Currently Approved CBER NDAs/ANDAs By Applicant As Of 30-AUG-2019

Arteriocyte Medical Systems, Inc
45 South Street, Suite 3
Hopkinton MA 01748

BA110057
Product Name: Anticoagulant Citrate Dextrose Solution (ACD)
Approved Date: 11-MAY-2012
Trade Name: Anticoagulant Citrate Dextrose Solution, USP (ACD-A)

B. Braun Medical, Inc.
901 Marcon Blvd
Allentown PA 18109

BA110013
Product Name: 6% Hydroxyethyl Starch 130/0.4 in 0.9% Sodium Chloride Injection
Approved Date: 09-JAN-2015
Trade Name: Expanza

BN890105
Product Name: Hetastarch
Approved Date: 04-APR-1991
Trade Name: HESPAN (R) 6% Hetastarch in 0.9% NaCl, 250, 500, 1000 ml EXCEL Containers

BioTime, Inc.
1301 Harbor Bay Pkwy
Alameda CA 94502

BN200952
Product Name: Hetastarch
Approved Date: 31-MAR-1999
Trade Name: Hextend HMW Hydroxyethyl Starch (6%)

Citra Labs, LLC
55 Messina Drive
Braintree MA 02184

BN010409
Product Name: Anticoagulant Sodium Citrate Solution
Approved Date: 10-JUL-2003
Trade Name: triCitrasol Anticoagulant Sodium Citrate Conc. 46.7% Trisodium Citrate, 30mL.

BN020037
Product Name: Anticoagulant Citrate Dextrose Solution, Solution A, (ACD-A)
Approved Date: 26-AUG-2003
Trade Name: Anticoagulant Citrate Dextrose Solution, Solution, U.S.P., (ACD-A). 50 mL, PN 6053

BN950522
Product Name: Rejuvesol
Approved Date: 26-FEB-1997
Trade Name: Rejuvesol, CPD, ADSOL (AS-1)
<table>
<thead>
<tr>
<th>Product Name</th>
<th>Approved Date</th>
<th>Trade Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anticoagulant Citrate Dextrose Solution (ACD)</td>
<td>29-AUG-2002</td>
<td>Adsol with ACD-A</td>
</tr>
<tr>
<td>Anticoagulant Citrate Dextrose Solution (ACD)</td>
<td>17-MAR-1978</td>
<td>ACD BLOOD PACK UNITS, USP, in PL 146 Plastic</td>
</tr>
<tr>
<td>Anticoagulant Citrate Dextrose Solution (CPD)</td>
<td>06-DEC-1977</td>
<td>CPD BLOOD-PACK Unit, (PL 146 Plastic) 500 mL bulk, 450 mL bag, ...</td>
</tr>
<tr>
<td>Anticoagulant Citrate Phosphate Dextrose Solution (CPDA-1)</td>
<td>12-MAY-1978</td>
<td>CPDA-1 BLOOD-PACK Unit, (PL 146 Plastic) 250, 450, 500 mL Blood Pack Units</td>
</tr>
<tr>
<td>Anticoagulant Sodium Citrate Solution</td>
<td>20-JAN-1978</td>
<td>Sodium Citrate Blood Pack Units, (PL 146 Plastic) 250 mL and 500 mL bulk units</td>
</tr>
<tr>
<td>Anticoagulant Citrate Dextrose Solution (CPD)</td>
<td>28-JUN-1983</td>
<td>CPD BLOOD-PACK Unit, (PL 1240 Plastic)</td>
</tr>
<tr>
<td>Anticoagulant Citrate Dextrose Solution (CPD)</td>
<td>16-MAY-1983</td>
<td>CPD, ADSOL Red Cell Preservation Solution, (PL 146) and/or SEPACELL Filter</td>
</tr>
<tr>
<td>Anticoagulant Citrate Dextrose Solution (CPD)</td>
<td>27-DEC-1991</td>
<td>ADSOL Red Cell Preservation Solution (PL 2209) CPD and ADSOL and/or SEPACELL in PL 2209</td>
</tr>
<tr>
<td>Anticoagulant Citrate Dextrose Solution (CPD)</td>
<td>27-DEC-1991</td>
<td>CPD Anticoagulant in PL 2209 Plastic</td>
</tr>
<tr>
<td>Anticoagulant Citrate Dextrose Adenine Solution (CPDA-1)</td>
<td>28-JUL-1994</td>
<td>CPDA-1 BLOOD PACK UNIT in PL 2209</td>
</tr>
</tbody>
</table>
Product Name: Platelet Additive Solution 3
Approved Date: 09-DEC-2009
Trade Name: InterSol Solution

Fresenius Kabi AG
Else-Kroner Strasse 1
D-61352
Bad Homburg 01 61352 Germany

Product Name: 6% Hydroxyethyl Starch 130/0.4 in 0.9% Sodium Chloride Injection
Approved Date: 27-DEC-2007
Trade Name: Voluven

Haemonetics Corporation
400 Wood Road
Braintree MA 02184

Product Name: Anticoagulant Citrate Dextrose Solution (ACD)
Approved Date: 06-FEB-2002
Trade Name: Anticoagulant Citrate Dextrose Solution Formula A

Product Name: Anticoagulant Citrate Phosphate 2X Dextrose Solution (CP2D)
Approved Date: 18-JAN-2002
Trade Name: Citrate Phosphate Double Dextrose/Additive Soln 3

Product Name: unidentifiable product
Approved Date: 25-APR-2013
Trade Name: LEUKOSEP® HWB-600-XL Leukocyte Reduction Filtration System for Whole Blood with CPD Anticoagulant and SOLX® Additive

Product Name: Anticoagulant Sodium Citrate 4% Solution
Approved Date: 03-MAR-2000
Trade Name: Anticoagulant Sodium Citrate, 4% w/v Solution USP

Haemonetics Manufacturing Inc.
400 Wood Road
Braintree MA 02184

Product Name: Anticoagulant Sodium Citrate Solution
Approved Date: 30-JUN-1978
Trade Name: Anticoagulant 4% Sodium Citrate Solution

Product Name: Anticoagulant Citrate Phosphate Dextrose Adenine Solution (CPDA-1)
Approved Date: 06-NOV-1980
Trade Name: CPDA-1

Product Name: Anticoagulant Citrate Phosphate Dextrose Solution (CPD)
Approved Date: 23-AUG-1982
Trade Name:
Product Name: Anticoagulant Citrate Phosphate 2X Dextrose Solution (CP2D)
Approved Date: 22-SEP-1983
Trade Name: CP2D and AS-3 Nutricel

Hospira, Inc.
275 N. Field Drive
Lake Forest IL 60045

BA720562
Product Name: Dextran 40
Approved Date: 30-OCT-1992
Trade Name: 500 mL Flexible Containers

BA720563
Product Name: Dextran 40
Approved Date: 30-OCT-1992
Trade Name: 10% Low Molecular Weight Dextrose (LMD) in 5% Dextrose

BA740193
Product Name: Hetastarch
Approved Date: 30-JAN-1995
Trade Name: 6% Hetastarch in 0.9% NaCl 500 mL in PVC Plastic

Macopharma
3675 Crestwood Parkway, Suite 260
Duluth GA 30096

BN040083
Product Name: Anticoagulant Citrate Phosphate Dextrose Solution (CPD)
Approved Date: 21-NOV-2005
Trade Name: MacoProductions S.A.S. CPD/AS-1: MacoPharma Leucoflex MTL1 Leukoreduction System for Blood Components known as MTL1-WB

BN125552
Product Name: Cord Blood Sterile Collection Bag, Anticoagulant Citrate Phosphate Dextrose Solution (CPD)
Approved Date: 21-DEC-2016
Trade Name:

Meda AB
Kanalvagen 18
P. O. Box 625
SE-194 26
Upplands Vasby Sweden

BN830715
Product Name: Dextran 1
Approved Date: 30-OCT-1984
Trade Name: PROMIT

TERUMO BCT
10811 W. Collins Ave
Lakewood CO 80215

BA125608
Product Name: Anticoagulant Sodium Citrate 4% Solution
Approved Date: 26-JUN-2018
Trade Name: unidentifiable product

Approved Date: 05-MAR-2013
Trade Name: Isoplate Solution

Terumo BCT, Inc
10811 W. Collins Ave.
Lakewood CO 80215

BA010228
Product Name: Anticoagulant Citrate Dextrose Solution (ACD)
Approved Date: 25-FEB-2002
Trade Name: ACD-A Solution

BA070025
Product Name: Anticoagulant Citrate Phosphate Dextrose Solution (CPD)
Approved Date: 06-JAN-2009
Trade Name: GAMBRO BCT

BN001214
Product Name: Additive Solution 3; AS-3
Approved Date: 29-MAY-2002
Trade Name:

Terumo Corporation
125 Blue Ball Road
Elkton MD 21921

BN781211
Product Name: Anticoagulant Citrate Phosphate Dextrose Solution (CPD)
Approved Date: 10-JUN-1981
Trade Name: Anticoagulant Citrate Phosphate Dextrose (CPD) Solution in TERUFLEX Blood Bag System

BN781214
Product Name: Anticoagulant Sodium Citrate Solution
Approved Date: 08-FEB-1980
Trade Name: Anticoagulant 4% Sodium Citrate Solution in TERUFLEX Blood Bag System

BN820528
Product Name: Anticoagulant Citrate Phosphate Dextrose Adenine Solution (CPDA-1)
Approved Date: 03-NOV-1982
Trade Name: Anticoagulant Citrate Phosphate Dextrose Adenine (CPDA-1) Solution in TERUFLEX Blood Bag System

BN880217
Product Name: Anticoagulant Citrate Phosphate Dextrose Solution (CPD)
Approved Date: 07-OCT-1988
Trade Name: (OPTISOL) Anticoagulant Citrate Phosphate Dextrose (CPD) Solution with OPTISOL Red Cell Preservative Solution in TERUFLEX (or IMUFLEX) Blood Bag System

Teva Pharmaceuticals USA, Inc.
19 Hughes
Irvine CA 92718
Product Name: Hetastarch
Approved Date: 12-NOV-1998
Trade Name: 6% Hetastarch in 0.9% NaCl in 500mL Plastic Bags