

Currently Approved CBER NDAs/ANDAs  
As of September 04, 2012  
Sorted by Applicant Name

BN860909 Alpha Therapeutic Corporation  
5555 Valley Boulevard  
Los Angeles, CA 90032  
Product Name: Perflurochemical Emulsion  
Trade Name:  
Approved Date: 26-DEC-1989

BA110057 Arterioocyte Medical Systems, Inc  
45 South Street, Suite 3  
Hopkinton, MA 01748  
Product Name: Anticoagulant Citrate Dextrose  
Solution (ACD)  
Trade Name: Anticoagulant Citrate Dextrose  
Solution, USP (ACD-A)  
Approved Date: 11-MAY-2012

BN090024 B. Braun Medical, Inc.  
901 Macron Blvd  
Allentown, PA 18109  
Product Name: Dextran 70  
Trade Name:  
Approved Date: 18-AUG-1969

BN160767 B. Braun Medical, Inc.  
901 Macron Blvd  
Allentown, PA 18109  
Product Name: Dextran 40  
Trade Name:  
Approved Date: 06-APR-1970

BN160889 B. Braun Medical, Inc.  
901 Macron Blvd  
Allentown, PA 18109  
Product Name: Hetastarch  
Trade Name: HESPAN 6% Hetastarch in 0.9% NaCl  
in Glass Bottles  
Approved Date: 17-JUL-1972

BN841207 B. Braun Medical, Inc.  
901 Macron Blvd  
Allentown, PA 18109  
Product Name: Pentastarch  
Trade Name: PENTASPAN 10% Pentastarch in 0.9%  
NaCl in 500mL Glass Bottl  
Approved Date: 19-MAY-1987

BN890104 B. Braun Medical, Inc.  
901 Macron Blvd  
Allentown, PA 18109  
Product Name: Pentastarch  
Trade Name: PENTASPAN (R) 10% Pentastarch in  
0.9% NaCl in EXCEL Containers  
Approved Date: 04-APR-1991  
Approved Under McGaw, Inc

BN890105 B. Braun Medical, Inc.  
901 Macron Blvd  
Allentown, PA 18109  
Product Name: Hetastarch  
Trade Name: HESPAN (R) 6% Hetastarch in 0.9%

NaCl , 250, 500, 1000 ml EXCEL  
Containers  
Approved Date: 04-APR-1991  
Approved Under McGaw, Inc

- BA740283 B. Braun Medical, Inc.  
901 Macron Blvd  
Allentown, PA 18109  
Product Name: Hetastarch  
Trade Name: HESPAN (R) 6% Hetastarch in 0.9%  
NaCl in EXCEL Containers  
Approved Date: 21-OCT-1998  
Approved Under McGaw, Inc
- BN160607 Baxter Healthcare Corporation  
1620 Waukegan Road, MPGR-AL  
McGaw Park, IL 60085  
Product Name: Dextran 70  
Trade Name: GENTRAN 70 6% Dextran 70 and 0.9%  
NaCl in PL 146  
Approved Date: 26-JAN-1970  
Approved Under Baxter Healthcare  
Corporation - I. V. Systems Division
- BN840619 Baxter Healthcare Corporation  
Route 120 & Wilson Road  
Round Lake, IL 60073-0490  
Product Name: Dextran 40  
Trade Name: GENTRAN 40 10% Dextran 40 and 5%  
Dextrose Inj in PL 146  
Approved Date: 22-FEB-1985  
Approved Under Baxter Healthcare  
Corporation - I. V. Systems Division
- BN840620 Baxter Healthcare Corporation  
Route 120 & Wilson Road  
Round Lake, IL 60073-0490  
Product Name: Dextran 40  
Trade Name: GENTRAN 40 10% Dextran 40 and  
0.9% NaCl Inj in PL 146  
Approved Date: 22-FEB-1985  
Approved Under Baxter Healthcare  
Corporation - I. V. Systems Division
- BN200952 BioTime, Inc.  
1301 Harbor Bay Pkwy  
Alameda, CA 94502  
Product Name: Hetastarch  
Trade Name: Hextend HMW Hydroxyethyl Starch  
(6%)  
Approved Date: 31-MAR-1999
- BN950522 Citra Labs, LLC  
55 Messina Drive  
Braintree, MA 02184  
Product Name: Rejuvesol  
Trade Name: Rejuvesol, CPD, ADSOL (AS-1)  
Approved Date: 26-FEB-1997  
Approved Under Cytosol Laboratories, Inc.
- BN020037 Citra Labs, LLC  
55 Messina Drive  
Braintree, MA 02184  
Product Name: Anti coagulant Citrate Dextrose

Solution (ACD)

Trade Name: Anticoagulant Citrate Dextrose Solution, Solution, U. S. P., (ACD-A). 50 mL, PN 6053  
Approved Date: 26-AUG-2003  
Approved Under Cytosol Laboratories, Inc.

BN010409 Cytosol Laboratories, Inc.  
55 Messina Drive  
Braintree, MA 02184-6783  
Product Name: Anticoagulant Sodium Citrate Solution  
Trade Name: tricitrasol Anticoagulant Sodium Citrate Conc. 46.7% Trisodium Citrate, 30mL.  
Approved Date: 10-JUL-2003

BN100855 Fenwal Inc  
Three Corporate Drive  
Lake Zurich, IL 60047  
Product Name: Anticoagulant Citrate Dextrose Solution (ACD)  
Trade Name:  
Approved Date: 03-JUN-1959  
Approved Under Baxter Healthcare Corporation

BN160918 Fenwal Inc  
Three Corporate Drive  
Lake Zurich, IL 60047  
Product Name: Anticoagulant Citrate Dextrose Solution (ACD)  
Trade Name: ACD BLOOD PACK UNITS, USP, in PL 146 Plastic 450mL bags; 500mL and 1000mL bulk  
Approved Date: 17-MAR-1978  
Approved Under Baxter Healthcare Corporation

BN770420 Fenwal Inc  
Three Corporate Drive  
Lake Zurich, IL 60047  
Product Name: Anticoagulant Citrate Phosphate Dextrose Adenine Solution (CPDA)  
Trade Name: CPDA-1 BLOOD-PACK Unit, (PL 146 Plastic) 250, 450, 500 mL Blood Pack Units  
Approved Date: 12-MAY-1978  
Approved Under Baxter Healthcare Corporation

BN770923 Fenwal Inc  
Three Corporate Drive  
Lake Zurich, IL 60047  
Product Name: Anticoagulant Sodium Citrate Solution  
Trade Name: Sodium Citrate Blood Pack Units, (PL 146 Plastic) 250 mL and 500 mL bulk units  
Approved Date: 20-JAN-1978  
Approved Under Baxter Healthcare Corporation

BN900224 Fenwal Inc  
 Three Corporate Drive  
 Lake Zurich, IL 60047  
 Product Name: Anti coagulant Citrate Phosphate  
 Dextrose Solution (CPD)  
 Trade Name: CPD Anti coagulant in PL 2209  
 Plastic  
 Approved Date: 27-DEC-1991  
 Approved Under Baxter Healthcare  
 Corporation

BN090480 Fenwal Inc  
 Three Corporate Drive  
 Lake Zurich, IL 60047  
 Product Name: Anti coagulant Ethylenedi amine  
 tetraacetic Acid (EDTA)  
 Trade Name:  
 Approved Date: 07-MAR-1955  
 Approved Under Baxter Healthcare  
 Corporation

BN170401 Fenwal Inc  
 Three Corporate Drive  
 Lake Zurich, IL 60047  
 Product Name: Anti coagulant Citrate Phosphate  
 Dextrose Solution (CPD)  
 Trade Name: CPD BLOOD-PACK Unit, (PL 146  
 Plastic) 500mL bulk, 450 mL bag,  
 . . .  
 Approved Date: 06-DEC-1977  
 Approved Under Baxter Healthcare  
 Corporation

BN811012 Fenwal Inc  
 Three Corporate Drive  
 Lake Zurich, IL 60047  
 Product Name: Anti coagulant Citrate Phosphate  
 Dextrose Solution (CPD)  
 Trade Name: CPD BLOOD-PACK Unit, (PL 1240  
 Plastic)  
 Approved Date: 28-JUN-1983  
 Approved Under Baxter Healthcare  
 Corporation

BN811104 Fenwal Inc  
 Three Corporate Drive  
 Lake Zurich, IL 60047  
 Product Name: Anti coagulant Citrate Phosphate  
 Dextrose Solution (CPD)  
 Trade Name: CPD, ADSOL Red Cell Preservation  
 Solution, (PL 146) and/or SEPACELL  
 Filter  
 Approved Date: 16-MAY-1983  
 Approved Under Baxter Healthcare  
 Corporation

BN900223 Fenwal Inc  
 Three Corporate Drive  
 Lake Zurich, IL 60047  
 Product Name: Anti coagulant Citrate Phosphate  
 Dextrose Solution (CPD)  
 Trade Name: ADSOL Red Cell Preservation  
 Solution (PL 2209) CPD and ADSOL  
 and/or SEPACELL in PL 2209

Approved Date: 27-DEC-1991  
Approved Under Baxter Healthcare  
Corporation

BN940404 Fenwal Inc  
Three Corporate Drive  
Lake Zurich, IL 60047  
Product Name: Anti coagulant Citrate Phosphate  
Dextrose Adenine Solution  
(CPDA)  
Trade Name: CPDA-1 BLOOD PACK UNIT in PL 2209  
Approved Date: 28-JUL-1994  
Approved Under Baxter Healthcare  
Corporation

BN000922 Fenwal Inc  
Three Corporate Drive  
Lake Zurich, IL 60047  
Product Name: Anti coagulant Citrate Dextrose  
Solution (ACD)  
Trade Name: Adsol with ACD-A  
Approved Date: 29-AUG-2002  
Approved Under Baxter Healthcare  
Corporation

BN080041 Fenwal Inc  
Three Corporate Drive  
2nd Floor  
Lake Zurich, IL 60047  
Product Name: unidentifiable product  
Trade Name: InterSol Solution  
Approved Date: 09-DEC-2009

BN070012 Fresenius Kabi Deutschland GmbH  
Else Kroner Strasse 1  
D-61352 Bad Homburg v. d. H.  
Germany  
Product Name: 6% Hydroxyethyl Starch 130/0.4  
in 0.9% Sodium Chloride  
Injection  
Trade Name: Voluven  
Approved Date: 27-DEC-2007  
Approved Under Fresenius Kabi

BN160702 Fresenius Medical Care North America  
920 Winter Street  
Walham, WA 02451  
Product Name: Anti coagulant Sodium Citrate  
Solution  
Trade Name:  
Approved Date: 28-DEC-1970  
Approved Under Fresenius USA, Inc.

BN110912 Fresenius Medical Care North America  
920 Winter Street  
Walham, WA 02451  
Product Name: Anti coagulant Citrate Dextrose  
Solution (ACD)  
Trade Name:  
Approved Date: 02-SEP-1959  
Approved Under Fresenius USA, Inc.

BN160907 Fresenius Medical Care North America  
920 Winter Street

Waltham, WA 02451  
 Product Name: Anti coagul ant Ci trate Phosphate  
 Dextrose Soluti on (CPD)  
 Trade Name:  
 Approved Date: 16-MAY-1973  
 Approved Under Freseni us USA, Inc.

BN770822 Freseni us Medi cal Care North Ameri ca  
 920 Winter Street  
 Waltham, WA 02451  
 Product Name: Anti coagul ant Heparin  
 Trade Name:  
 Approved Date: 17-MAY-1978  
 Approved Under Freseni us USA, Inc.

BN780519 Freseni us Medi cal Care North Ameri ca  
 920 Winter Street  
 Waltham, WA 02451  
 Product Name: Anti coagul ant Ci trate Phosphate  
 Dextrose Soluti on (CPD)  
 Trade Name:  
 Approved Date: 23-APR-1980  
 Approved Under Freseni us USA, Inc.

BA010228 Gambro BCT, Inc  
 10811 W. Collins Ave.  
 Lakewood, CO 80215-4498  
 Product Name: Anti coagul ant Ci trate Dextrose  
 Soluti on (ACD)  
 Trade Name: ACD-A Soluti on  
 Approved Date: 25-FEB-2002

BN001214 Gambro BCT, Inc  
 10811 W. Collins Ave.  
 Lakewood, CO 80215  
 Product Name: Anti coagul ant Ci trate Dextrose  
 Soluti on (ACD)  
 Trade Name: AS3 Soluti on/ACD-A  
 Approved Date: 29-MAY-2002

BA070025 Gambro BCT, Inc  
 10811 W. Collins Ave.  
 Lakewood, CO 80215-4498  
 Product Name: Anti coagul ant Ci trate Phosphate  
 Dextrose Soluti on (CPD)  
 Trade Name: GAMBRO BCT  
 Approved Date: 06-JAN-2009

BA980728 Haemoneti cs Corporati on  
 400 Wood Road  
 Braintree, MA 02184-9114  
 Product Name: Anti coagul ant Ci trate Dextrose  
 Soluti on (ACD)  
 Trade Name: Anti coagul ant Ci trate Dextrose  
 Soluti on Formul a A  
 Approved Date: 06-FEB-2002

BN000127 Haemoneti cs Corporati on  
 400 Wood Road  
 Braintree, MA 02184-9114  
 Product Name: Anti coagul ant Ci trate Phosphate  
 2X Dextrose Soluti on (CP2D)  
 Trade Name: Ci trate Phosphate Double  
 Dextrose/Addi ti ve Sol n 3

Approved Date: 18-JAN-2002

BN980123 Haemonetics Corporation  
400 Wood Road  
Braintree, MA 02184-9114  
Product Name: Anti coagulant Sodium Citrate  
Solution  
Trade Name: Anti coagulant Sodium Citrate, 4%  
w/v Solution U. S.  
Approved Date: 03-MAR-2000

BN800222 Haemonetics Manufacturing Inc.  
400 Wood Road  
Braintree, MA 02184  
Product Name: Anti coagulant Citrate Phosphate  
Dextrose Solution (CPD)  
Trade Name:  
Approved Date: 23-AUG-1982  
Approved Under Medsep Corporation

BN160375 Hospira, Inc.  
275 N. Field Drive  
D-0389, Bldg. H2-2  
Lake Forest, IL 60045-5046  
Product Name: Dextran 40  
Trade Name: 10% LMD w/v Dextran 40 in 5%  
Dextrose or/ 0.9%NaCl  
Approved Date: 25-JUL-1967

BA720562 Hospira, Inc.  
275 N. Field Drive  
D-0389, Bldg. H2-2  
Lake Forest, IL 60045-5046  
Product Name: Dextran 40  
Trade Name: 500 mL Flexible Containers  
Approved Date: 30-OCT-1992  
Approved Under Abbott Laboratories -  
Hospital Products Division.

BA720563 Hospira, Inc.  
275 N. Field Drive  
D-0389, Bldg. H2-2  
Lake Forest, IL 60045-5046  
Product Name: Dextran 40  
Trade Name: 10% Low Molecular Weight Dextrose  
(LMD) in 5% Dextrose  
Approved Date: 30-OCT-1992  
Approved Under Abbott Laboratories -  
Hospital Products Division.

BA720746 Hospira, Inc.  
275 N. Field Drive  
D-0389, Bldg. H2-2  
Lake Forest, IL 60045-5046  
Product Name: Hetastarch  
Trade Name: 500 mL Glass Bottles  
Approved Date: 07-FEB-1996  
Approved Under Abbott Laboratories -  
Hospital Products Division.

BA740193 Hospira, Inc.  
275 N. Field Drive  
D-0389, Bldg. H2-2  
Lake Forest, IL 60045-5046

Product Name: Hetastarch  
Trade Name: 6% Hetastarch in 0.9% NaCl 500 mL  
in PVC Plastic  
Approved Date: 30-JAN-1995  
Approved Under Abbott Laboratories -  
Hospital Products Division.

BN040083 MacoProductions S. A. S.  
c/o Hoppe Regulatory Consultants  
2335 massey Lane  
Decatur, GA 30033  
Product Name: Anti coagulant Citrate Phosphate  
Dextrose Solution (CPD)  
Trade Name: MacoProductions S. A. S. CPD/AS-1:  
MacoPharma Leucoflex MTL1  
Leukoreduction System for Blood  
Components known as MTL1-WB  
Approved Date: 21-NOV-2005

BN830715 Meda AB  
Kanalvagen 18  
P. O. Box 625  
SE-194 26  
Upplands Vasby, Sweden  
Product Name: Dextran 1  
Trade Name: PROMIT  
Approved Date: 30-OCT-1984

BN760305 Medsep Corporation  
1630 Industrial Park Street  
Covina, CA 91722  
Product Name: Anti coagulant Sodium Citrate  
Solution  
Trade Name: Anti coagulant 4% Sodium Citrate  
Solution  
Approved Date: 30-JUN-1978

BN800077 Medsep Corporation  
1630 Industrial Park Street  
Covina, CA 91722  
Product Name: Anti coagulant Citrate Phosphate  
Dextrose Adenine Solution  
(CPDA)  
Trade Name: CPDA-1  
Approved Date: 06-NOV-1980

BN820915 Medsep Corporation  
1630 Industrial Park Street  
Covina, CA 91722  
Product Name: Anti coagulant Citrate Phosphate  
2X Dextrose Solution (CP2D)  
Trade Name: CP2D and AS-3 Nutri cel  
Approved Date: 22-SEP-1983

BN080716 Miles, Inc.  
4th and Parker Streets, P. O. Box 1986  
Berkeley, CA 94701-1986  
Product Name: Dextran 70  
Trade Name:  
Approved Date: 13-MAR-1953

BN100102 Miles, Inc.  
4th and Parker Streets, P. O. Box 1986  
Berkeley, CA 94701-1986

Product Name: Anti coagul ant Ci trate Dextrose  
Soluti on (ACD)  
Trade Name:  
Approved Date: 14-DEC-1961

BN160527 Miles, Inc.  
4th and Parker Streets, P. O. Box 1986  
Berkeley, CA 94701-1986  
Product Name: Anti coagul ant Ci trate Phosphate  
Dextrose Soluti on (CPD)  
Trade Name:  
Approved Date: 22-JUN-1970

BN160653 Miles, Inc.  
4th and Parker Streets, P. O. Box 1986  
Berkeley, CA 94701-1986  
Product Name: Dextran 40  
Trade Name:  
Approved Date: 23-SEP-1969

BN080564 Pharmachem Corporati on  
P. O. Box 1035  
Bethlehem, PA 18016-1035  
Product Name: Dextran 75  
Trade Name: 6% Dextran 75 Inj in 0.9% NaCl  
Approved Date: 19-SEP-1952

BN160759 Pharmachem Corporati on  
P. O. Box 1035  
Bethlehem, PA 18016-1035  
Product Name: Dextran 75  
Trade Name: 6% Dextran 75 in 0.9% NaCl in  
Polyethylene Contain  
Approved Date: 19-AUG-1970

BN160836 Pharmachem Corporati on  
P. O. Box 1035  
Bethlehem, PA 18016-1035  
Product Name: Dextran 40  
Trade Name: LMWD 10% (Dextran 40) in 0.9%  
NaCl or 5% Dextrose  
Approved Date: 14-NOV-1972

BN781211 Terumo Medi cal Corporati on  
125 Blue Ball Road  
Elkton, MD 21921  
Product Name: Anti coagul ant Ci trate Phosphate  
Dextrose Soluti on (CPD)  
Trade Name: Anti coagul ant Ci trate Phosphate  
Dextrose (CPD) Soluti on in  
TERUFLEX Blood Bag System  
Approved Date: 10-JUN-1981

BN781214 Terumo Medi cal Corporati on  
125 Blue Ball Road  
Elkton, MD 21921  
Product Name: Anti coagul ant Sodi um Ci trate  
Soluti on  
Trade Name: Anti coagul ant 4% Sodi um Ci trate  
Soluti on in TERUFLEX Blood Bag  
System  
Approved Date: 08-FEB-1980

BN820528 Terumo Medi cal Corporati on

125 Blue Ball Road  
Elkton, MD 21921  
Product Name: Anti coagulant Citrate Phosphate  
Dextrose Adenine Solution  
(CPDA)  
Trade Name: Anti coagulant Citrate Phosphate  
Dextrose Adenine (CPDA-1)  
Solution in TERUFLEX Blood Bag  
System  
Approved Date: 03-NOV-1982

BN880217 Terumo Medical Corporation  
125 Blue Ball Road  
Elkton, MD 21921  
Product Name: Anti coagulant Citrate Phosphate  
Dextrose Solution (CPD)  
Trade Name: (OPTISOL) Anti coagulant Citrate  
Phosphate Dextrose (CPD) Solution  
with OPTISOL Red Cell  
Preservative Solution in TERUFLEX  
(or IMUFLEX) Blood Bag System  
Approved Date: 07-OCT-1988

BA740592 Teva Parenteral Medicines, Inc.  
19 Hughes  
Irvine, CA 92718-1902  
Product Name: Hetastarch  
Trade Name: 6% Hetastarch in 0.9% NaCl in  
500mL Plastic Bags  
Approved Date: 12-NOV-1998  
Approved Under Gensia Laboratories, Ltd