South Texas Blood & Tissue Center

"Serving the community for over 30 years"

FORM APPROVED: OMB No. 0910-0052. Expiration Date: March 31, 2009. See instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
BLOOD ESTABLISHMENT REGISTRATION AND PRODUCT LISTING

1. REGISTRATION NUMBER
FEI: 1676815
CFN: 1676815

2. U.S. LICENSE NUMBER
678

3. REASON FOR SUBMISSION
.1 ☑ ANNUAL REGISTRATION
.2 ☐ INITIAL REGISTRATION
.3 ☐ CHANGE IN INFORMATION

FOR FDA USE ONLY 31

DISTRICT OFFICE: Dallas
VALIDATED BY FDA: 13-DEC-2008
PRINTED BY FDA: 15-DEC-2008

PLEASE READ INSTRUCTIONS CAREFULLY. Be sure to indicate any changes in your legal name or actual location in item 4, and any changes in your mailing address in item 6. Print all entries and make all corrections in red ink, if possible. Enter your phone number in item 8.3 and the phone number of your actual location in item 4.1. Sign the form and return to FDA. After validation, you will receive your Official Registration for the ensuing year.

This form is authorized by Sections 510(b), (j) and 704 of the Federal Food, Drug, and Cosmetic Act (Title 21, United States Code 360(b), (j) and 374). Failure to report this information is a violation of Section 301(f) and (p) of the Act (Title 21, United States Code 331(f) and (p)) and can result in a fine of up to $1,000 or imprisonment up to one year or both, pursuant to Section 303(a) of the Act (Title 21, United States Code 33.3(a)).

ENTER ALL CHANGES IN RED INK AND CIRCLE.

4. LEGAL NAME AND LOCATION (Include legal name, number and street, city, state, country, and post office code)

South Texas Blood and Tissue Center
6211 IH10 West at First Park Ten Blvd.
San Antonio, TX 78201

4.1 PHONE 210-731-5555

5. OTHER NAMES USED AT THIS LOCATION (Include trade name, doing-business-as, previous names, and other firms co-located. If applicable, include registration number.)

Qualtex Laboratories

6. MAILING ADDRESS OF REPORTING OFFICIAL (Include institution name if applicable, number and street, city, state, country, and post office code)

South Texas Blood and Tissue Center
ATTN: Norman D. Kalmin, M.D.
6211 IH10 West
San Antonio, TX 78201

7. U.S. AGENT (Include name, institution name if applicable, number and street, city, state, and zip code)

7.1 E-MAIL ADDRESS
7.2 PHONE

8. REPORTING OFFICIAL'S SIGNATURE

N.D. Kalmin

8.1 TYPED NAME Norman D. Kalmin, M.D.
8.2 E-MAIL ADDRESS patricia.cappelli@bloodntissue.org
8.3 PHONE 210-731-5543 8.4 DATE

9. TYPE OF OWNERSHIP
.1 ☐ SINGLE PROPRIETORSHIP
.2 ☐ PARTNERSHIP
.3 ☑ CORPORATION profit ___ non-profit ☑
.4 ☐ COOPERATIVE ASSOCIATION
.5 ☐ FEDERAL (non-military)
.6 ☐ U.S. MILITARY
.7 ☐ STATE
.8 ☐ COUNTY/MUNICIPAL/HOSPITAL AUTHORITY
.9 ☐ OTHER (Specify) :

10. TYPE ESTABLISHMENT (Check all boxes that describe routine or autologous operations.)
.1 ☑ COMMUNITY (NON-HOSPITAL) BLOOD BANK
.2 ☐ HOSPITAL BLOOD BANK
.3 ☐ PLASMAPHERESIS CENTER
.4 ☐ PRODUCT TESTING LABORATORY
a. ___ INDEPENDENT
___ ASSOCIATED W/ COMMUNITY or HOSPITAL BLOOD BANK
.5 ☐ HOSPITAL TRANSFUSION SERVICE
a. ___ APPROVED FOR MEDICARE REIMBURSEMENT
___ NOT APPROVED FOR MEDICARE REIMBURSEMENT
.6 ☐ COMPONENT PREPARATION FACILITY
.7 ☐ COLLECTION FACILITY
.8 ☐ DISTRIBUTION CENTER
U.S. LICENSE NUMBER OF PARENT FIRM
.9 ☐ BROKER/WAREHOUSE
.10 ☐ OTHER (Specify) :

11. PRODUCTS

		X ALLOGENEIC	X AUTOLOGOUS	X DIRECTED	COLLECT (.1)	MANUAL APHERESIS (.2)	AUTOMATED APHERESIS (.3)	PREPARE (.4)	LEUKOCYTES REDUCED (.5)	IRRADIATED (.6)	DONOR RETESTED (.7)	TEST (.8)	STORE and DISTRIBUTE to OTHERS (.9)
WHOLE BLOOD	1				X					X			X
RED BLOOD CELLS (RBC)	2						X	X	X	X			X
RBC FROZEN	3							X	X				X
RBC DEGLYCEROLIZED	4							X	X	X			X
RBC REJUVENATED	5												
RBC REJUVENATED FROZEN	6												
RBC REJUVENATED DEGLYCEROLIZED	7												
CRYOPRECIPITATED AHF	8							X					X
PLATELETS	9						X	X	X	X			X
LEUKOCYTES/GRANULOCYTES	10												
PLASMA	11						X	X					X
PLASMA CRYOPRECIPITATE REDUCED	12							X					X
FRESH FROZEN PLASMA	13						X	X					X
LIQUID PLASMA	14							X					X
THERAPEUTIC EXCHANGE PLASMA	15												
SOURCE LEUKOCYTES	16												X
SOURCE PLASMA	17												
RECOVERED PLASMA	18							X					X
BLOOD PRODUCTS FOR DIAGNOSTIC USE	19												
BLOOD BANK REAGENTS	20												
OTHER	21												

FORM FDA 2830 (11/2000) PREVIOUS EDITION IS OBSOLETE

ISO REGISTERED FIRM

Main Office: 6211 IH 10 West at First Part Ten Blvd. • San Antonio, Texas 78201 • (210) 731-5555 • 1-800-292-5534 • FAX (210) 731-5505
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