

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

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 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 Nutrice1

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 Solution
Approved Date: 26-JUN-2018
Trade Name:

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