

Currently Approved CBER NDAs/ANDAs By Applicant As Of 28-FEB-2025

B. Braun Medical, Inc.

901 Marcon Blvd
Allentown PA 18109

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

Baxter Healthcare Corporation

One Baxter Parkway
Deerfield IL 60015

BN980123

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

Citra Labs, LLC

55 Messina Drive
Braintree MA 02184

BN010409

Product Name: Anticoagulant Sodium Citrate Solution
Approved Date: 10-JUL-2003
Trade Name: triCitrinol 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)

CSL Plasma, Inc.

900 Broken Sound Parkway
Suite 440
Boca Raton FL 33487

BA125750

Product Name: Anticoagulant Sodium Citrate 4% Solution
Approved Date: 25-APR-2022
Trade Name:

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

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 AG

Else-Kroner Strasse 1
D-61352
Bad Homburg 01 61352 GERMANY

BN125695

Product Name: 0.9% Sodium Chloride Injection USP Solution

Approved Date: 05-SEP-2019

Trade Name:

Fresenius Kabi USA, LLC

Three Corporate Drive
Lake Zurich IL 60047

BN080041

Product Name: Platelet Additive Solution 3

Approved Date: 09-DEC-2009

Trade Name: InterSol Solution

Global Life Science Solutions USA, LLC

100 Results Way
Marlborough MA 01762

BN800222

Product Name: Anticoagulant Citrate Phosphate Dextrose Solution

(CPD)
Approved Date: 23-AUG-1982
Trade Name:

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

Haemonetics Manufacturing Inc.

400 Wood Road
Braintree MA 02184

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

BN820915

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

Hemerus Medical, LLC

5000 Township Parkway
St. Paul MN 55110

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

Hospira, Inc.

275 N. Field Drive
Bldg H1
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

BN200952

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

Laboratorios Grifols, S.A.

Paseo Fluvial, 24 - Polígono Industrial
08150 Parets del Vallès
Barcelona 56 SPAIN

BA125697

Product Name: Anticoagulant Sodium Citrate 4% Solution
Approved Date: 25-OCT-2019
Trade Name:

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:

BN090067

Product Name: Isoplate Solution Platelet Additive Solution
[PAS-F]
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
BA110057
Product Name: Anticoagulant Citrate Dextrose Solution (ACD)
Approved Date: 11-MAY-2012
Trade Name: Anticoagulant Citrate Dextrose Solution, USP
(ACD-A)
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.

Irvine CA 92718

BA740592

Product Name: Hetastarch

Approved Date: 12-NOV-1998

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