1.21%***
Stored at incorrect temperature	11	0.63%
Product not packaged in accordance with specifications	6	0.35%

Of the 3,926 reports submitted by unlicensed blood establishments, 987 (25%) involved labeling deviations and unexpected events.

- The number of these reports decreased by 6% (FY05 – 1,052).
- The number of reports involving labeling of the transfusion record decreased by 12% (FY05 – 309).
- The number of reports involving labeling of the crossmatch tag or tie tag decreased by 6% (FY05 - 467).

Most Frequent BPD Reports - Labeling
From *Unlicensed Blood Establishments*

Table 18

LABELING (LA) 987	#Reports	% of Total LA
Crossmatch tag or tie tag labels incorrect or missing information	***435***	***44.07%***
Recipient identification missing or incorrect	170	17.22%
Autologous unit	3	0.30%
Crossmatch tag switched, both units intended for the same patient	88	8.92%
Unit, lot, or pool number incorrect or missing	57	5.78%
Blood unit labels	***282***	***28.57%***
Extended expiration date or time	137	13.88%
Donor number or lot number incorrect or missing	35	3.55%
ABO and/or Rh incorrect	31	3.14%
Product type or code incorrect	26	2.63%
Transfusion record (crossmatch slip) incorrect or missing information	***270***	***27.36%***
Recipient identification missing or incorrect	61	6.18%
Transfusion record switched, both units intended for the same patient	59	5.98%
Unit, lot, or pool number incorrect or missing	36	3.65%

Of the 3,926 reports submitted by unlicensed blood establishments, 483 (12.3%) reports involved post donation information.

- The number of these reports decreased by 9% (FY05 - 530).
- The number of reports of involving post donation illness decreased from 70 in FY05 to 47 in FY06.

Most Frequent BPD Reports - Post Donation Information
From *Unlicensed Blood Establishments*

Table 19

POST DONATION INFORMATION (PD) 483	# Reports	% of Total (PD)
Behavior/History	***429***	***88.82%***
Travel to malaria endemic area/history of malaria	164	33.95%
Risk factors associated with Creutzfeldt-Jakob Disease (CJD) – travel	109	22.57%
History of cancer	16	3.31%
Donor received tattoo	15	3.11%
History of disease	15	3.11%
Illness	***47***	***9.73%***
Post donation illness (not hepatitis, HIV, HTLV-I, STD, or cold/flu related)	26	5.38%
Post donation diagnosis of cancer	18	3.73%
Testing*	***6***	***1.24%***

*Includes: tested positive for viral marker either prior to or post donation

Of the 3,926 reports submitted by unlicensed blood establishments, 386 (9.8%) reports involved routine testing deviations and unexpected events.

- The number and distribution of these reports were similar to the reports received in the previous fiscal years (FY03 – 404, FY04 – 386, FY05 - 391).

Most Frequent BPD Reports - Routine Testing
From *Unlicensed Blood Establishments*

Table 20

ROUTINE TESTING (RT) 386	# Reports	% of Total RT
Incorrectly tested for:	***221***	***57.25%***
Antibody screening or identification	75	19.43%
Compatibility	63	16.32%
Antigen typing	32	8.29%
Sample (used for testing) identification	***118***	***30.57%***
Sample used for testing was incorrectly or incompletely labeled	93	24.09%
Unsuitable sample used for testing (e.g., too old)	14	3.63%
Incorrect sample tested	9	2.33%
Reagent QC unacceptable or expired reagents used	***46***	***11.92%***
Antigen typing	14	3.63%
Antibody screening or identification	10	2.59%
Multiple testing	7	1.81%

D. Most Frequent BPD Reports Submitted by Transfusion Services

Of the 1,510 reports submitted by transfusion services, 800 (53.0%) reports involved quality control and distribution deviations and unexpected events.

- The number of these reports increased by 10% (FY05 – 727).
- The number of reports involving the release of a product in which required testing was not performed or documented increased from 94 in FY05 to 118 in FY06.

Most Frequent BPD Reports - Quality Control & Distribution
From *Transfusion Services*

Table 21

QC & Distribution (QC) 800	# Reports	% of Total QC
Distribution procedures not performed in accordance with blood bank transfusion service's specifications	***578***	***72.25%***
Product not documented as issued in the computer	258	32.25%
Product not irradiated as required	67	8.38%
Procedure for issuing not performed or documented in accordance with specifications	39	4.88%
Improper ABO or Rh type selected for patient	39	4.88%
Product not leukoreduced as required	32	4.00%
Unit issued from the blood bank to the wrong patient	31	3.88%
Product released prior to obtaining current sample for ABO, Rh, antibody screen or compatibility testing	30	3.73%
Required testing not performed or documented for:	***118***	***14.75%***
Antigen screen	34	4.25%
ABO and Rh	30	3.75%
Antibody screen or identification	17	2.13%
Distribution of product that did not meet specifications:	***46***	***5.75%***
Outdated product	19	2.38%
Product with unacceptable, undocumented or incomplete product QC - pH for bacterial detection testing	18	2.25%
Required testing incomplete or positive:	***30***	***3.75%***
ABO and Rh	9	1.13%
Compatibility	8	1.00%
Shipping and storage	***27***	***3.38%***
Stored at incorrect temperature	11	1.38%
Temperature not recorded or unacceptable upon receipt, unit redistributed	6	0.75%

Of the 1,510 reports submitted by transfusion services, 400 (26.4%) reports involved labeling deviations and unexpected events.

- The number of these reports decreased by 19% (FY05 - 492).
- The number of reports involving the labeling of the transfusion record decreased from 156 in FY05 to 117 in FY06.

Most Frequent BPD Reports - Labeling
From *Transfusion Services*

Table 22

LABELING (LA) 400	# Reports	% of Total (LA)
Crossmatch tag or tie tag labels incorrect or missing information	***232***	***58.00%***
Recipient identification incorrect or missing	94	23.50%
Unit or pool number incorrect or missing	38	9.50%
Crossmatch tag switched, both units intended for the same patient	32	8.00%
Crossmatch tag incorrect or missing	18	4.50%
Unit ABO and/or Rh incorrect or missing	12	3.00%
Expiration date or time extended or missing	8	2.00%
Transfusion record (crossmatch slip) incorrect or missing information	***117***	***29.25%***
Recipient identification incorrect or missing	39	9.75%
Transfusion record switched, both units intended for the same patient	19	4.75%
Transfusion record released w/unit incorrect or labeled with incorrect or missing information	14	3.50%
Unit or pool number incorrect or missing	11	2.75%
Blood unit labels	***51***	***12.69%***
Expiration date or time extended or missing	19	4.75%
Product type or code incorrect	7	1.75%
Donor number or lot number incorrect or missing	6	1.50%

Of the 1,510 reports submitted by transfusion services, 302 (20%) reports involved routine testing deviations and unexpected events.

- The number and distribution of these reports was similar to the reports received in the previous fiscal year (FY05 - 292).

Most Frequent BPD Reports - Routine Testing
From *Transfusion Services*

Table 23

ROUTINE TESTING (RT) 302	# Reports	% of Total RT
Incorrectly tested for:	***177***	***58.61%***
Antibody screening or identification	57	18.87%
Compatibility	46	15.23%
Rh typing	23	7.62%
Antigen typing	20	6.62%
Sample (used for testing) identification	***83***	***27.48%***
Sample used for testing was incorrectly or incompletely labeled	62	20.53%
Unsuitable sample used for testing	11	3.64%
Incorrect sample tested	10	3.31%
Reagent QC unacceptable or expired reagents used	***39***	***12.91%***
Antibody screening or identification	10	3.31%
Multiple testing	8	2.65%
Rh typing	5	1.66%
Antigen typing	5	1.66%

E. Most Frequent BPD Reports Submitted by Plasma Centers

Of the 5,359 reports submitted by Source Plasma centers, 4,989 (93%) involved post donation information.

- The number of these reports increased by 13% (FY05 - 4,424).
- The number of post donation information reports in which the donor had a history of a tattoo or piercing increased by 31% (FY05 – 2367).

Most Frequent BPD Reports - Post Donation Information
From *Plasma Centers*

Table 24

POST DONATION INFORMATION (PD) 4,989	# Reports	% of Total (PD)
Behavior/History	***4,826***	***96.73%***
Donor received tattoo within 12 months of donation	2,045	40.99%
Donor received body piercing within 12 months of donation	857	17.18%
Incarcerated	392	7.86%
Risk factors associated with Creutzfeldt-Jakob Disease (CJD) – travel	237	4.75%
Donor received ear piercing within 12 months of donation	196	3.93%
Non-sexual exposure to Hepatitis C	182	3.65%
Donor received tattoo and piercing within 12 months of donation	134	2.69%
IV drug use	116	2.33%
Sex partner tested reactive for HCV	114	2.29%
Testing*	***116***	***2.33%***
Tested reactive at another center, specific testing unknown	71	1.42%
Tested reactive for HCV post donation	18	0.36%
Tested reactive for HIV post donation	11	0.22%
Illness	***47***	***0.94%***

*Includes testing positive for viral marker prior to or post donation

Of the 5,359 reports submitted by Source Plasma centers, 173 (3.2%) reports involved donor screening deviations and unexpected events.

- The number of these reports decreased by 7% (FY05 - 187).
- The number of reports in which the donor provided disqualifying information and was not deferred increased from 39 in FY05 to 56 in FY06.
- The number of reports in which the plasma center did not perform deferral screening decreased from 48 in FY05 to 25 in FY06.

Most Frequent BPD Reports - Donor Screening
From *Plasma Centers*

Table 25

DONOR SCREENING (DS) 173	# Reports	% of Total (DS)
Donor gave history which warranted deferral and was not deferred	***56***	***32.37%***
Donor received tattoo within 12 months of donation	15	8.67%
Risk factors associated with Creutzfeldt-Jakob Disease (vCJD) - travel	7	4.05%
Donor received vaccine or immune globulin	5	2.89%
History of disease or surgery	5	2.89%
Donor record incomplete or incorrect	***54***	***31.21%***
Donor history questions	29	16.76%
Arm inspection	11	6.36%
Donor signature missing	6	3.47%
Donor did not meet acceptance criteria	***32***	***18.50%***
Medical review or physical not performed or inadequate	18	10.40%
Temperature unacceptable or not documented	8	4.62%
Deferral screening not done	***25***	***14.45%***
Donor previously deferred due to history	***18***	***10.40%***
Deferred by another center	5	2.89%
IV drug user	4	2.31%
Donor previously deferred due to testing	***7***	***4.05%***
Incorrect ID used during deferral search	***6***	***3.47%***
Donor previously deferred due to history	***3***	***1.73%***
Donor previously deferred due to testing	***2***	***1.16%***
Donor not previously deferred	***1***	***0.58%***

F. Timeliness of BPD Reports

BLOOD AND PLASMA ESTABLISHMENTS

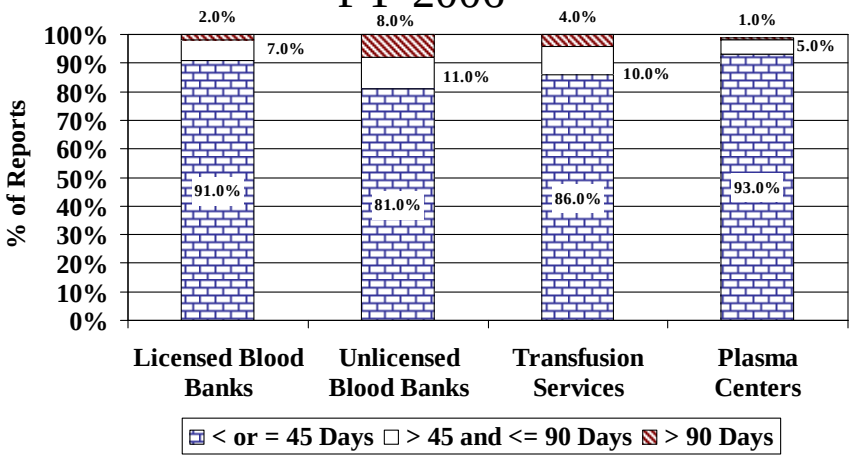
Adherence To 45 Day Required Timeframe For Reporting
(Reporting Time = Date of FDA receipt – Date of discovery of BPD)

Table 26

Reporting Time (days)	Licensed Establishments		Unlicensed Establishments		Transfusion Services		Plasma Centers		Total	
< or = 45	**24,993**	**91%**	**3,179**	**81%**	**1,304**	**86%**	**5,005**	**93%**	**34,481**	**90%**
> 45 and <=90	1,902	7%	424	11%	151	10%	275	5%	2,752	7%
> 90	498	2%	323	8%	54	4%	79	1%	954	2%
Total	27,393	100%	3,926	100%	1,509	100%	5,359	100%	38,187	100%
*Reporting time=0	31		98		51		0		180	

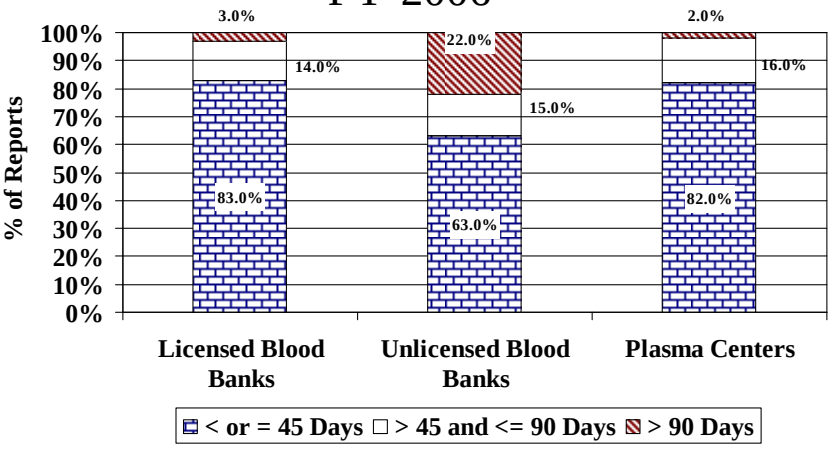
*Reporting time = 0 - reports were submitted electronically on the day discovered.

Biological Product Deviation Reports
Blood and Plasma Establishments
Reporting Time – Total Reports
FY-2006



Total Reports = 38,188
Licensed Blood Est. = 27,393; Unlicensed Blood Est. = 3,926; Transfusion Services = 1,510; Plasma Centers = 5,359

Biological Product Deviation Reports
Blood and Plasma Establishments
Reporting Time – Potential Recalls
FY-2006



Total Reports = 1,982
Licensed Blood Est. = 1,706; Unlicensed Blood Est. = 78; Plasma Centers = 198

III. BPD Reports Submitted by Manufacturers of Biological Products Other Than Blood and Blood Components (Non-Blood)

Non-blood manufacturers submitted 26% fewer reports in FY06 than in the previous year (FY05 – 384) *{Table 2}.*

- Allergenic manufacturers submitted 51 fewer reports (FY05 – 200).
  - 116 of 125 (93%) of product specification reports were related to precipitate discovered in allergenic extracts.
- Derivative manufacturers submitted 12 fewer reports (FY05 – 47).
- In vitro diagnostic manufacturers submitted 40 fewer reports (FY05 – 100).
- Vaccine manufacturers submitted 4 more reports (FY05 – 37).
- There were 19 fewer reports identified as potential recall situations (FY05 – 33).

Total BPD Reports By Manufacturing System

Table 27

MANUFACTURING SYSTEM	Allergenic	Derivative	In Vitro Diagnostic	Vaccine	351 HCT/P	TOTAL	
Incoming Material	0	2	2	1	0	5	1.8%
Process Controls	9	5	10	2	0	26	9.1%
Testing	6	2	5	5	0	18	6.3%
Labeling	7	2	16	8	0	33	11.5%
Product Specifications	125	20	18	17	1	181	63.3%
Quality Control & Distribution	2	3	9	8	0	22	7.7%
Miscellaneous	0	1	0	0	0	1	0.3%
Total	**149**	**35**	**60**	**41**	**1**	**286**	**100%**

***Potential* Recalls By Manufacturing System**

Table 28

MANUFACTURING SYSTEM	Allergenic	Derivative	In Vitro Diagnostic	Vaccine	TOTAL	
Incoming Material	0	0	0	0	0	0%
Process Controls	1	1	0	0	2	14.3%
Testing	2	0	0	0	2	14.3%
Labeling	2	0	1	1	4	28.6%
Product Specifications	0	0	6	0	6	42.9%
Quality Control & Distribution	0	0	0	0	0	0%
Miscellaneous	0	0	0	0	0	0%
Total	**5**	**1**	**7**	**1**	**14**	**100%**

A. Timeliness of BPD Reports

NON-BLOOD MANUFACTURES

Adherence To 45 Day Required Time For Reporting

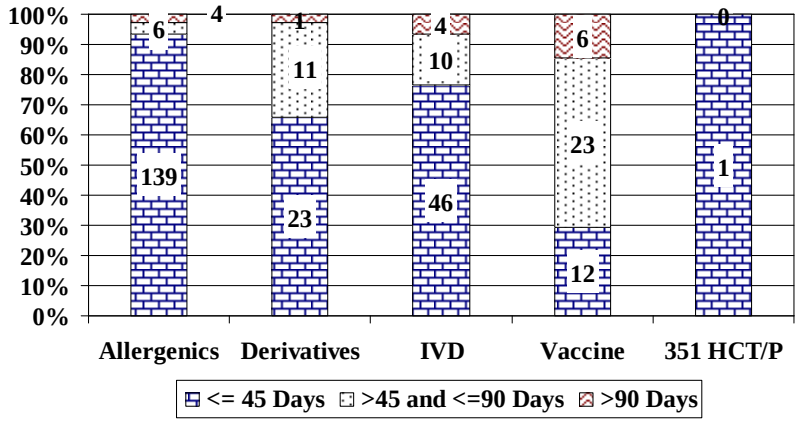
(Reporting Time = Date of FDA receipt – Date of discovery of BPD)

Table 29

Reporting Time (days)	Allergenics		Derivatives		In Vitro Diagnostics		Vaccines		351 HCT/P		Total	
< or = 45	**139**	**93%**	**23**	**66%**	**46**	**77%**	**12**	**29%**	**1**	**100%**	**221**	**77%**
> 45 and <=90	6	4%	11	31%	10	17%	23	56%	0	0%	50	17%
> 90	4	3%	1	3%	4	7%	6	15%	0	0%	15	5%
Total	149	100%	35	100%	60	100%	41	100%	1	100%	286	100%
*Reporting time=0	5		0		0		0		0		5	

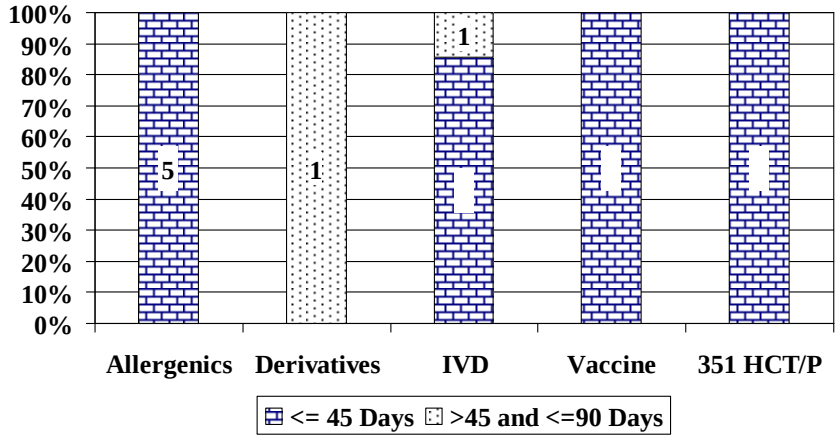
*Reporting time = 0 - reports were submitted electronically on the day discovered.

Biological Product Deviation Reports
Non-Blood Manufacturers
Reporting Time – Total Reports
FY-2006



Total Reports = 286
Allergenic=149; Derivatives=35; In-Vitro Diagnostics=60; Vaccines=41; 351 HCT/P=1

Biological Product Deviation Reports
Non-Blood Manufacturers
Reporting Time – Potential Recalls
FY-2006



Total Reports = 15
Allergenic=5; Derivatives=1; In-Vitro Diagnostics=7; Vaccines=1; 351 HCT/P=1

IV. HCT/P Deviation Reports Submitted by Manufacturers of 361 HCT/Ps

The deviation reporting requirement for HCT/Ps regulated under section 361 of the PHS Act became effective on May 25, 2005. FY06 is the first full fiscal year in which manufacturers submitted reports. Cellular HCT/Ps includes peripheral and cord stem cells. Tissue HCT/Ps includes all other HCT/Ps, such as bone, skin, cornea, etc.

- Cellular HCT/Ps:
  - Of the 27 reports involving donor testing, 22 reports involved Nucleic Acid Testing (NAT) for viral markers performed on pooled samples rather than the required individual sample.
  - Of the 30 reports involving receipt, pre-distribution, shipment & distribution, 26 reports involved inappropriate distribution of product that was contaminated or potentially contaminated.
- Tissue HCT/Ps:
  - Of the 30 reports involving donor eligibility submitted by tissue manufacturers, 27 reports involved the acceptance of ineligible donors.

Total Reports and *Possible* Recalls
By Manufacturing System

Table 30

	Cellular HCT/P		Tissue HCT/P		Total		Possible Recall	
HCT/P Deviation Code	Total	Poss. Recall	Total	Poss. Recall				
Donor Eligibility	2	0	30	26	32	22.2%	26	53.1%
Donor Screening	0	0	12	4	12	8.3%	4	8.2%
Donor Testing	27	1	8	5	35	24.3%	6	12.2%
Environmental Control	0	0	1	0	1	0.7%	0	0.0%
Supplies and Reagents	2	0	1	1	3	2.1%	1	2.0%
Recovery	2	0	0	0	2	1.4%	0	0.0%
Processing and Processing Controls	11	4	3	1	14	9.7%	5	10.2%
Labeling Controls	0	0	1	1	1	0.7%	1	2.0%
Storage	0	0	1	0	1	0.7%	0	0.0%
Receipt, Pre-Distribution, Shipment & Distribution	30	0	13	6	43	29.9%	6	12.2%
Total	**74**	**5**	**70**	**44**	**144**	**100%**	**49**	**100%**

A. Timeliness of BPD Reports

361 HCT/P MANUFACTURES

Adherence To 45 Day Required Time For Reporting

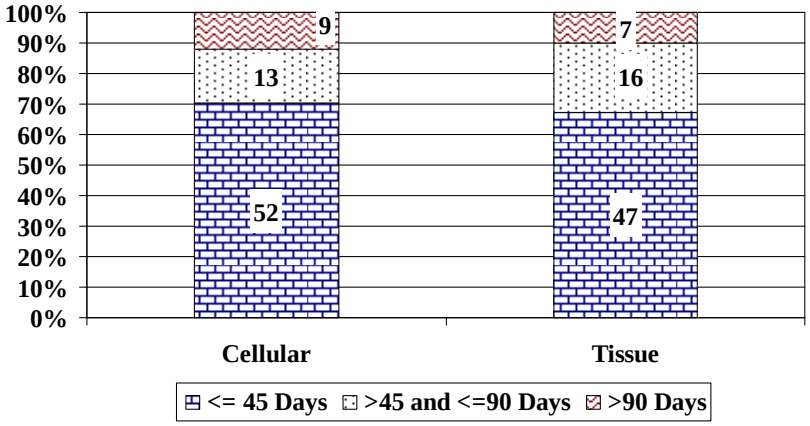
(Reporting Time = Date of FDA receipt – Date of discovery of BPD)

Table 31

Reporting Time (days)	Cellular		Tissue		Total	
< or = 45	**52**	**70%**	**47**	**67%**	**99**	**69%**
> 45 and <=90	13	18%	16	23%	29	20%
> 90	9	12%	7	10%	16	11%
Total	74	100%	70	100%	144	100%
*Reporting time=0	1		0		1	

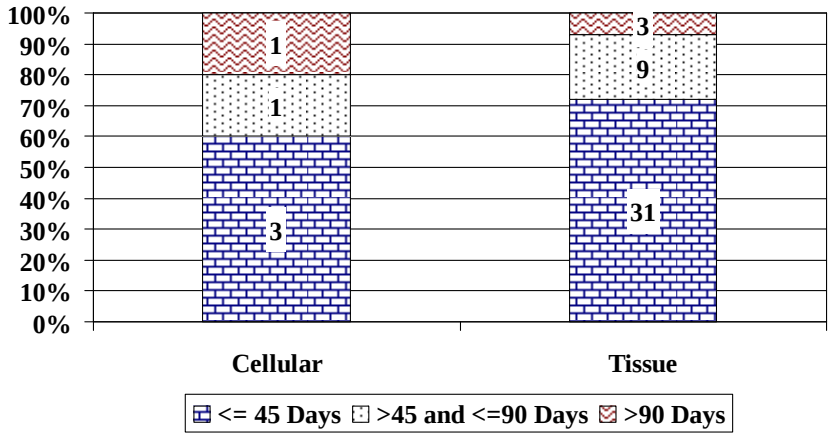
*Reporting time = 0 - reports were submitted electronically on the day discovered.

HCT/P Deviation Reports
361 HCT/P Manufacturers
Reporting Time – Total Reports
FY-2006



Total Reports = 144
Cellular = 74; Tissue = 70

HCT/P Deviation Reports
361 HCT/P Manufacturers
Reporting Time – Potential Recalls
FY-2006



Total Reports = 49
Cellular = 5; Tissue = 44

V. Attachments

1 – Table-Number of BPD Reports by Type of Blood Establishments
2 – List of BPD Codes for Blood and Plasma Establishments
3 – Table-Number of BPDs by Type of Licensed Non-Blood Manufacturer
4 – List of BPD Codes for Non-Blood Manufacturers
5 – Table-Number of HCT/P Deviations by Type of 361 HCT/P Manufacturer
6 – List of HCT/P Deviation Codes for 361 HCT/P Manufacturers