

DEPARTMENT OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C.

ESTABLISHMENT LICENSE

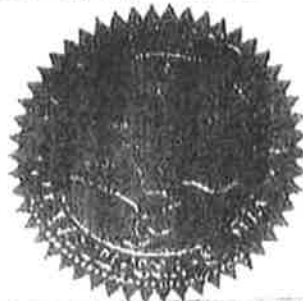
FOR THE MANUFACTURE OF
BIOLOGICAL PRODUCTS

This is to certify that Establishment License No. 634 is hereby issued
to Central Kentucky Blood Center, Inc., the manufacturer,
located at Lexington, Kentucky, through the establishment
identified as Central Kentucky Blood Center, Inc.
located at Lexington, Kentucky


DUPLICATE


pursuant to Section 351 of the Public Health Service Act, approved July 1, 1944 (58 Stat. 702, 42 U.S.C. 262), as amended, and the regulations thereunder. The license authorizes the manufacturer to maintain an establishment for the propagation or manufacture and preparation for sale, barter, or exchange in the District of Columbia, or for sending, carrying, or bringing for sale, barter, or exchange from any State or possession into any other State or possession or into any foreign country, or from any foreign country into any State or possession, any virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product, or streptococci or its derivatives, for which the manufacturer holds an unsuspended and unrevoked product license issued by the Secretary of Health and Human Services pursuant to said Act and regulation.


Date July 7, 1976



[Signature]
Director, Center for Biological
Evaluation and Research
Food and Drug Administration

| DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION BLOOD ESTABLISHMENT REGISTRATION AND PRODUCT LISTING | | 1. REGISTRATION NUMBER FBI: 1048401 CFN: 1048401 | 3. REASON FOR SUBMISSION .1 <input checked="" type="checkbox"/> ANNUAL REGISTRATION .2 <input type="checkbox"/> INITIAL REGISTRATION .3 <input type="checkbox"/> CHANGE IN INFORMATION | FOR FDA USE ONLY  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| 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. ENTER ALL CHANGES IN RED INK AND CIRCLE. | | 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)). | | DISTRICT OFFICE: Cincinnati VALIDATED BY FDA: 30-DEC-2016 PRINTED BY FDA: 18-JAN-2017 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 4. LEGAL NAME AND LOCATION (Include legal name, number and street, city, state, country, and post office code) Kentucky Blood Center, Inc. 10 Stonegate Centre Somerset, KY 42503 4.1 PHONE 606-679-7413 | 9. TYPE OF OWNERSHIP .1 <input type="checkbox"/> SINGLE PROPRIETORSHIP .2 <input type="checkbox"/> PARTNERSHIP .3 <input checked="" type="checkbox"/> CORPORATION profit <input type="checkbox"/> non-profit <input checked="" type="checkbox"/> .4 <input type="checkbox"/> COOPERATIVE ASSOCIATION .5 <input type="checkbox"/> FEDERAL (non-military) .6 <input type="checkbox"/> U.S. MILITARY .7 <input type="checkbox"/> STATE .8 <input type="checkbox"/> COUNTY/MUNICIPAL/HOSPITAL AUTHORITY .9 <input type="checkbox"/> OTHER (Specify): _____ | 10. TYPE ESTABLISHMENT (Check all boxes that describe routine or autologous operations.) .1 <input type="checkbox"/> COMMUNITY (NON-HOSPITAL) BLOOD BANK .2 <input type="checkbox"/> HOSPITAL BLOOD BANK .3 <input type="checkbox"/> PLASMAPHERESIS CENTER .4 <input type="checkbox"/> PRODUCT TESTING LABORATORY a. <input type="checkbox"/> INDEPENDENT <input type="checkbox"/> ASSOCIATED W/ COMMUNITY or HOSPITAL BLOOD BANK .5 <input type="checkbox"/> HOSPITAL TRANSFUSION SERVICE a. <input type="checkbox"/> APPROVED FOR MEDICARE REIMBURSEMENT <input type="checkbox"/> NOT APPROVED FOR MEDICARE REIMBURSEMENT .6 <input type="checkbox"/> COMPONENT PREPARATION FACILITY .7 <input checked="" type="checkbox"/> COLLECTION FACILITY .8 <input type="checkbox"/> DISTRIBUTION CENTER .9 <input type="checkbox"/> BROKER/WAREHOUSE .10 <input type="checkbox"/> OTHER (Specify): _____ | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 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.) Kentucky Blood Center - Somerset | <table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr> <th style="text-align: left;">11. PRODUCTS</th> <th>COLLECT</th> <th>MANUAL APHERESIS</th> <th>AUTOMATED APHERESIS</th> <th>PREPARE</th> <th>LEUKOCYTES REDUCED</th> <th>IRRADIATED</th> <th>DONOR RETESTED</th> <th>TEST</th> <th>STORE and DISTRIBUTE to OTHERS</th> </tr> <tr> <th style="text-align: left;"> <input checked="" type="checkbox"/> ALLOGENEIC <input checked="" type="checkbox"/> AUTOLOGOUS <input checked="" type="checkbox"/> DIRECTED </th> <th>(1)</th> <th>(2)</th> <th>(3)</th> <th>(4)</th> <th>(5)</th> <th>(6)</th> <th>(7)</th> <th>(8)</th> <th>(9)</th> </tr> </thead> <tbody> <tr><td>WHOLE BLOOD</td><td>1</td><td style="text-align: center;">X</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>RED BLOOD CELLS (RBC)</td><td>2</td><td></td><td style="text-align: center;">X</td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>RBC FROZEN</td><td>3</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>RBC DEGLYCEROLIZED</td><td>4</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>RBC REJUVENATED</td><td>5</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>RBC REJUVENATED FROZEN</td><td>6</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>RBC REJUVENATED DEGLYCEROLIZED</td><td>7</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>CRYOPRECIPITATED AHF</td><td>8</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>PLATELETS</td><td>9</td><td></td><td style="text-align: center;">X</td><td></td><td style="text-align: center;">X</td><td></td><td></td><td></td><td></td></tr> <tr><td>LEUKOCYTES/GRANULOCYTES</td><td>10</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>PLASMA</td><td>11</td><td></td><td style="text-align: center;">X</td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>PLASMA CRYOPRECIPITATE REDUCED</td><td>12</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>FRESH FROZEN PLASMA</td><td>13</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>LIQUID PLASMA</td><td>14</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>THERAPEUTIC EXCHANGE PLASMA</td><td>15</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>SOURCE LEUKOCYTES</td><td>16</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>SOURCE PLASMA</td><td>17</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>RECOVERED PLASMA</td><td>18</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>BLOOD PRODUCTS FOR DIAGNOSTIC USE</td><td>19</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>BLOOD BANK REAGENTS</td><td>20</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>OTHER</td><td>21</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> </tbody> </table> | | | | 11. PRODUCTS | COLLECT | MANUAL APHERESIS | AUTOMATED APHERESIS | PREPARE | LEUKOCYTES REDUCED | IRRADIATED | DONOR RETESTED | TEST | STORE and DISTRIBUTE to OTHERS | <input checked="" type="checkbox"/> ALLOGENEIC <input checked="" type="checkbox"/> AUTOLOGOUS <input checked="" type="checkbox"/> DIRECTED | (1) | (2) | (3) | (4) | (5) | (6) | (7) | (8) | (9) | WHOLE BLOOD | 1 | X | | | | | | | | RED BLOOD CELLS (RBC) | 2 | | X | | | | | | | RBC FROZEN | 3 | | | | | | | | | RBC DEGLYCEROLIZED | 4 | | | | | | | | | RBC REJUVENATED | 5 | | | | | | | | | RBC REJUVENATED FROZEN | 6 | | | | | | | | | RBC REJUVENATED DEGLYCEROLIZED | 7 | | | | | | | | | CRYOPRECIPITATED AHF | 8 | | | | | | | | | PLATELETS | 9 | | X | | X | | | | | LEUKOCYTES/GRANULOCYTES | 10 | | | | | | | | | PLASMA | 11 | | X | | | | | | | PLASMA CRYOPRECIPITATE REDUCED | 12 | | | | | | | | | FRESH FROZEN PLASMA | 13 | | | | | | | | | LIQUID PLASMA | 14 | | | | | | | | | THERAPEUTIC EXCHANGE PLASMA | 15 | | | | | | | | | SOURCE LEUKOCYTES | 16 | | | | | | | | | SOURCE PLASMA | 17 | | | | | | | | | RECOVERED PLASMA | 18 | | | | | | | | | BLOOD PRODUCTS FOR DIAGNOSTIC USE | 19 | | | | | | | | | BLOOD BANK REAGENTS | 20 | | | | | | | | | OTHER | 21 | | | | | | | | |
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| PLATELETS | 9 | | X | | X | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| PLASMA | 11 | | X | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| LIQUID PLASMA | 14 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| SOURCE LEUKOCYTES | 16 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| RECOVERED PLASMA | 18 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| BLOOD BANK REAGENTS | 20 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| OTHER | 21 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 6. MAILING ADDRESS OF REPORTING OFFICIAL (Include institution name if applicable, number and street, city, state, country, and post office code) Kentucky Blood Center, Inc. ATTN: Debra Bowman, Executive Director of Quality & Reg 3121 Beaumont Centre Circle Lexington, KY 40513-1709 | 7.1 E-MAIL ADDRESS 7.2 PHONE | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 7. U.S. AGENT (Include name, institution name if applicable, number and street, city, state, and zip code) | 8. REPORTING OFFICIAL'S SIGNATURE 8.1 TYPED NAME Debra Bowman, Executive Director of Quality & Reg 8.2 E-MAIL ADDRESS dbowman@kybloodcenter.org 8.3 PHONE 859-519-3717 8.4 DATE | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |

| DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION BLOOD ESTABLISHMENT REGISTRATION AND PRODUCT LISTING | 1. REGISTRATION NUMBER FEI: 3011192341 CFN: 2. U.S. LICENSE NUMBER 1836 | 3. REASON FOR SUBMISSION .1 <input checked="" type="checkbox"/> ANNUAL REGISTRATION .2 <input type="checkbox"/> INITIAL REGISTRATION .3 <input type="checkbox"/> CHANGE IN INFORMATION | FOR FDA USE ONLY  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| 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) Kentucky Blood Center, Inc. 12905 Shelbyville Rd Suite 4 Louisville, KY 40243 4.1 PHONE 502-290-0537 | | 9. TYPE OF OWNERSHIP .1 <input type="checkbox"/> SINGLE PROPRIETORSHIP .2 <input type="checkbox"/> PARTNERSHIP .3 <input checked="" type="checkbox"/> CORPORATION profit <input type="checkbox"/> non-profit <input checked="" type="checkbox"/> .4 <input type="checkbox"/> COOPERATIVE ASSOCIATION .5 <input type="checkbox"/> FEDERAL (non-military) .6 <input type="checkbox"/> U.S. MILITARY .7 <input type="checkbox"/> STATE .8 <input type="checkbox"/> COUNTY/MUNICIPAL/HOSPITAL AUTHORITY .9 <input type="checkbox"/> OTHER (Specify): _____ | 10. TYPE ESTABLISHMENT (Check all boxes that describe routine or autologous operations.) .1 <input type="checkbox"/> COMMUNITY (NON-HOSPITAL) BLOOD BANK .2 <input type="checkbox"/> HOSPITAL BLOOD BANK .3 <input type="checkbox"/> PLASMAPHERESIS CENTER .4 <input type="checkbox"/> PRODUCT TESTING LABORATORY a. <input type="checkbox"/> INDEPENDENT <input type="checkbox"/> ASSOCIATED W/ COMMUNITY or HOSPITAL BLOOD BANK .5 <input type="checkbox"/> HOSPITAL TRANSFUSION SERVICE a. <input type="checkbox"/> APPROVED FOR MEDICARE REIMBURSEMENT <input type="checkbox"/> NOT APPROVED FOR MEDICARE REIMBURSEMENT .6 <input type="checkbox"/> COMPONENT PREPARATION FACILITY .7 <input checked="" type="checkbox"/> COLLECTION FACILITY .8 <input type="checkbox"/> DISTRIBUTION CENTER .9 <input type="checkbox"/> BROKER/WAREHOUSE .10 <input type="checkbox"/> OTHER (Specify): _____ | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 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.) Kentucky Blood Center - Middletown | | <table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr> <th rowspan="2">11. PRODUCTS</th> <th rowspan="2">COLLECT (.1)</th> <th rowspan="2">MANUAL APHERESIS (.2)</th> <th rowspan="2">AUTOMATED APHERESIS (.3)</th> <th rowspan="2">PREPARE (.4)</th> <th rowspan="2">LEUKOCYTES REDUCED (.5)</th> <th rowspan="2">IRRADIATED (.6)</th> <th rowspan="2">DONOR RETESTED (.7)</th> <th rowspan="2">TEST (.8)</th> <th rowspan="2">STORE and DISTRIBUTE to OTHERS (.9)</th> </tr> <tr> <th>ALLOGENEIC <input checked="" type="checkbox"/></th> <th>AUTOLOGOUS <input checked="" type="checkbox"/></th> <th>DIRECTED <input checked="" type="checkbox"/></th> </tr> </thead> <tbody> <tr><td>WHOLE BLOOD</td><td>1</td><td style="text-align: center;">X</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>RED BLOOD CELLS (RBC)</td><td>2</td><td></td><td style="text-align: center;">X</td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>RBC FROZEN</td><td>3</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>RBC DEGLYCEROLIZED</td><td>4</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>RBC REJUVENATED</td><td>5</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>RBC REJUVENATED FROZEN</td><td>6</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>RBC REJUVENATED DEGLYCEROLIZED</td><td>7</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>CRYOPRECIPITATED AHF</td><td>8</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>PLATELETS</td><td>9</td><td></td><td style="text-align: center;">X</td><td></td><td style="text-align: center;">X</td><td></td><td></td><td></td><td></td></tr> <tr><td>LEUKOCYTES/GRANULOCYTES</td><td>10</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>PLASMA</td><td>11</td><td></td><td style="text-align: center;">X</td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>PLASMA CRYOPRECIPITATE REDUCED</td><td>12</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>FRESH FROZEN PLASMA</td><td>13</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>LIQUID PLASMA</td><td>14</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>THERAPEUTIC EXCHANGE PLASMA</td><td>15</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>SOURCE LEUKOCYTES</td><td>16</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>SOURCE PLASMA</td><td>17</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>RECOVERED PLASMA</td><td>18</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>BLOOD PRODUCTS FOR DIAGNOSTIC USE</td><td>19</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>BLOOD BANK REAGENTS</td><td>20</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>OTHER</td><td>21</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> </tbody> </table> | | 11. PRODUCTS | 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) | ALLOGENEIC <input checked="" type="checkbox"/> | AUTOLOGOUS <input checked="" type="checkbox"/> | DIRECTED <input checked="" type="checkbox"/> | WHOLE BLOOD | 1 | X | | | | | | | | RED BLOOD CELLS (RBC) | 2 | | X | | | | | | | RBC FROZEN | 3 | | | | | | | | | RBC DEGLYCEROLIZED | 4 | | | | | | | | | RBC REJUVENATED | 5 | | | | | | | | | RBC REJUVENATED FROZEN | 6 | | | | | | | | | RBC REJUVENATED DEGLYCEROLIZED | 7 | | | | | | | | | CRYOPRECIPITATED AHF | 8 | | | | | | | | | PLATELETS | 9 | | X | | X | | | | | LEUKOCYTES/GRANULOCYTES | 10 | | | | | | | | | PLASMA | 11 | | X | | | | | | | PLASMA CRYOPRECIPITATE REDUCED | 12 | | | | | | | | | FRESH FROZEN PLASMA | 13 | | | | | | | | | LIQUID PLASMA | 14 | | | | | | | | | THERAPEUTIC EXCHANGE PLASMA | 15 | | | | | | | | | SOURCE LEUKOCYTES | 16 | | | | | | | | | SOURCE PLASMA | 17 | | | | | | | | | RECOVERED PLASMA | 18 | | | | | | | | | BLOOD PRODUCTS FOR DIAGNOSTIC USE | 19 | | | | | | | | | BLOOD BANK REAGENTS | 20 | | | | | | | | | OTHER | 21 | | | | | | | | |
| 11. PRODUCTS | 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) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | | | | ALLOGENEIC <input checked="" type="checkbox"/> | AUTOLOGOUS <input checked="" type="checkbox"/> | DIRECTED <input checked="" type="checkbox"/> | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| WHOLE BLOOD | 1 | X | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| RED BLOOD CELLS (RBC) | 2 | | X | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| RBC FROZEN | 3 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| RBC DEGLYCEROLIZED | 4 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| RBC REJUVENATED | 5 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| RBC REJUVENATED FROZEN | 6 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| RBC REJUVENATED DEGLYCEROLIZED | 7 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| CRYOPRECIPITATED AHF | 8 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| PLATELETS | 9 | | X | | X | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| PLASMA | 11 | | X | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| SOURCE PLASMA | 17 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| 6. MAILING ADDRESS OF REPORTING OFFICIAL (Include institution name if applicable, number and street, city, state, country, and post office code) Kentucky Blood Center ATTN: Debra D. Bowman 3121 Beaumont Centre Circle Lexington, KY 40513 | | 1836 U.S. LICENSE NUMBER OF PARENT FIRM | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 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 | | 8.1 TYPED NAME Debra D. Bowman 8.2 E-MAIL ADDRESS dbowman@kybloodcenter.org 8.3 PHONE 859-519-3717 8.4 DATE | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |

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|---|---|---|--|
| DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION BLOOD ESTABLISHMENT REGISTRATION AND PRODUCT LISTING | 1. REGISTRATION NUMBER FEI: 3013450009 CFN: 2. U.S. LICENSE NUMBER | 3. REASON FOR SUBMISSION .1 <input type="checkbox"/> ANNUAL REGISTRATION .2 <input type="checkbox"/> INITIAL REGISTRATION .3 <input type="checkbox"/> CHANGE IN INFORMATION | FOR FDA USE ONLY  |
|---|---|---|--|

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)).

DISTRICT OFFICE: Cincinnati
 VALIDATED BY FDA: 24-APR-2017
 PRINTED BY FDA: 24-APR-2017

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)

Kentucky Blood Center, Inc.
 2605 Kentucky Ave.
 MP3 Suite 104
 Paducah, KY 42003

4.1 PHONE 270-557-7821

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.)

Kentucky Blood Center - Paducah

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

Kentucky Blood Center, Inc.
 ATTN: Debra D. Bowman
 3121 Beaumont Centre Circle
 Lexington, KY 40513

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

8.1 TYPED NAME Debra D. Bowman
 8.2 E-MAIL ADDRESS dbowman@kybloodcenter.org
 8.3 PHONE 859-519-3717 8.4 DATE

| 11. PRODUCTS | 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 |
| RED BLOOD CELLS (RBC) | 2 | | | | | | | | X |
| 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 | | | | | | | | |
| PLASMA | 11 | | | | | | | | |
| PLASMA CRYOPRECIPITATE REDUCED | 12 | | | | | | | | |
| FRESH FROZEN PLASMA | 13 | | | | | | | | X |
| LIQUID PLASMA | 14 | | | | | | | | |
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| BLOOD BANK REAGENTS | 20 | | | | | | | | |
| OTHER | 21 | | | | | | | | |

| DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/Ps) (See reverse side for instructions) | | 1. REGISTRATION NUMBER (FDA Establishment Identifier) FEI: 0001070402 | 2. REASON FOR SUBMISSION a. <input type="checkbox"/> INITIAL REGISTRATION / LISTING b. <input checked="" type="checkbox"/> ANNUAL REGISTRATION / LISTING c. <input type="checkbox"/> CHANGE IN INFORMATION d. <input type="checkbox"/> INACTIVE | VALIDATION—FOR FDA USE ONLY VALIDATED BY FDA:30-DEC-2016 DISTRICT: Cincinnati PRINTED BY FDA:09-JAN-2017 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| PART I - ESTABLISHMENT INFORMATION 3. OTHER FDA REGISTRATIONS a. BLOOD FDA 2830 NO. FEI: 0001070402 b. DEVICES FDA 2891 NO. _____ c. DRUG FDA 2858 NO. _____ 4. PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and post office code) Kentucky Blood Center 3121 Beaumont Centre Circle Lexington, Kentucky 40513-1709 a. PHONE 859-276-2534 EXT _____ b. <input type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. _____) c. <input type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY 5. ENTER CORRECTIONS TO ITEM 4 6. MAILING ADDRESS OF REPORTING OFFICIAL (Include institution name if applicable, number and street, city, state, country, and post office code) Kentucky Blood Center Attn: Debra Bowman, MT(ASCP)SBB CQA(ASQ) 3121 Beaumont Centre Circle Lexington, Kentucky 40513-1709 a. PHONE 859-519-3717 EXT _____ 7. ENTER CORRECTIONS TO ITEM 6 b. PHONE _____ 8. U.S. AGENT a. E-MAIL _____ 9. REPORTING OFFICIAL'S SIGNATURE a. TYPED NAME Debra Bowman, MT(ASCP)SBB CQA(ASQ) b. E-MAIL dbowman@ckbc.org c. TITLE Exec. Director of Quality & Regulatory d. DATE 29-DEC-2016 | | PART II - PRODUCT INFORMATION 10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps <table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr> <th rowspan="2">Types of HCT / Ps</th> <th colspan="8">Establishment Functions</th> <th rowspan="2">11. HCT/Ps DESCRIBED IN 21 CFR 127.110</th> <th rowspan="2">12. HCT/Ps REGULATED AS MEDICAL DEVICES</th> <th rowspan="2">13. HCT/Ps REGULATED AS DRUGS OR BIOLOGICAL DRUGS</th> <th rowspan="2">14. PROPRIETARY NAME(S)</th> </tr> <tr> <th>Recover</th> <th>Screen</th> <th>Test</th> <th>Package</th> <th>Process</th> <th>Store</th> <th>Label</th> <th>Distribute</th> </tr> </thead> <tbody> <tr><td>a. Bone</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>b. Cartilage</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>c. Cornea</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>d. Dura Mater</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>e. Embryo <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>f. Faecis</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>g. Heart Valve</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>h. Ligament</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>i. Oocyte <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>j. Pericardium</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>k. Peripheral Blood Stem <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input checked="" type="checkbox"/> Allogeneic</td><td>X</td><td>X</td><td></td><td>X</td><td>X</td><td>X</td><td>X</td><td>X</td><td></td><td></td><td>X</td><td></td></tr> <tr><td>l. Sclera</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>m. Semen <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>n. Skin</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>o. Somatic Cell Therapy Products <input checked="" type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic</td><td>X</td><td></td><td></td><td>X</td><td></td><td></td><td></td><td></td><td></td><td></td><td>X</td><td></td></tr> <tr><td>p. Tendon</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>q. Umbilical Cord Blood <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>r. Vascular Graft</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>s. Therapeutic Cells</td><td>X</td><td>X</td><td></td><td>X</td><td>X</td><td>X</td><td>X</td><td>X</td><td></td><td></td><td>X</td><td></td></tr> <tr><td>t.</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>u.</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> <tr><td>v.</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr> </tbody> </table> | | | | | | | | Types of HCT / Ps | Establishment Functions | | | | | | | | 11. HCT/Ps DESCRIBED IN 21 CFR 127.110 | 12. HCT/Ps REGULATED AS MEDICAL DEVICES | 13. HCT/Ps REGULATED AS DRUGS OR BIOLOGICAL DRUGS | 14. PROPRIETARY NAME(S) | Recover | Screen | Test | Package | Process | Store | Label | Distribute | a. Bone | | | | | | | | | | | | | b. Cartilage | | | | | | | | | | | | | c. Cornea | | | | | | | | | | | | | d. Dura Mater | | | | | | | | | | | | | e. Embryo <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous | | | | | | | | | | | | | f. Faecis | | | | | | | | | | | | | g. Heart Valve | | | | | | | | | | | | | h. Ligament | | | | | | | | | | | | | i. Oocyte <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous | | | | | | | | | | | | | j. Pericardium | | | | | | | | | | | | | k. Peripheral Blood Stem <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input checked="" type="checkbox"/> Allogeneic | X | X | | X | X | X | X | X | | | X | | l. Sclera | | | | | | | | | | | | | m. Semen <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous | | | | | | | | | | | | | n. Skin | | | | | | | | | | | | | o. Somatic Cell Therapy Products <input checked="" type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic | X | | | X | | | | | | | X | | p. Tendon | | | | | | | | | | | | | q. Umbilical Cord Blood <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic | | | | | | | | | | | | | r. Vascular Graft | | | | | | | | | | | | | s. Therapeutic Cells | X | X | | X | X | X | X | X | | | X | | t. | | | | | | | | | | | | | u. | | | | | | | | | | | | | v. | | | | | | | | | | | | |
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| a. Bone | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| b. Cartilage | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| c. Cornea | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| d. Dura Mater | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| e. Embryo <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| f. Faecis | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| g. Heart Valve | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| h. Ligament | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| i. Oocyte <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| j. Pericardium | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| k. Peripheral Blood Stem <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input checked="" type="checkbox"/> Allogeneic | X | X | | X | X | X | X | X | | | X | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| m. Semen <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| n. Skin | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| o. Somatic Cell Therapy Products <input checked="" type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic | X | | | X | | | | | | | X | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| p. Tendon | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| q. Umbilical Cord Blood <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| r. Vascular Graft | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| s. Therapeutic Cells | X | X | | X | X | X | X | X | | | X | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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