

Currently Approved CBER NDAs/ANDAs  
As of January 31, 2010  
Sorted by Applicant Name

BN761021 Abbott Laboratories - Pharmaceutical  
Products Division  
D-389, AP30  
Pharmaceutical Products Division  
200 Abbott Park Road  
Abbott Park, IL 60064-6157  
Product Name: Urokinase  
Trade Name: Abbokinase  
Approved Date: 16-JAN-1978

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

BN19862 Amersham Health  
2636 South Clearbrook Drive  
Arlington Heights, IL 60005  
Product Name: Indium In-111 Chloride Sterile  
Solution  
Trade Name: Indiclone  
Approved Date: 29-DEC-1992  
Approved Under Medi-Physics, Inc.

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

- 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 Cytosol Laboratories, Inc.  
55 Messina Drive  
Braintree, MA 02184-6783  
Product Name: Rejuvesol  
Trade Name: Rejuvesol, CPD, ADSOL (AS-1)  
Approved Date: 26-FEB-1997
- BN010409 Cytosol Laboratories, Inc.  
55 Messina Drive  
Braintree, MA 02184-6783  
Product Name: Anti coagulant Sodium Citrate  
Solution

Trade Name: triCi trasol Anti coagul ant Sodi um  
Ci trate Conc. 46.7% Tri sodi um  
Ci trate, 30mL.  
Approved Date: 10-JUL-2003

BN020037 Cytosol Laboratories, Inc.  
55 Messi na Drive  
Braintree, MA 02184-6783  
Product Name: Anti coagul ant Ci trate Dextrose  
Sol uti on (ACD)  
Trade Name: Anti coagul ant Ci trate Dextrose  
Sol uti on, Sol uti on, U. S. P., (ACD-  
A). 50 mL, PN 6053  
Approved Date: 26-AUG-2003

BN100855 Fenwal Inc  
25212 W. Illi nois Route 120, RLP-34  
Round Lake, IL 60073  
Product Name: Anti coagul ant Ci trate Dextrose  
Sol uti on (ACD)  
Trade Name:  
Approved Date: 03-JUN-1959  
Approved Under Baxter Heal thcare  
Corporati on

BN160918 Fenwal Inc  
25212 W. Illi nois Route 120, RLP-34  
Round Lake, IL 60073  
Product Name: Anti coagul ant Ci trate Dextrose  
Sol uti on (ACD)  
Trade Name: ACD BLOOD PACK UNITS, USP, in PL  
146 Plasti c 450mL bags; 500mL and  
1000mL bul k  
Approved Date: 17-MAR-1978  
Approved Under Baxter Heal thcare  
Corporati on

BN770420 Fenwal Inc  
25212 W. Illi nois Route 120, RLP-34  
Round Lake, IL 60073  
Product Name: Anti coagul ant Ci trate Phosphate  
Dextrose Adeni ne Sol uti on  
(CPDA)  
Trade Name: CPDA-1 BLOOD-PACK Uni t, (PL 146  
Plasti c) 250, 450, 500 mL Bl ood  
Pack Uni ts  
Approved Date: 12-MAY-1978  
Approved Under Baxter Heal thcare  
Corporati on

BN770923 Fenwal Inc  
25212 W. Illi nois Route 120, RLP-34  
Round Lake, IL 60073  
Product Name: Anti coagul ant Sodi um Ci trate  
Sol uti on  
Trade Name: Sodi um Ci trate Bl ood Pack Uni ts,  
(PL 146 Plasti c) 250 mL and 500  
mL bul k uni ts  
Approved Date: 20-JAN-1978  
Approved Under Baxter Heal thcare  
Corporati on

BN900224 Fenwal Inc  
25212 W. Illi nois Route 120, RLP-34

Round Lake, IL 60073  
Product Name: Anti coagul ant Ci trate Phosphate  
Dextrose Soluti on (CPD)  
Trade Name: CPD Anti coagul ant in PL 2209  
Pl astic  
Approved Date: 27-DEC-1991  
Approved Under Baxter Heal thcare  
Corporati on

BN090480 Fenwal Inc  
25212 W. Illinois Route 120, RLP-34  
Round Lake, IL 60073  
Product Name: Anti coagul ant Ethyl enedi ami ne  
tetraacetic Acid (EDTA)  
Trade Name:  
Approved Date: 07-MAR-1955  
Approved Under Baxter Heal thcare  
Corporati on

BN170401 Fenwal Inc  
25212 W. Illinois Route 120, RLP-34  
Round Lake, IL 60073  
Product Name: Anti coagul ant Ci trate Phosphate  
Dextrose Soluti on (CPD)  
Trade Name: CPD BLOOD-PACK Uni t, (PL 146  
Pl astic) 500mL bul k, 450 mL bag,  
Approved Date: 06-DEC-1977  
Approved Under Baxter Heal thcare  
Corporati on

BN811012 Fenwal Inc  
25212 W. Illinois Route 120, RLP-34  
Round Lake, IL 60073  
Product Name: Anti coagul ant Ci trate Phosphate  
Dextrose Soluti on (CPD)  
Trade Name: CPD BLOOD-PACK Uni t, (PL 1240  
Pl astic)  
Approved Date: 28-JUN-1983  
Approved Under Baxter Heal thcare  
Corporati on

BN811104 Fenwal Inc  
25212 W. Illinois Route 120, RLP-34  
Round Lake, IL 60073  
Product Name: Anti coagul ant Ci trate Phosphate  
Dextrose Soluti on (CPD)  
Trade Name: CPD, ADSOL Red Cell Preservati on  
Soluti on, (PL 146) and/or SEPACELL  
Filter  
Approved Date: 16-MAY-1983  
Approved Under Baxter Heal thcare  
Corporati on

BN900223 Fenwal Inc  
25212 W. Illinois Route 120, RLP-34  
Round Lake, IL 60073  
Product Name: Anti coagul ant Ci trate Phosphate  
Dextrose Soluti on (CPD)  
Trade Name: ADSOL Red Cell Preservati on  
Soluti on (PL 2209) CPD and ADSOL  
and/or SEPACELL in PL 2209  
Approved Date: 27-DEC-1991  
Approved Under Baxter Heal thcare

Corporation

- BN940404 Fenwal Inc  
25212 W. Illinois Route 120, RLP-34  
Round Lake, IL 60073  
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  
25212 W. Illinois Route 120, RLP-34  
Round Lake, IL 60073  
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  
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: 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  
Walham, 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  
Walham, 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: Anti coagulant 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: Anti coagulant 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  
Product Name: Anti coagulant 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: Anti coagulant 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: Anti coagulant 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: Anti coagulant Citrate Dextrose  
Solution (ACD)  
Trade Name: Anti coagulant Citrate Dextrose  
Solution Formula A  
Approved Date: 06-FEB-2002
- BN000127 Haemonetics Corporation  
400 Wood Road  
Braintree, MA 02184-9114  
Product Name: Anti coagulant Citrate Phosphate  
2X Dextrose Solution (CP2D)  
Trade Name: Citrate Phosphate Double  
Dextrose/Additive 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

BN080819 Hospira, Inc.  
275 N. Field Drive  
D-0389, Bldg. H2-2  
Lake Forest, IL 60045-5046  
Product Name: Dextran 70  
Trade Name: 6% Dextran 70 and 0.9% NaCl or/  
5% Dextrose 500 mL Glass Bottle  
Approved Date: 31-MAR-1953

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

BN19841 Mallinckrodt Medical, Inc.  
675 McDonnell Boulevard  
St. Louis, MO 63134  
Product Name: Indium In-111 Chloride Sterile  
Solution  
Trade Name: Indium In-111 Chloride Sterile  
Solution  
Approved Date: 27-SEP-1994

BN060826 Meda AB  
Kanalvagen 18  
P. O. Box 625  
SE-194 26  
Upplands Vasby, Sweden  
Product Name: Dextran 70  
Trade Name: MACRODEX 6% w/v Dextran 70 in  
0.9% NaCl or/ 5% Dextrose  
Approved Date: 08-JUN-1954

BN140716 Meda AB  
Kanalvagen 18  
P. O. Box 625  
SE-194 26  
Upplands Vasby, Sweden  
Product Name: Dextran 40  
Trade Name: RHEOMACRODEX 10% w/v Dextran 40  
in 0.9% NaCl or/ 5% Dextrose  
Approved Date: 18-JAN-1967

BN830527 Meda AB  
Kanalvagen 18  
P. O. Box 625  
SE-194 26  
Upplands Vasby, Sweden  
Product Name: Dextran 40  
Trade Name: RHEOMACRODEX 10% w/v Dextran 40  
in 0.9% NaCl 500 mL PVC Bags  
Approved Date: 27-MAR-1985

BN830613 Meda AB  
Kanalvagen 18  
P. O. Box 625  
SE-194 26  
Upplands Vasby, Sweden  
Product Name: Dextran 70  
Trade Name: MACRODEX 6% w/v Dextran 70 in

0.9% NaCl in 500 mL PVC Bags  
Approved Date: 27-MAR-1985

- BN830627 Meda AB  
Kanalvagen 18  
P. O. Box 625  
SE-194 26  
Upplands Vasby, Sweden  
Product Name: Dextran 40  
Trade Name: RHEOMACRODEX 10% w/v Dextran 40  
in 5% Dextrose 500 mL PVC Bags  
Approved Date: 27-MAR-1985
- BN830629 Meda AB  
Kanalvagen 18  
P. O. Box 625  
SE-194 26  
Upplands Vasby, Sweden  
Product Name: Dextran 70  
Trade Name: MACRODEX 6% w/v Dextran 70 in 5%  
Dextrose  
Approved Date: 27-MAR-1985
- 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: Anticoagulant Sodium Citrate  
Solution  
Trade Name: Anticoagulant 4% Sodium Citrate  
Solution  
Approved Date: 30-JUN-1978
- BN800077 Medsep Corporation  
1630 Industrial Park Street  
Covina, CA 91722  
Product Name: Anticoagulant Citrate Phosphate  
Dextrose Adenine Solution  
(CPDA)  
Trade Name: CPDA-1  
Approved Date: 06-NOV-1980
- BN800222 Medsep Corporation  
1630 Industrial Park Street  
Covina, CA 91722  
Product Name: Anticoagulant Citrate Phosphate  
Dextrose Solution (CPD)  
Trade Name:  
Approved Date: 23-AUG-1982
- BN820915 Medsep Corporation  
1630 Industrial Park Street  
Covina, CA 91722  
Product Name: Anticoagulant 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 coagulant 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: Anti coagulant 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: Anti coagulant Citrate Phosphate  
Dextrose Solution (CPD)  
Trade Name: Anti coagulant 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