

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


1. REGISTRATION NUMBER
FEI: 3000718968
CFN: 1062493

2. U.S. LICENSE NUMBER

3. REASON FOR SUBMISSION

1 ANNUAL REGISTRATION
2 INITIAL REGISTRATION
3 CHANGE IN INFORMATION

FOR FDA USE ONLY 47



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 333(a)).

DISTRICT OFFICE: New Orleans
VALIDATED BY FDA: 27-NOV-2007
PRINTED BY FDA: 27-NOV-2007

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)

Research & Diagnostic Laboratories, Inc.
4402 Terrace View Road
Louisville, TN 37777

4.1 PHONE 865-273-6019

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
9 BROKER/WAREHOUSE
10 OTHER (Specify): _____

U.S. LICENSE NUMBER OF PARENT FIRM _____

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.)

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

Research & Diagnostic Laboratories, Inc.
ATTN: Ernest W. Fuson, Ph.D.
P.O. Box 160
Louisville, TN 37777

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

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

B. REPORTING OFFICIAL'S SIGNATURE

Ernest W. Fuson
8.1 TYPED NAME Ernest W. Fuson, Ph.D.
8.2 E-MAIL ADDRESS EWFuson@Aol.com
8.3 PHONE 865-977-5598
8.4 DATE 12/10/07