

Currently Approved CBER NDAs/ANDAs  
By Applicant As Of 17-JUL-2017

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)

Fenwal Inc

Three Corporate Drive  
Lake Zurich IL 60047

BN000922

Product Name: Anticoagulant Citrate Dextrose Solution (ACD)  
Approved Date: 29-AUG-2002  
Trade Name: Adsol with ACD-A

BN080041

Product Name: unidentifiable product  
Approved Date: 09-DEC-2009  
Trade Name: InterSol Solution

BN160918

Product Name: Anticoagulant Citrate Dextrose Solution (ACD)  
Approved Date: 17-MAR-1978  
Trade Name: ACD BLOOD PACK UNITS, USP, in PL 146 Plastic 450mL bags; 500mL and 1000mL bulk

BN170401

Product Name: Anticoagulant Citrate Phosphate Dextrose Solution (CPD)  
Approved Date: 06-DEC-1977  
Trade Name: CPD BLOOD-PACK Unit, (PL 146 Plastic) 500mL bulk, 450 mL bag, ...

BN770420

Product Name: Anticoagulant Citrate Phosphate Dextrose Adenine Solution (CPDA-1)  
Approved Date: 12-MAY-1978  
Trade Name: CPDA-1 BLOOD-PACK Unit, (PL 146 Plastic) 250, 450, 500 mL Blood Pack Units

BN770923

Product Name: Anticoagulant Sodium Citrate Solution  
Approved Date: 20-JAN-1978  
Trade Name: Sodium Citrate Blood Pack Units, (PL 146 Plastic) 250 mL and 500 mL bulk units

BN811012

Product Name: Anticoagulant Citrate Phosphate Dextrose Solution (CPD)  
Approved Date: 28-JUN-1983  
Trade Name: CPD BLOOD-PACK Unit, (PL 1240 Plastic)

BN811104

Product Name: Anticoagulant Citrate Phosphate Dextrose Solution

(CPD)  
Approved Date: 16-MAY-1983  
Trade Name: CPD, ADSOL Red Cell Preservation Solution, (PL 146) and/or SEPACELL Filter  
BN900223  
Product Name: Anticoagulant Citrate Phosphate Dextrose Solution (CPD)  
Approved Date: 27-DEC-1991  
Trade Name: ADSOL Red Cell Preservation Solution (PL 2209) CPD and ADSOL and/or SEPACELL in PL 2209  
BN900224  
Product Name: Anticoagulant Citrate Phosphate Dextrose Solution (CPD)  
Approved Date: 27-DEC-1991  
Trade Name: CPD Anticoagulant in PL 2209 Plastic  
BN940404  
Product Name: Anticoagulant Citrate Phosphate Dextrose Adenine Solution (CPDA-1)  
Approved Date: 28-JUL-1994  
Trade Name: CPDA-1 BLOOD PACK UNIT in PL 2209

Fresenius Kabi Deutschland GmbH

Else Kroner Strasse 1  
D-61352 Bad Homburg v.d.H.  
UNKNOWN Germany

BN070012  
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

BA980728  
Product Name: Anticoagulant Citrate Dextrose Solution (ACD)  
Approved Date: 06-FEB-2002  
Trade Name: Anticoagulant Citrate Dextrose Solution Formula A  
BN000127  
Product Name: Anticoagulant Citrate Phosphate 2X Dextrose Solution (CP2D)  
Approved Date: 18-JAN-2002  
Trade Name: Citrate Phosphate Double Dextrose/Additive Soln 3  
BN110059  
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

BN980123

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

Haemonetics Manufacturing Inc.

400 Wood Road  
Braintree MA 02184

BA710497

Product Name: Anticoagulant Citrate Dextrose Solution (ACD)  
Approved Date: 06-NOV-1987  
Trade Name: ACDA

BN760305

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

BN800077

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

BN800222

Product Name: Anticoagulant Citrate Phosphate Dextrose Solution  
(CPD)  
Approved Date: 23-AUG-1982  
Trade Name:

BN820915

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  
D-0389, Bldg. H2-2  
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

BN090067

Product 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: Anticoagulant Citrate Dextrose Solution (ACD)  
Approved Date: 29-MAY-2002  
Trade Name: AS3 Solution/ACD-A

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 Parenteral Medicines, Inc.

19 Hughes  
Irvine CA 92718

BA740592  
Product Name: Hetastarch  
Approved Date: 12-NOV-1998

Trade Name: 6% Hetastarch in 0.9% NaCl in 500mL Plastic Bags