

| S.No. | Applicant | Generic Name | Tradename | NDA | Approval Date | Type | Patent Number | Patent Expiration | Patented / Exclusive Use |
|-------|-----------|--------------|-----------|-------|---------------|------|---------------|-------------------|--|
| 3 | Novartis | cyclosporine | NEORAL | 50716 | 14-Jul-95 | RX | 5,916,589 | 13-Sep-09 | PROPHYLAXIS OF ORGAN REJECTION IN KIDNEY, LIVER AND HEART ALLOGENIC TRANSPLANTS; TREATMENT OF PATIENTS WITH SEVERE ACTIVE, RHEUMATOID ARTHRITIS; TREATMENT OF ADULT, NONIMMUNOCOMPROMISED PATIENTS WITH SEVERE, RECALCITRANT, PLAQUE PSORIASIS |
| 4 | Novartis | cyclosporine | NEORAL | 50716 | 14-Jul-95 | RX | 5,962,014 | 13-Sep-09 | PROPHYLAXIS OF ORGAN REJECTION IN KIDNEY, LIVER AND HEART ALLOGENIC TRANSPLANTS; TREATMENT OF PATIENTS WITH SEVERE ACTIVE, RHEUMATOID ARTHRITIS; TREATMENT OF ADULT, NONIMMUNOCOMPROMISED PATIENTS WITH SEVERE, RECALCITRANT, PLAQUE PSORIASIS |
| 5 | Novartis | cyclosporine | NEORAL | 50716 | 14-Jul-95 | RX | 5,962,017 | 13-Sep-09 | PROPHYLAXIS OF ORGAN REJECTION IN KIDNEY, LIVER AND HEART ALLOGENIC TRANSPLANTS; TREATMENT OF PATIENTS WITH SEVERE ACTIVE, RHEUMATOID ARTHRITIS; TREATMENT OF ADULT, NONIMMUNOCOMPROMISED PATIENTS WITH SEVERE, |

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| | | | | | | | | | RECALCITRANT, PLAQUE PSORIASIS |
| 5 | Novartis | cyclosporine | NEORAL | 50716 | 14-Jul-95 | RX | 5,962,017 | 13-Sep-09 | PROPHYLAXIS OF ORGAN REJECTION IN KIDNEY, LIVER AND HEART ALLOGENIC TRANSPLANTS; TREATMENT OF PATIENTS WITH SEVERE ACTIVE, RHEUMATOID ARTHRITIS; TREATMENT OF ADULT, NONIMMUNOCOMPROMISED PATIENTS WITH SEVERE, RECALCITRANT, PLAQUE PSORIASIS |
| 6 | Novartis | cyclosporine | NEORAL | 50716 | 14-Jul-95 | RX | 6,007,840 | 13-Sep-09 | PROPHYLAXIS OF ORGAN REJECTION IN KIDNEY, LIVER AND HEART ALLOGENIC TRANSPLANTS; TREATMENT OF PATIENTS WITH SEVERE ACTIVE, RHEUMATOID ARTHRITIS; TREATMENT OF ADULT, NONIMMUNOCOMPROMISED PATIENTS WITH SEVERE, RECALCITRANT, PLAQUE PSORIASIS |
| 7 | Novartis | cyclosporine | NEORAL | 50716 | 14-Jul-95 | RX | 6,024,978 | 13-Sep-09 | PROPHYLAXIS OF ORGAN REJECTION IN KIDNEY, LIVER AND HEART ALLOGENIC TRANSPLANTS; TREATMENT OF PATIENTS WITH SEVERE ACTIVE, RHEUMATOID ARTHRITIS; TREATMENT OF |

| | | | | | | | | | ADULT, NONIMMUNOCOMPROMISED PATIENTS WITH SEVERE, RECALCITRANT, PLAQUE PSORIASIS |
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| 8 | Merck | cilastatin sodium; imipenem | PRIMAXIN | 50587 | 26-Nov-85 | RX | 5,147,868 | 15-Sep-09 | TREATMENT OF BACTERIAL INFECTIOUS DISEASE |
| 9 | Merck | cilastatin sodium; imipenem | PRIMAXIN | 50630 | 14-Dec-90 | DISCN | 5,147,868 | 15-Sep-09 | TREATMENT OF BACTERIAL INFECTIOUS DISEASE |
| 10 | Merck | cilastatin sodium; imipenem | PRIMAXIN | 50630 | 14-Dec-90 | RX | 5,147,868 | 15-Sep-09 | TREATMENT OF BACTERIAL INFECTIOUS DISEASE |
| 11 | Alcon | dexamethasone; tobramycin | TOBRADEX | 50592 | 18-Aug-88 | RX | 5,149,694 | 22-Sep-09 | METHOD OF TREATING OPHTHALMIC INFLAMMATION AND INFECTION |
| 12 | Alcon | dexamethasone; tobramycin | TOBRADEX | 50616 | 28-Sep-88 | RX | 5,149,694 | 22-Sep-09 | METHOD OF TREATING OPHTHALMIC INFLAMMATION AND INFECTION |
| 13 | Alcon | dexamethasone; tobramycin | TOBRADEX ST | 50818 | 13-Feb-09 | RX | 5,149,694 | 22-Sep-09 | METHOD OF TREATING OPHTHALMIC INFLAMMATION AND INFECTION |
| 14 | Alcon | fluorometholone acetate; tobramycin | TOBRASONE | 50628 | 21-Jul-89 | DISCN | 5,149,693 | 22-Sep-09 | METHOD OF TREATING OPHTHALMIC INFLAMMATION AND INFECTION |
| 15 | Meda Pharms | felbamate | FELBATOL | 20189 | 29-Jul-93 | RX | 4,978,680 | 26-Sep-09 | TREATMENT OF SEIZURES |

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| 24 | Novartis | nateglinide | STARLIX | 21204 | 22-Dec-00 | RX | RE34878 | 8-Sep-09 | |
| 25 | Takeda Pharms Na | lansoprazole; naproxen | PREVACID NAPRAPAC 500 (COPACKAGED) | 21507 | 14-Nov-03 | DISCN | 4,628,098 | 10-Nov-09 | |
| 26 | Takeda Pharms Na | amoxicillin; clarithromycin; lansoprazole | PREVPAC | 50757 | 2-Dec-97 | RX | 4,628,098 | 10-Nov-09 | |
| 27 | Ekr Therap | nicardipine hydrochloride | CARDENE | 19734 | 30-Jan-92 | RX | 5,164,405 | 17-Nov-09 | |
| 28 | Pfizer | alatrofloxacin mesylate | TROVAN PRESERVATIVE FREE | 20760 | 18-Dec-97 | DISCN | 5,164,402 | 17-Nov-09 | METHOD OF TREATING BACTERIAL INFECTIONS |
| 29 | R Tech Ueno Ltd | unoprostone isopropyl | RESCULA | 21214 | 3-Aug-00 | RX | 5,166,178 | 24-Nov-09 | METHOD OF TREATING OCULAR HYPERTENSION |
| 30 | 3m | albuterol sulfate | PROVENTIL-HFA | 20503 | 15-Aug-96 | RX | 6,352,684 | 28-Nov-09 | |
| 31 | Boehringer Ingelheim | ipratropium bromide | ATROVENT HFA | 21527 | 27-Nov-04 | RX | 5,766,573 | 28-Nov-09 | RELIEF OF NAUSEA AND VOMITTING |
| 32 | Sepracor | levalbuterol tartrate | XOPENEX HFA | 21730 | 11-Mar-05 | RX | 6,352,684 | 28-Nov-09 | |
| 33 | Teva Global | albuterol sulfate | PROAIR HFA | 21457 | 29-Oct-04 | RX | 5,766,573 | 28-Nov-09 | DELIVERING A MEDICINAL AEROSOL FORMULATION USING CFC-FREE PROPELLANT 134A. |

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| 34 | Teva Global | albuterol sulfate | PROAIR HFA | 21457 | 29-Oct-04 | RX | 6,352,684 | 28-Nov-09 | |
| 35 | Teva Global | beclomethasone dipropionate | QVAR 40 | 20911 | 15-Sep-00 | RX | 5,766,573 | 28-Nov-09 | DELIVERING A MEDICINAL AEROSOL FORMULATION USING CFC-FREE PROPELLANT 134A. |
| 36 | Teva Global | beclomethasone dipropionate | QVAR 40 | 20911 | 15-Sep-00 | RX | 6,352,684 | 28-Nov-09 | |
| 37 | Teva Global | beclomethasone dipropionate | QVAR 80 | 20911 | 15-Sep-00 | RX | 5,766,573 | 28-Nov-09 | DELIVERING A MEDICINAL AEROSOL FORMULATION USING CFC-FREE PROPELLANT 134A. |
| 38 | Teva Global | beclomethasone dipropionate | QVAR 80 | 20911 | 15-Sep-00 | RX | 6,352,684 | 28-Nov-09 | |
| 39 | Allergan | ketorolac tromethamine | ACULAR | 19700 | 9-Nov-92 | RX | 5,110,493 | 5-Nov-09 | RELIEF OF OCULAR ITCHING DUE TO SEASONAL ALLERGIC CONJUNCTIVITIS |
| 40 | Allergan | ketorolac tromethamine | ACULAR LS | 21528 | 30-May-03 | RX | 5,110,493 | 5-Nov-09 | |
| 41 | Sciele Pharma Inc | ceftibuten dihydrate | CEDAX | 50685 | 20-Dec-95 | RX | 4,634,697 | 1-Oct-09 | METHOD OF TREATING BACTERIAL INFECTIONS |
| 42 | Sciele Pharma Inc | ceftibuten dihydrate | CEDAX | 50685 | 20-Dec-95 | RX | 4,634,697 | 1-Oct-09 | TREATMENT OF COMMUNITY ACQUIRED PNEUMONIA, ACUTE EXACERBATION OF CHRONIC BRONCHITIS, AND ACUTE BACTERIAL SINUSITIS CAUSED BY SUSCEPTIBLE STRAINS OF DESIGNATED |

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| 47 | Valeant Pharm Intl | pergolide mesylate | PERMAX | 19385 | 30-Dec-88 | DISCN | 5,114,948 | 19-Oct-09 | |
| 48 | Colgate Palmolive | sodium fluoride; triclosan | COLGATE TOTAL | 20231 | 11-Jul-97 | OTC | 5,156,835 | 20-Oct-09 | |
| 49 | Ortho Biotech | doxorubicin hydrochloride | DOXIL | 50718 | 13-Jun-00 | RX | 5,013,556 | 20-Oct-09 | METHOD TO TREAT AIDS-RELATED KAPOSI'S SARCOMA |
| 50 | Ortho Biotech | doxorubicin hydrochloride | DOXIL | 50718 | 13-Jun-00 | RX | 5,013,556 | 20-Oct-09 | METHOD TO TREAT MULTIPLE MYELOMA |
| 51 | Ortho Biotech | doxorubicin hydrochloride | DOXIL | 50718 | 13-Jun-00 | RX | 5,013,556 | 20-Oct-09 | METHOD TO TREAT OVARIAN CANCER |
| 52 | Ortho Biotech | doxorubicin hydrochloride | DOXIL | 50718 | 13-Jun-00 | RX | 5,213,804 | 20-Oct-09 | METHOD TO TREAT AIDS-RELATED KAPOSI'S SARCOMA |
| 53 | Ortho Biotech | doxorubicin hydrochloride | DOXIL | 50718 | 13-Jun-00 | RX | 5,213,804 | 20-Oct-09 | METHOD TO TREAT OVARIAN CANCER |
| 54 | Ortho Biotech | doxorubicin hydrochloride | DOXIL | 50718 | 17-Nov-95 | RX | 5,013,556 | 20-Oct-09 | METHOD TO TREAT AIDS-RELATED KAPOSI'S SARCOMA |
| 55 | Ortho Biotech | doxorubicin hydrochloride | DOXIL | 50718 | 17-Nov-95 | RX | 5,013,556 | 20-Oct-09 | METHOD TO TREAT MULTIPLE MYELOMA |
| 56 | Ortho Biotech | doxorubicin hydrochloride | DOXIL | 50718 | 17-Nov-95 | RX | 5,013,556 | 20-Oct-09 | METHOD TO TREAT OVARIAN CANCER |
| 57 | Ortho Biotech | doxorubicin hydrochloride | DOXIL | 50718 | 17-Nov-95 | RX | 5,213,804 | 20-Oct-09 | METHOD TO TREAT AIDS-RELATED KAPOSI'S SARCOMA |

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| 58 | Ortho Biotech | doxorubicin hydrochloride | DOXIL | 50718 | 17-Nov-95 | RX | 5,213,804 | 20-Oct-09 | METHOD TO TREAT OVARIAN CANCER |
| 59 | Gd Searle Llc | verapamil hydrochloride | COVERA-HS | 20552 | 26-Feb-96 | RX | 5,785,994 | 22-Oct-09 | METHOD FOR ADMINISTERING DRUG TO GASTROINTESTINAL TRACT |
| 60 | Boehringer Ingelheim | tamsulosin hydrochloride | FLOMAX | 20579 | 15-Apr-97 | RX | 4,703,063 | 27-Oct-09 | |
| 61 | Johnson And Johnson | paliperidone palmitate | INVEGA SUSTENNA | 22264 | 31-Jul-09 | RX | 5,254,556 | 27-Oct-09 | TREATMENT OF SCHIZOPHRENIA |
| 62 | Otsuka America | urea, c-13 | BREATHTEK UBT FOR H-PYLORI | 20586 | 10-May-01 | RX | 4,830,010 | 27-Oct-09 | DETECTION OF GASTROINTESTINAL DISORDERS AND THE SUBSEQUENT BREATH COLLECTION AND MEASUREMENT OF 13CO2 |
| 63 | Otsuka America | urea, c-13 | MERETEK UBT KIT (W/ PRANACTIN) | 20586 | 17-Sep-96 | DISCN | 4,830,010 | 27-Oct-09 | DETECTION OF GASTROINTESTINAL DISORDERS AND THE SUBSEQUENT BREATH COLLECTION AND MEASUREMENT OF 13CO2 |
| 64 | Novartis | cyclosporine | NEORAL | 50715 | 14-Jul-95 | DISCN | 5,866,159 | 13-Sep-09 | PROPHYLAXIS OF ORGAN REJECTION IN KIDNEY, LIVER AND HEART ALLOGENIC TRANSPLANTS; TREATMENT OF PATIENTS WITH SEVERE ACTIVE, RHEUMATOID ARTHRITIS; TREATMENT OF ADULT, NONIMMUNOCOMPROMISED |

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| | | | | | | | | | PATIENTS WITH SEVERE, RECALCITRANT, PLAQUE PSORIASIS |
| 65 | Novartis | cyclosporine | NEORAL | 50715 | 14-Jul-95 | DISCN | 5,916,589 | 13-Sep-09 | PROPHYLAXIS OF ORGAN REJECTION IN KIDNEY, LIVER AND HEART ALLOGENIC TRANSPLANTS; TREATMENT OF PATIENTS WITH SEVERE ACTIVE, RHEUMATOID ARTHRITIS; TREATMENT OF ADULT, NONIMMUNOCOMPROMISED PATIENTS WITH SEVERE, RECALCITRANT, PLAQUE PSORIASIS |
| 66 | Novartis | cyclosporine | NEORAL | 50715 | 14-Jul-95 | DISCN | 5,962,014 | 13-Sep-09 | PROPHYLAXIS OF ORGAN REJECTION IN KIDNEY, LIVER AND HEART ALLOGENIC TRANSPLANTS; TREATMENT OF PATIENTS WITH SEVERE ACTIVE, RHEUMATOID ARTHRITIS; TREATMENT OF ADULT, NONIMMUNOCOMPROMISED PATIENTS WITH SEVERE, RECALCITRANT, PLAQUE PSORIASIS |
| 67 | Novartis | cyclosporine | NEORAL | 50715 | 14-Jul-95 | DISCN | 5,962,017 | 13-Sep-09 | PROPHYLAXIS OF ORGAN REJECTION IN KIDNEY, LIVER AND HEART ALLOGENIC TRANSPLANTS; TREATMENT OF PATIENTS WITH SEVERE ACTIVE, RHEUMATOID ARTHRITIS; TREATMENT OF |

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| | | | | | | | | | ADULT, NONIMMUNOCOMPROMISED PATIENTS WITH SEVERE, RECALCITRANT, PLAQUE PSORIASIS |
| 68 | Novartis | cyclosporine | NEORAL | 50715 | 14-Jul-95 | DISCN | 6,007,840 | 13-Sep-09 | PROPHYLAXIS OF ORGAN REJECTION IN KIDNEY, LIVER AND HEART ALLOGENIC TRANSPLANTS; TREATMENT OF PATIENTS WITH SEVERE ACTIVE, RHEUMATOID ARTHRITIS; TREATMENT OF ADULT, NONIMMUNOCOMPROMISED PATIENTS WITH SEVERE, RECALCITRANT, PLAQUE PSORIASIS |
| 69 | Novartis | cyclosporine | NEORAL | 50715 | 14-Jul-95 | DISCN | 6,024,978 | 13-Sep-09 | PROPHYLAXIS OF ORGAN REJECTION IN KIDNEY, LIVER AND HEART ALLOGENIC TRANSPLANTS; TREATMENT OF PATIENTS WITH SEVERE ACTIVE, RHEUMATOID ARTHRITIS; TREATMENT OF ADULT, NONIMMUNOCOMPROMISED PATIENTS WITH SEVERE, RECALCITRANT, PLAQUE PSORIASIS |
| 70 | Novartis | cyclosporine | NEORAL | 50715 | 14-Jul-95 | RX | 5,866,159 | 13-Sep-09 | PROPHYLAXIS OF ORGAN REJECTION IN KIDNEY, LIVER AND HEART ALLOGENIC TRANSPLANTS; TREATMENT OF PATIENTS WITH SEVERE |

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| | | | | | | | | | ACTIVE, RHEUMATOID ARTHRITIS; TREATMENT OF ADULT, NONIMMUNOCOMPROMISED PATIENTS WITH SEVERE, RECALCITRANT, PLAQUE PSORIASIS |
| 71 | Novartis | cyclosporine | NEORAL | 50715 | 14-Jul-95 | RX | 5,916,589 | 13-Sep-09 | PROPHYLAXIS OF ORGAN REJECTION IN KIDNEY, LIVER AND HEART ALLOGENIC TRANSPLANTS; TREATMENT OF PATIENTS WITH SEVERE ACTIVE, RHEUMATOID ARTHRITIS; TREATMENT OF ADULT, NONIMMUNOCOMPROMISED PATIENTS WITH SEVERE, RECALCITRANT, PLAQUE PSORIASIS |
| 72 | Novartis | cyclosporine | NEORAL | 50715 | 14-Jul-95 | RX | 5,962,014 | 13-Sep-09 | PROPHYLAXIS OF ORGAN REJECTION IN KIDNEY, LIVER AND HEART ALLOGENIC TRANSPLANTS; TREATMENT OF PATIENTS WITH SEVERE ACTIVE, RHEUMATOID ARTHRITIS; TREATMENT OF ADULT, NONIMMUNOCOMPROMISED PATIENTS WITH SEVERE, RECALCITRANT, PLAQUE PSORIASIS |
| 73 | Novartis | cyclosporine | NEORAL | 50715 | 14-Jul-95 | RX | 5,962,017 | 13-Sep-09 | PROPHYLAXIS OF ORGAN REJECTION IN KIDNEY, LIVER AND HEART ALLOGENIC |

| | | | | | | | | | TRANSPLANTS; TREATMENT OF PATIENTS WITH SEVERE ACTIVE, RHEUMATOID ARTHRITIS; TREATMENT OF ADULT, NONIMMUNOCOMPROMISED PATIENTS WITH SEVERE, RECALCITRANT, PLAQUE PSORIASIS |
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| 74 | Novartis | cyclosporine | NEORAL | 50715 | 14-Jul-95 | RX | 6,007,840 | 13-Sep-09 | PROPHYLAXIS OF ORGAN REJECTION IN KIDNEY, LIVER AND HEART ALLOGENIC TRANSPLANTS; TREATMENT OF PATIENTS WITH SEVERE ACTIVE, RHEUMATOID ARTHRITIS; TREATMENT OF ADULT, NONIMMUNOCOMPROMISED PATIENTS WITH SEVERE, RECALCITRANT, PLAQUE PSORIASIS |
| 75 | Novo Nordisk Inc | metformin hydrochloride; repaglinide | PRANDIMET | 22386 | 23-Jun-08 | RX | RE37035 | 14-Mar-09 | |
| 76 | Novo Nordisk Inc | repaglinide | PRANDIN | 20741 | 22-Dec-97 | RX | RE37035 | 14-Mar-09 | |
| 77 | Schering | desloratadine | CLARINEX | 21312 | 26-Jun-02 | RX | 4,863,931 | 15-Mar-09 | |
| 78 | Schering Plough | desloratadine | CLARINEX | 21165 | 21-Dec-01 | RX | 4,863,931 | 15-Mar-09 | |

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| 218 | Smithkline Beecham | abacavir sulfate; lamivudine | EPZICOM | 21652 | 2-Aug-04 | RX | 5,089,500 | 26-Dec-09 | |
| 219 | Pharmacia And Upjohn | ibutilide fumarate | CORVERT | 20491 | 28-Dec-95 | RX | 5,155,268 | 28-Dec-09 | |
| 220 | Valeant | dihydroergotamine mesylate | MIGRANAL | 20148 | 8-Dec-97 | RX | 5,169,849 | 8-Dec-09 | NASAL ADMINISTRATION |
| 221 | Ge Healthcare | mangafodipir trisodium | TESLASCAN | 20652 | 26-Nov-97 | DISCN | 5,091,169 | 25-Feb-09 | |
| 222 | Amag Pharms Inc | ferumoxides | FERIDEX I.V. | 20416 | 30-Aug-96 | RX | 5,102,652 | 6-Feb-09 | |
| 223 | Glaxosmithkline | sumatriptan | IMITREX | 20626 | 26-Aug-97 | RX | 5,037,845 | 6-Feb-09 | |
| 224 | Glaxosmithkline | sumatriptan succinate | IMITREX | 20080 | 28-Dec-92 | RX | 5,037,845 | 6-Feb-09 | |

**Source: www.usfda.org*