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FDA Workshop, March 1995
Recognition of special product category

Risks and benefits of leukocyte reduction
1996 FDA memorandum
- Product criteria & process controls
- Registration and licensure

Indications for use: FNHTR
- Experimental: CMV, HLA, TRIM
- Medical practice

BPAC, September 1997
Indication for CMV

Question for BPAC	Yes	No
Effective against CMV?	8	1
Equivalent to CMV Neg?	1	7
Methods equivalent?	0	9

Product labeling: Revise *Circular*

BPAC, September 1998
Leukocyte Reduction

Is the benefit-risk ratio associated with LR sufficiently great to justify the universal LR of all non-leukocyte transfusion blood components, irrespective of the theoretical considerations for TT-CJD?

YES	NO	ABS
13	0	3

- Consumer & Industry representatives: YES
- Cost / reimbursement NOT considered

FDA Workshop, December 1999
Implementation of Universal Leukocyte Reduction

- Implement within 2 yrs of FDA statement
- Center-specific implementation plan
- Update recommendations on QC testing
- Streamline licensing

FDA's Current Thinking

Advances in understanding the role of leukocytes
- Growing list of indications for LR
- Effective in reducing vCJD risk?

Routine use of LR components

Continue to recognize LR and non-LR components

Reimbursement
- Only significant concern against ULR
- DHHS level with PHS-AC as focal point
- Minimize adverse impact on health care delivery

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