

MID-AMERICA TRANSPLANT SERVICES

5265 '00 FEB -1 A11 56

1139 Olivette Executive Parkway
St. Louis, MO 63132-3205
314-991-1661
314-991-2805 Fax
www.mts-stl.org

January 31, 2000

Medical Directors

Keith A. Hruska, M.D.
314-454-7771
khruska@imgate.wustl.edu
Martin D. Jendrisak, M.D.
314-569-6225
Robert P. Saylor, M.D.
417-886-5000
rsaylor@dialnet.net

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

RE: Docket #97N-484S
21 CFR Parts 210, 211, 820, 1271

Board of Directors

Charles B. Anderson, M.D.
Robert Bezanson
Marianne Blake
Richard P. Ellerbrake
Paul J. Garvin, M.D.
Michael Graham, M.D.
Todd K. Howard, M.D.
Kathryn L. Kiefer
Nicholas T. Kouchoukos, M.D.
Lawrence A. Kriegshauser, M.D.
J. Alexander Marchosky, M.D.
Lawrence A. McBride, M.D.
Robert E. Murphy
Gerald Ortvals
Jay S. Pepose, M.D.
Pam Reese
Will Ross, M.D.
Darwin W. Schlag, Jr., C.P.A.
William C. Schoenhard
Daniel Scodary, M.D.
Gregorio A. Sicard, M.D.
Kenneth R. Smith, Jr., M.D.
Marc D. Smith, Ph.D.
Patricia Talone, R.S.M., Ph.D.
Christopher Veremakis, M.D.
Mary Vieth
Robert Vieth

President

Dean F. Kappel
dfkappel@mts-stl.org

Dear Sir or Madam,

Mid-America Transplant Services (MTS) Eye and Tissue Bank appreciates the opportunity to comment on the proposed rule 21 CFR Part 1271 "Suitability Determination for Donors of Human Cellular and Tissue-Based Products". Our specific comments are outlined below.

General:

'Manufacturers' - tissue banks do not manufacture tissue, but rather process it. Although this seems a minor point, consistency in terminology is needed in order to distinguish the processing of human tissue for transplant from terminology normally found in the manufacturing industry. The term 'manufacturers' is used throughout the regulation and should be removed.

'Product' - this term is also used throughout the document, and has historically been avoided in the tissue industry. Product also implies the production of something – not the processing of donated human tissue into a useable graft.

Medical/Social History Questionnaire - MTS Eye and Tissue Bank supports requiring a medical/social history interview on each tissue and/or eye donor. Legislative consent regulations have allowed eye banks to retrieve and distribute corneas from donors without assessing high-risk behaviors – behaviors that may not be evident during an autopsy. Requiring this screening on all donors would enhance the safety of the cornea supply. In addition, part of the justification for legislative consent has been that there is a cornea shortage in this

97N-484S

C452

country - current donation rates have enabled most eye banks to become exporters of tissue.

Implementation Dates – The final regulation needs to be very specific as to implementation dates. Tissue that has been retrieved, processed, and has been cleared for distribution under current rules may be distributed after the new rules have been enacted. Current regulations went into effect for tissue retrieved after the implementation date – we would recommend a similar approach with this regulation.

1271.80:

(b) – *The donor specimen shall be collected at the time of the recovery of cells or tissue from the donor or within 48 hours after recovery, except that the ...* This requirement does not allow for the substitution of a pre-transfusion sample. Pre-transfusion samples can be obtained several hours, or even several days, prior to death. In some cases, samples obtained at the time of death have been hemodiluted, and a pre-transfusion sample is required. This section appears to run counter to previous regulation indicating that pre-transfusions samples are required and/or preferred in some instances.

1271.1 (o):

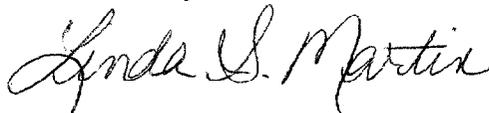
The *Donor medical history interview* definition indicates that a 'documented dialogue' is necessary. What is the definition of a documented dialogue – does this include telephone, in-person, written exchanges, etc.?

1271.3 (t):

Quarantine - "...in a physically separate area..." . What is the definition of a physically separate area? Does that mean an area in the same refrigeration unit, or does it mean in a completely different unit?

Thank you for the opportunity to comment on this pending regulation. We hope that these comments will be considered in developing the final regulation.

Sincerely,



Linda S. Martin
Director, Eye and Tissue Bank Operations

FedEx USA Airbill

FedEx Tracking Number

8157 4702 4890

Form ID No.

0215

Recipients Copy

RECIPIENT: PEEL HERE

1 From This portion can be removed for Recipient's records. FedEx Tracking Number 815747024890

Date 1-31-00 FedEx Tracking Number

Sender's Name M. J. ... Phone 314 991-1661

Company MID-AMERICA EYE & TISSUE BANK

Address 1139 OLIVETTE EXECUTIVE PKWY Dept./Floor/Suite/Room

City OLIVETTE State MO ZIP 63132

2 Your Internal Billing Reference

3 To Recipient's Name Dockab Mgt Branch Phone

Company Food and Drug Administration

Address 5630 Fisher Lane, # 1021 Dept./Floor/Suite/Room

We cannot deliver to P.O. Boxes or P.O. ZIP codes.

To "HOLD" at FedEx location, print FedEx address here.

City Rockville State MD ZIP 20852



4a Express Package Service

FedEx Priority Overnight Next business morning

FedEx Standard Overnight Next business afternoon

FedEx First Overnight Earliest next business morning delivery to select locations

FedEx 2Day* Second business day

FedEx Express Saver* Third business day

* FedEx Letter Rate not available. Minimum charge: One-pound rate.

4b Express Freight Service

FedEx 1Day Freight* Next business day

FedEx 2Day Freight Second business day

FedEx 3Day Freight Third business day

* Call for Confirmation.

5 Packaging

FedEx Letter* FedEx Pak* Other Pkg. Includes FedEx Box, FedEx Tube, and customer pkg.

* Declared value limit \$500

6 Special Handling

Saturday Delivery Available for FedEx Priority Overnight and FedEx 2Day to select ZIP codes

Sunday Delivery Available for FedEx Priority Overnight to select ZIP codes

HOLD Weekday at FedEx Location Not available with FedEx First Overnight

HOLD Saturday at FedEx Location Available for FedEx Priority Overnight and FedEx 2Day to select locations

Does this shipment contain dangerous goods?
One box must be checked.

No Yes As per attached Shipper's Declaration Yes Shipper's Declaration not required

Dry Ice Dry Ice, 5 UN 1845 x _____ kg

Cargo Aircraft Only

Dangerous Goods cannot be shipped in FedEx packaging.

7 Payment Bill to:

Sender Acct. No. in Section I will be billed

Recipient Third Party Credit Card Cash/Check

Enter FedEx Acct. No. or Credit Card No. below. Obtain Recip. Acct. No.

Total Packages 1 Total Weight _____ Total Charges _____

Credit Card Auth. _____

*Our liability is limited to \$100 unless you declare a higher value. See the FedEx Service Guide for details.

8 Release Signature Sign to authorize delivery without obtaining signature.

By signing you authorize us to deliver this shipment without obtaining a signature and agree to indemnify and hold us harmless from any resulting claims.

Questions? Call 1-800-Go-FedEx (800-463-3339)

Visit our Web site at www.fedex.com

SRP 999 • Rev. Date 11/98 • Part #154813S • © 1994-98 FedEx • PRINTED IN U.S.A.

359

0111972076