



MEMBER  
EYE BANK ASSOCIATION OF AMERICA

841 Mountain Ave.  
Springfield, NJ 07081  
Marshall S. Klein  
Executive Director

# LIONS EYE BANK



# OF NEW JERSEY



01774 '99 DEC 30 10 57  
1-800-NJ-EYES-9  
(973) 921-1222  
(24 Hours)

Darrell J. Fisher, MS PA-C  
Technical Program Mgr.

December 28, 1999

Docket Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, room 1061  
Rockville, MD 20852

RE: 21 CFR, parts 210, 211, 820 and 1271  
(Docket No. 97N-484S)

**Proposed Rule: Suitability Determination for Donors of Human Cellular and Tissue Based Products**

Dear Sir or Madam:

The Lions Eye Bank of New Jersey is an affiliate of Tissue Bank International (TBI) and a member of the Eye Bank Association of America (EBAA). I have read the position paper sent to you by Richard Fuller, President/CEO of TBI and I wholeheartedly lend my complete support to this document.

I have been in eye banking since 1959 and have seen all of the changes that have occurred during these past 40 years and have noticed one common denominator and that is, every time there is a new regulation, the cost of eye banking goes up dramatically. A case in point is that prior to 1980, the cost of acquiring eyes were very low as we were able to count on volunteers to remove eyes (funeral directors), state police to transport them and eye residents to receive the transfer of donor eyes.

In 1980, a new regulation stated that we now must do serology and begin to take more history regarding the donor. We realized that we had to hire trained technicians who were capable of not only removing eyes, but also remove the cornea and follow up on all donor information before a cornea was released.

In those days prior to 1980, there wasn't a case where there was an adverse reaction. It seems to me, that our goal for perfection carries a high price tag. The EBAA has done a terrific job in monitoring the member eye banks by holding on site inspections, certifying eye bank technicians and carrying out their main function through the Medical Standards Committee.

97N 484S

C346

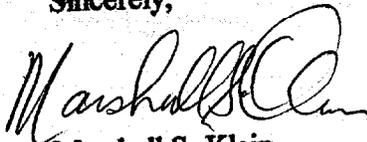
page (2)

The Lions Eye Bank of New Jersey is an eye only eye bank and is not involved with other tissue. As an affiliate of TBI, we certainly understand their other operations and support their position.

As an old time eye banker, I have always admired TBI's vision for the future as they have been involved with the many changes that have occurred during these past 20 plus years. As we approach the next century, it is very comfortable to know that there are organizations like TBI and the EBAA looking out for their member eye banks and also the individuals who benefit from transplants.

It is indeed an honor for me to be part of an organization that has the best interest of the public. I know that as individual eye bank we could never have the impact of those two organizations.

Sincerely,



Marshall S. Klein,  
Executive Director

RECIPIENT:  
The sender has requested notification upon delivery.  
Immediately upon receipt, please telephone:

Name: \_\_\_\_\_  
Tel. No.: ( ) \_\_\_\_\_



9252

PAID  
JAMESBURG, NJ  
08831  
DEC 28 '99  
AMOUNT

\$11.75  
00069652-02

**EXPRESS MAIL**  
UNITED STATES POSTAL SERVICE

www.usps.gov



**POST OFFICE TO ADDRESSEE**

E19956160690S

**ORIGIN (POSTAL USE ONLY)**

PO ZIP Code	Day of Delivery <input type="checkbox"/> Next <input type="checkbox"/> Second <input type="checkbox"/>	Flat Rate Envelope <input type="checkbox"/>
Date In Mo. Day Year	<input type="checkbox"/> 12 Noon <input type="checkbox"/> 3 PM	Postage \$ 11.75
Time In <input type="checkbox"/> AM <input type="checkbox"/> PM		
Weight lbs ozs	Int'l Alpha Country Code	
No Delivery <input type="checkbox"/> Weekend <input type="checkbox"/> Holiday	Acceptance Clerk Initials	Total Postage & Fees \$ 11.75

**DELIVERY (POSTAL USE ONLY)**

Delivery Attempt	Time <input type="checkbox"/> AM <input type="checkbox"/> PM	Employee Signature
Mo. Day		
Delivery Attempt	Time <input type="checkbox"/> AM <input type="checkbox"/> PM	Employee Signature
Mo. Day		
Date of Delivery	Time <input type="checkbox"/> AM <input type="checkbox"/> PM	Employee Signature
Mo. Day		
Signature of Addressee or Agent <i>[Signature]</i>		
X Name - Please Print		
X		

Addressee Copy



**CUSTOMER USE ONLY**  
TO FILE A CLAIM FOR DAMAGE OR LOSS OF CONTENTS, YOU MUST PRESENT THE ARTICLE, CONTAINER AND PACKAGING.

WAIVER OF SIGNATURE (Domestic Only): I wish delivery to be made without obtaining signature of addressee or package agent. If delivery employee judges that article can be left in secure location and I authorize that delivery employee's signature constitutes valid proof of delivery.

NO DELIVERY  Weekend  Holiday

**FROM: (PLEASE PRINT)** \_\_\_\_\_  
PHONE \_\_\_\_\_  
*Springfield, NJ*

**TO: (PLEASE PRINT)** \_\_\_\_\_  
PHONE \_\_\_\_\_  
*HFA-300*  
*5630*  
*1066*

FOR PICKUP OR TRACKING CALL 1-800-222-1811

