Currently Approved CBER NDAs/ANDAs By Applicant As Of 30-SEP-2026

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: 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)

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:

GVS TM, Inc.

1630 West Industrial Park Street
Covina  CA 91722

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

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., a Pfizer Company

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 Hydroxyethel Starch (6%)

Laboratorios Grifols, S.A.

Paseo Fluvial, 24 Pol gono Industrial
08150 Parets del Vall s
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:

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 Syste

Teva Pharmaceuticals USA, 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