

Currently Approved CBER NDAs/ANDAs  
As of October 01, 2012  
Sorted by Applicant Name

BN860909    Alpha Therapeutic Corporation  
                  5555 Valley Boulevard  
                  Los Angeles, CA 90032  
Product Name: Perfluorochemical 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: Anticoagulant 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: Anticoagulant Citrate Phosphate  
Dextrose Solution (CPD)  
Trade Name: CPD Anticoagulant 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: Anticoagulant Ethylenediamine  
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: Anticoagulant 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: Anticoagulant 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: Anticoagulant 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: Anticoagulant 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: Anticoagulant 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: Anticoagulant 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  
Waltham, WA 02451  
Product Name: Anticoagulant Sodium Citrate  
Solution  
Trade Name:  
Approved Date: 28-DEC-1970  
Approved Under Fresenius USA, Inc.
- BN110912 Fresenius Medical Care North America  
920 Winter Street  
Waltham, WA 02451  
Product Name: Anticoagulant 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: Anticoagulant Citrate Phosphate  
Dextrose Solution (CPD)  
Trade Name:  
Approved Date: 16-MAY-1973  
Approved Under Fresenius USA, Inc.
- BN770822 Fresenius Medical Care North America  
920 Winter Street  
Waltham, WA 02451  
Product Name: Anticoagulant Heparin  
Trade Name:  
Approved Date: 17-MAY-1978  
Approved Under Fresenius USA, Inc.
- BN780519 Fresenius Medical Care North America  
920 Winter Street  
Waltham, WA 02451  
Product Name: Anticoagulant Citrate Phosphate  
Dextrose Solution (CPD)  
Trade Name:  
Approved Date: 23-APR-1980

Approved Under Fresenius USA, Inc.

BA010228 Gambro BCT, Inc  
10811 W. Collins Ave.  
Lakewood, CO 80215-4498  
Product Name: Anticoagulant Citrate Dextrose  
Solution (ACD)  
Trade Name: ACD-A Solution  
Approved Date: 25-FEB-2002

BN001214 Gambro BCT, Inc  
10811 W. Collins Ave.  
Lakewood, CO 80215  
Product Name: Anticoagulant Citrate Dextrose  
Solution (ACD)  
Trade Name: AS3 Solution/ACD-A  
Approved Date: 29-MAY-2002

BA070025 Gambro BCT, Inc  
10811 W. Collins Ave.  
Lakewood, CO 80215-4498  
Product Name: Anticoagulant Citrate Phosphate  
Dextrose Solution (CPD)  
Trade Name: GAMBRO BCT  
Approved Date: 06-JAN-2009

BA980728 Haemonetics Corporation  
400 Wood Road  
Braintree, MA 02184-9114  
Product Name: Anticoagulant Citrate Dextrose  
Solution (ACD)  
Trade Name: Anticoagulant Citrate Dextrose  
Solution Formula A  
Approved Date: 06-FEB-2002

BN000127 Haemonetics Corporation  
400 Wood Road  
Braintree, MA 02184-9114  
Product Name: Anticoagulant Citrate Phosphate  
2X Dextrose Solution (CP2D)  
Trade Name: Citrate Phosphate Double  
Dextrose/Additive Soln 3  
Approved Date: 18-JAN-2002

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

BN760305 Haemonetics Manufacturing Inc.  
400 Wood Road  
Braintree, MA 02184  
Product Name: Anticoagulant Sodium Citrate

Solution  
Trade Name: Anticoagulant 4% Sodium Citrate  
Solution  
Approved Date: 30-JUN-1978  
Approved Under Medsep Corporation

BN800077 Haemonetics Manufacturing Inc.  
400 Wood Road  
Braintree, MA 02184  
Product Name: Anticoagulant Citrate Phosphate  
Dextrose Adenine Solution  
(CPDA)  
Trade Name: CPDA-1  
Approved Date: 06-NOV-1980  
Approved Under Medsep Corporation

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

BN820915 Haemonetics Manufacturing Inc.  
400 Wood Road  
Braintree, MA 02184  
Product Name: Anticoagulant Citrate Phosphate  
2X Dextrose Solution (CP2D)  
Trade Name: CP2D and AS-3 Nutricel  
Approved Date: 22-SEP-1983  
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: Anticoagulant 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

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: Anticoagulant Citrate Dextrose  
Solution (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: Anticoagulant Citrate Phosphate  
Dextrose Solution (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 Corporation  
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 Corporation  
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 Corporation  
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 Medical Corporation  
125 Blue Ball Road  
Elkton, MD 21921  
Product Name: Anticoagulant Citrate Phosphate  
Dextrose Solution (CPD)  
Trade Name: Anticoagulant Citrate Phosphate  
Dextrose (CPD) Solution in  
TERUFLEX Blood Bag System  
Approved Date: 10-JUN-1981

BN781214 Terumo Medical Corporation  
125 Blue Ball Road

Elkton, MD 21921  
Product Name: Anticoagulant Sodium Citrate  
Solution  
Trade Name: Anticoagulant 4% Sodium Citrate  
Solution in TERUFLEX Blood Bag  
System  
Approved Date: 08-FEB-1980

BN820528 Terumo Medical Corporation  
125 Blue Ball Road  
Elkton, MD 21921  
Product Name: Anticoagulant Citrate Phosphate  
Dextrose Adenine Solution  
(CPDA)  
Trade Name: Anticoagulant 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: Anticoagulant Citrate Phosphate  
Dextrose Solution (CPD)  
Trade Name: (OPTISOL) Anticoagulant 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