

Currently Approved CBER NDAs/ANDAs By Applicant As Of 30-SEP-2018

Arterioocyte Medical Systems, Inc

45 South Street, Suite 3
Hopkinton MA 01748

BA110057

Product Name: Anti coagulant Citrate Dextrose Solution (ACD)
Approved Date: 11-MAY-2012
Trade Name: Anti coagulant 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: Anti coagulant Sodium Citrate Solution
Approved Date: 10-JUL-2003
Trade Name: tri Citrasol Anti coagulant Sodium Citrate Conc.
46.7% Trisodium Citrate, 30mL.

BN020037

Product Name: Anti coagulant Citrate Dextrose Solution, Solution
A, (ACD-A)
Approved Date: 26-AUG-2003
Trade Name: Anti coagulant 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: Anti coagulant Citrate Dextrose Solution (ACD)
Approved Date: 29-AUG-2002
Trade Name: Adsol with ACD-A

BN080041

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

BN160918

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

BN811104

Product Name: Anti coagulant 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: Anti coagulant 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: Anti coagulant Citrate Phosphate Dextrose Solution
(CPD)
Approved Date: 27-DEC-1991
Trade Name: CPD Anti coagulant in PL 2209 Plastic

BN940404

Product Name: Anti coagulant 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

El se-Kroner Strasse 1
D-61352
Bad Homburg 01 61352 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: undifferentiable 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 USP

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 Nutri cel

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: Anti coagulant 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, Anti coagulant 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: Anti coagulant Sodium Citrate Solution
Approved Date: 26-JUN-2018
Trade Name:

BN090067

Product Name: uni denti fi abl e product
Approved Date: 05-MAR-2013
Trade Name: I sopl ate Sol uti on

Terumo BCT, Inc

10811 W. Collins Ave.
Lakewood CO 80215

BA010228

Product Name: Anti coagul ant Ci trate Dextrose Sol uti on (ACD)
Approved Date: 25-FEB-2002
Trade Name: ACD-A Sol uti on

BA070025

Product Name: Anti coagul ant Ci trate Phosphate Dextrose Sol uti on
(CPD)
Approved Date: 06-JAN-2009
Trade Name: GAMBRO BCT

BN001214

Product Name: Anti coagul ant Ci trate Dextrose Sol uti on (ACD)
Approved Date: 29-MAY-2002
Trade Name: AS3 Sol uti on/ACD-A

Terumo Corporation

125 Blue Ball Road
Elkton MD 21921

BN781211

Product Name: Anti coagul ant Ci trate Phosphate Dextrose Sol uti on
(CPD)
Approved Date: 10-JUN-1981
Trade Name: Anti coagul ant Ci trate Phosphate Dextrose (CPD)
Sol uti on i n TERUFLEX Bl ood Bag System

BN781214

Product Name: Anti coagul ant Sod ium Ci trate Sol uti on
Approved Date: 08-FEB-1980
Trade Name: Anti coagul ant 4% Sod ium Ci trate Sol uti on i n
TERUFLEX Bl ood Bag System

BN820528

Product Name: Anti coagul ant Ci trate Phosphate Dextrose Adeni ne
Sol uti on (CPDA-1)
Approved Date: 03-NOV-1982
Trade Name: Anti coagul ant Ci trate Phosphate Dextrose Adeni ne
(CPDA-1) Sol uti on i n TERUFLEX Bl ood Bag System

BN880217

Product Name: Anti coagul ant Ci trate Phosphate Dextrose Sol uti on
(CPD)
Approved Date: 07-OCT-1988
Trade Name: (OPTI SOL) Anti coagul ant Ci trate Phosphate
Dextrose (CPD) Sol uti on wi th OPTI SOL Red Cel l
Preservati ve Sol uti on i n TERUFLEX (or IMUFLEX)
Bl ood Bag Syste

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