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## Paragraph IV Patent Certifications As of August 16, 2004

Below is a list of drug products for which an Abbreviated New Drug Application (ANDA) has been received by the Office of Generic Drugs (OGD) containing a "Paragraph IV" patent certification. This list includes the name of the drug product, dosage form, strength (subject of Paragraph IV certification), reference listed drug (RLD), **and the date on which the first substantially complete generic drug application was submitted to the Agency (on a prospective basis beginning 3/2/04)**. The Agency will not disclose the identity of the applicant. This information will be updated on a **bi-monthly** basis and will be as current as the last update. This information should be used for reference only. The Agency will make every effort to ensure the accuracy of the information disclosed in this list. However, any discrepancies or disparities should be discussed with the Regulatory Support Branch at 301-827-5862, before making any decisions based on this information.

Any additions from the preceding list will be highlighted in red (Note, new additions are not always received).

- [FDA News: FDA announces measure to improve generic drug access](#)
- [Docket # 2000P-1556 Policy regarding ANDA holder confidentiality](#)

| DRUG NAME                                | DOSAGE FORM              | STRENGTH                        | RLD                 | DATE OF SUBMISSION |
|--|--------------------------|---------------------------------|---------------------|--------------------|
| Acetaminophen                            | Extended-release Tablets | 650 mg                          | Tylenol             |                    |
| Acetaminophen/ Aspirin/ Caffeine         | Tablets                  | 250 mg/250 mg/<br>65 mg         | Excedrin (migraine) |                    |
| Acetaminophen and Tramadol Hydrochloride | Tablets                  | 325 mg/ 37.5 mg                 | Ultracet            |                    |
| Acyclovir Sodium                         | Injection                | 50 mg/mL, 10 mL and 20 mL vials | Zovirax             |                    |
| Albuterol Sulfate                        | Oral Syrup               | 2 mg(base)/ 5 mL                | Ventolin            |                    |
| Albuterol Sulfate                        | Extended-release Tablets | 4 mg and 8 mg                   | Volmax              |                    |

|  |                          |  |               |           |
|--|--------------------------|--|---------------|-----------|
| Albuterol Sulfate/ Ipratropium Bromide           | Inhalation Solution      | 0.083%/0.017%  | Duoneb        |           |
| Alendronate Sodium                               | Tablets                  | 5 mg, 10 mg, 35 mg, 40 mg and 70 mg                  | Fosamax       |           |
| Alprazolam                                       | Tablets                  | 0.25 mg, 0.5 mg, 1 mg and 2 mg                       | Xanax         |           |
| Amifostine                                       | For Injection            | 500 mg/vial  | Ethiol        | 4/16/2004 |
| Amlodipine Besylate                              | Tablets                  | 2.5 mg, 5 mg and 10 mg                               | Norvasc       |           |
| Amlodipine Besylate and Benazepril Hydrochloride | Capsules                 | 2.5 mg/10 mg, 5 mg/10 mg, 5 mg/20 mg and 10 mg/20 mg | Lotrel        | 6/9/2004  |
| Atenolol   | Tablets                  | 25 mg, 50 mg and 100 mg                              | Tenormin      |           |
| Atenolol/ Chlorthalidone                         | Tablets                  | 50 mg/25 mg and 100 mg/25 mg                         | Tenoretic     |           |
| Atorvastatin Calcium                             | Tablets                  | 10 mg, 20 mg, 40 mg and 80 mg                        | Lipitor       |           |
| Betaxolol  | Ophthalmic Solution      | 0.5%(base)   | Betoptic      |           |
| Brimonidine Tartrate                             | Ophthalmic Solution      | 0.2%   | Alphagan      |           |
| Bupropion Hydrochloride                          | Extended-release Tablets | 150 mg   | Zyban         |           |
| Bupropion Hydrochloride                          | Extended-release Tablets | 100 mg, 150 mg and 200 mg                            | Wellbutrin SR |           |
| Bupropion Hydrochloride                          | Tablets                  | 75 mg and 100 mg                                     | Wellbutrin    |           |
| Buspiron Hydrochloride                           | Tablets                  | 5 mg, 7.5 mg, 10 mg, 15 mg and 30 mg                 | Buspar        |           |
| Butorphanol Tartrate                             | Nasal Spray              | 10 mg/mL   | Stadol NS     |           |
| Calcitonin-Salmon                                | Nasal Spray              | 200 IU/spray   | Miacalcin     |           |

|  |                           |   |                            |          |
|--|---------------------------|---|----------------------------|----------|
| Calcitriol                                   | Injection                 | 1 mcg/mL and 2 mcg/mL, 1 mL vials       | Calcijex                   |          |
| Captopril                                    | Tablets                   | 12.5 mg, 25 mg, 50 mg, and 100 mg       | Capoten                    |          |
| Carbamazepine                                | Extended-release Tablets  | 200 mg and 400 mg                       | Tegretol XR                |          |
| Carbamazepine                                | Extended-release Capsules | 300 mg                                  | Carbatrol                  |          |
| Carbidopa/ Levodopa                          | Extended-release Tablets  | 25 mg/100 mg and 50 mg/200 mg           | Sinemet CR                 |          |
| Carboplatin                                  | For Injection             | 50 mg/vial, 150 mg/vial and 450 mg/vial | Paraplatin                 |          |
| Carboplatin                                  | Injection                 | 50 mg/vial, 150 mg/vial and 450 mg/vial | Paraplatin                 |          |
| Carisoprodol/ Aspirin                        | Tablets                   | 200 mg/ 325 mg                          | Soma Compound              |          |
| Carisoprodol/ Aspirin/Codeine                | Tablets                   | 200 mg/ 325 mg/ 16 mg                   | Soma Compound with Codeine |          |
| Carvedilol                                   | Tablets                   | 3.125 mg, 6.25 mg, 12.5 mg and 25 mg    | Coreg                      |          |
| Celecoxib                                    | Capsules                  | 100 mg, 200 mg and 400 mg               | Celebrex                   |          |
| Cetirizine Hydrochloride and Pseudoephedrine | Extended-release Tablets  | 5 mg/120 mg                             | Zytrec-D                   | 6/2/2004 |
| Chlorhexidine Gluconate                      | Scrub brush/sponge        | 4%                                      | Hibiclens                  |          |
| Ciprofloxacin Hydrochloride                  | Tablets                   | 100 mg, 250                             | Cipro                      |          |

|   |                           |  |              |           |
|---|---------------------------|--|--------------|-----------|
|   |                           | mg, 500 mg and 750 mg  |              |           |
| Cisplatin   | Injection                 | 1 mg/mL, 10 mL, 50 mL, 100 mL and 200 mL vials               | Platinol-AQ  |           |
| Cisplatin   | For Injection             | 10 mg/vial and 50 mg/vial                                    | Platinol     |           |
| Clonidine Hydrochloride   | Transdermal System        | 0.1 mg/day, 0.2 mg/day, and 0.3 mg/day                       | Catapres-TTS |           |
| Clopidogrel Bisulfate   | Tablets                   | 75 mg  | Plavix       |           |
| Conjugated Estrogens  | Tablets                   | 0.3 mg and 0.625 mg  | Premarin     |           |
| Cyclobenzaprine Hydrochloride   | Tablets                   | 10 mg  | Flexeril     |           |
| Cyclophosphamide  | For Injection             | 100 mg/vial, 200 mg/vial, 500 mg/vial, 1 g/vial and 2 g/vial | Cytosan      |           |
| Desmopressin Acetate  | Injection                 | 4 mcg/mL, 1 mL and 10 mL vials                               | DDAVP        |           |
| Desmopressin Acetate  | Nasal Spray               | 0.01%  | DDAVP        |           |
| Desmopressin Acetate  | Tablets                   | 0.1 mg and 0.2 mg  | DDAVP        |           |
| Desogestrel; Ethinyl Estradiol Tablets  | Tablets                   | 0.15mg/ 0.02 mg and 0.01 mg                                  | Mircette     |           |
| Dexmethylphenidate Hydrochloride  | Tablets                   | 5 mg and 10 mg   | Focalin      | 5/27/2004 |
| Dexrazoxane   | For Injection             | 250 mg/vial  | Zinecard     |           |
| Dextroamphetamine saccharate; Amphetamine aspartate; Dextroamphetamine Sulfate; Amphetamine Sulfate | Extended-release Capsules | 5 mg, 10 mg, 15 mg, 20 mg, 25 mg and 30 mg                   | Adderall XR  |           |
| Dextroamphetamine saccharate; Amphetamine aspartate; Dextroamphetamine Sulfate; Amphetamine Sulfate | Tablets                   | 7.5 mg, 12.5 mg and 15 mg                                    | Adderall     |           |
| Diazepam  | Tablets                   | 2 mg, 5 mg   | Valium       |           |

|                         |                           |   |             |           |
|-------------------------|---------------------------|---|-------------|-----------|
|                         |                           | and 10 mg   |             |           |
| Diazepam                | Rectal Gel                | 2.5 mg/0.5 mL, 5 mg/mL, 10 mg/2 mL, 15 mg/3 mL and 20 mg/4 mL                           | Diastat     | 3/23/2004 |
| Didanosine              | Delayed-release Capsules  | 200 mg, 250 mg and 400 mg   | Videx EC    | 6/1/2004  |
| Diltiazem Hydrochloride | Extended-release Capsules | 120 mg, 180 mg and 240 mg   | Dilacor XR  |           |
| Diltiazem Hydrochloride | Extended-release Capsules | 120 mg, 180 mg, 240 mg, 300 mg, 360 mg and 420 mg                                       | Tiazac      |           |
| Diltiazem Hydrochloride | Extended-release Capsules | 120 mg, 180 mg, 240 mg and 300 mg   | Cardizem CD |           |
| Diltiazem Hydrochloride | Extended-release Capsules | 60 mg, 90 mg and 120 mg   | Cardizem SR |           |
| Divalproex Sodium       | Delayed-release Tablets   | 125 mg, 250 mg and 500 mg   | Depakote    |           |
| Divalproex Sodium       | Extended-release Tablets  | 250 mg  | Depakote ER | 5/3/2004  |
| Donepezil Hydrochloride | Tablets                   | 5 mg and 10 mg  | Aricept     |           |
| Doxazosin Mesylate      | Tablets                   | 1 mg, 2 mg, 4 mg and 8 mg   | Cardura     |           |
| Enalapril Maleate       | Tablets                   | 2.5 mg, 5 mg, 10 mg and 20 mg   | Vasotec     |           |
| Enoxaparin Sodium       | Injection                 | 100 mg/mL, 0.3 mL, 0.4 mL, 0.6 mL, 0.8 mL and 1 mL prefilled syringes<br><br>150 mg/mL, | Lovenox     |           |

|                                       |                                   |  |                      |  |
|---------------------------------------|-----------------------------------|--|----------------------|--|
|                                       |                                   | 0.6 mL, 0.8 mL and 1 mL prefilled syringes               |                      |  |
| Escitalopram Oxalate                  | Tablets                           | 5 mg, 10 mg and 20 mg                                    | Lexapro              |  |
| Esmolol Hydrochloride                 | Injection                         | 10 mg/mL, 10 mL vial                                     | Brevibloc            |  |
| Estradiol                             | Transdermal System                | 0.05 mg/day and 0.1 mg/day                               | Climara              |  |
| Estradiol; Estradiol and Norgestimate | Tablets                           | 1 mg; 1 mg and 0.09 mg                                   | Prefest              |  |
| Etodolac                              | Extended-release Tablets          | 400 mg, 500 mg and 600 mg                                | Lodine XL            |  |
| Famotidine                            | Tablets                           | 10 mg (OTC)  | Pepcid AC            |  |
| Famotidine                            | Tablets                           | 20 mg and 40 mg  | Pepcid               |  |
| Famotidine                            | Injection                         | 10 mg/mL, 4 mL and 20 mL vials; preserved                | Pepcid               |  |
| Famotidine                            | Injection                         | 10 mg/mL, 50 mL vial, pharmacy bulk package; unpreserved | Pepcid               |  |
| Famotidine                            | Injection                         | 10 mg/mL, 2 mL vials; unpreserved                        | Pepcid               |  |
| Famotidine                            | Tablets (Chewable)                | 10 mg (OTC)  | Pepcid AC (chewable) |  |
| Felodipine                            | Extended-release Tablets          | 2.5 mg, 5 mg and 10 mg                                   | Plendil ER           |  |
| Fenofibrate                           | Capsules                          | 67 mg, 134 mg and 200 mg                                 | Tricor               |  |
| Fenofibrate                           | Tablets                           | 54 mg, 107 mg and 160 mg                                 | Tricor               |  |
| Fentanyl                              | Transdermal Extended-release Film | 0.6 mg/24 hr, 1.2 mg/ 24 hr, 1.8 mg/ 24                  | Duragesic            |  |

|  |                          |                                  |                              |  |
|--|--------------------------|----------------------------------|------------------------------|--|
|  |                          | hr and 2.4 mg/ 24 hr             |                              |  |
| Fexofenadine Hydrochloride                                   | Capsules                 | 60 mg                            | Allegra                      |  |
| Fexofenadine Hydrochloride                                   | Tablets                  | 30 mg, 60 mg and 180 mg          | Allegra                      |  |
| Fexofenadine Hydrochloride and Pseudoephedrine Hydrochloride | Extended-release Tablets | 60 mg/120 mg                     | Allegra-D                    |  |
| Finasteride  | Tablets                  | 5 mg                             | Proscar                      |  |
| Finasteride  | Tablets                  | 1 mg                             | Propecia                     |  |
| Flecainide Acetate   | Tablets                  | 50 mg, 100 mg and 150 mg         | Tambocor                     |  |
| Fluconazole  | Tablets                  | 50 mg, 100 mg, 150 mg and 200 mg | Diflucan                     |  |
| Fluconazole  | For Oral Suspension      | 50 mg/5 mL and 200 mg/5 mL       | Diflucan for Oral Suspension |  |
| Flunisolide  | Nasal Solution           | 0.025%                           | Nasalide                     |  |
| Fluocinonide   | Ointment                 | 0.05%                            | Lidex                        |  |
| Fluoxetine Hydrochloride                                     | Tablets                  | 10 mg and 20 mg                  | Prozac                       |  |
| Fluoxetine Hydrochloride                                     | Capsules                 | 10 mg, 20 mg and 40 mg           | Prozac                       |  |
| Fluoxetine Hydrochloride                                     | Delayed-release Capsules | 90 mg                            | Prozac Weekly                |  |
| Fluoxetine Hydrochloride                                     | Oral Solution            | 20 mg (base)/5 mL                | Prozac                       |  |
| Fluoxetine Hydrochloride                                     | Capsules                 | 10 mg and 20 mg                  | Sarafem                      |  |
| Flutamide  | Capsule                  | 125 mg                           | Eulexin                      |  |
| Fosinopril Sodium  | Tablets                  | 10 mg, 20 mg and 40 mg           | Monopril                     |  |
| Fosinopril Sodium and Hydrochlorothiazide                    | Tablets                  | 10 mg/12.5 mg and 20 mg/12.5 mg  | Monopril HCT                 |  |
| Gabapentin   | Capsules                 | 100 mg, 300                      | Neurontin                    |  |

|   |                          |  |   |                  |
|---|--------------------------|--|---|------------------|
|   |                          | mg and 400 mg                                |   |                  |
| Gabapentin                                  | Tablets                  | 600 mg and 800 mg                            | Neurontin                                 |                  |
| Gabapentin                                  | Oral Solution            | 250 mg/5 mL                                  | Neurontin                                 |                  |
| Gatifloxacin                                | Tablets                  | 200 mg and 400 mg                            | Tequin                                    |                  |
| Ganciclovir Sodium                          | Capsules                 | 250 mg and 500 mg                            | Cytovene                                  |                  |
| Glipizide                                   | Extended-release Tablets | 2.5 mg, 5 mg and 10 mg                       | Glucotrol XL                              |                  |
| Glyburide                                   | Tablets                  | 1.5 mg, 3 mg, 4.5 mg and 6 mg                | Glynase                                   |                  |
| Glyburide/Metformin Hydrochloride           | Tablets                  | 1.25mg/250 mg, 2.5 mg/500 mg and 5 mg/500 mg | Glucovance                                |                  |
| Granisetron Hydrochloride                   | Injection                | 1 mg/mL, 1 mL vials                          | Kytril                                    | 6/1/2004         |
| <b>Granisetron Hydrochloride</b>            | <b>Injection</b>         | <b>1 mg/mL, 4 mL multi-dose vials</b>        | <b>Kytril</b>                             | <b>7/19/2004</b> |
| Hydrocodone Bitartrate and Ibuprofen        | Tablets                  | 7.5 mg/200 mg                                | Vicoprofen                                |                  |
| Ibuprofen                                   | Chewable Tablets         | 50 mg and 100 mg                             | Children's Motrin, Junior Strength Motrin |                  |
| Ibuprofen                                   | Oral Suspension          | 100 mg/5 mL (Rx)                             | Motrin                                    |                  |
| Ibuprofen                                   | Oral Suspension          | 100 mg/5 mL (OTC)                            | Children's Motrin                         |                  |
| Ibuprofen                                   | Oral Drops               | 40 mg/mL                                     | Children's Motrin Drops                   |                  |
| Ibuprofen and Pseudoephedrine Hydrochloride | Tablets                  | 200 mg/30 mg                                 | Advil Cold and Sinus                      |                  |
| Ibuprofen and Pseudoephedrine Hydrochloride | Oral Suspension          | 100 mg/ 15 mg per 5 mL                       | Children's Motrin Cold                    |                  |



|                        |                                 |   |                  |           |
|------------------------|---------------------------------|---|------------------|-----------|
| Ifosfamide             | For Injection                   | 1 g/vial and 3 g/vial   | Ifex             |           |
| Ifosfamide             | Injection                       | 50 mg/mL, 20 mL vials and 60 mL vials                                 | Ifex             |           |
| Ifosfamide/Mesna       | For Injection/<br>Injection Kit | 1 g/vial; 100 mg/mL, 10 mL vials and 3 g/vial; 100 mg/mL, 10 mL vials | Ifex/ Mesnex Kit |           |
| Ifosfamide/Mesna       | Injection/<br>Injection Kit     | 50 mg/mL, 20 mL and 60 mL vials; 100 mg/mL, 10 mL vial                | Ifex/ Mesnex Kit |           |
| Indomethacin           | Extended-release Capsules       | 75 mg   | Indocin SR       |           |
| Irbesartan             | Tablets                         | 75 mg, 150 mg and 300 mg  | Avapro           | 5/25/2004 |
| Itraconazole           | Capsules                        | 100 mg  | Sporanox         |           |
| Ketoprofen             | Capsules                        | 25 mg, 50 mg and 75 mg  | Orudis           |           |
| Ketorolac Tromethamine | Injection                       | 15 mg/mL and 30 mg/mL   | Toradol          |           |
| Ketorolac Tromethamine | Ophthalmic Solution             | 0.5%  | Acular           |           |
| Ketorolac Tromethamine | Tablets                         | 10 mg   | Toradol          |           |
| Lactulose              | Oral Syrup                      | 10 g/15 mL  | Cephulac         |           |
| Lactulose              | Oral Syrup                      | 10 g/15 mL  | Chronulac        |           |
| Lamotrigine            | Tablets                         | 25 mg, 100 mg, 150 mg and 200 mg                                      | Lamictal         |           |
| Lamotrigine            | Chewable Tablets                | 2 mg, 5 mg and 25 mg  | Lamictal CD      |           |
| Latanoprost            | Ophthalmic Solution             | 0.005%  | Xalatan          |           |
| Leuprolide Acetate     | Injection (depot)               | 7.5 mg/vial   | Lupron Depot     |           |
| Levetiracetam          | Tablets                         | 250 mg, 500   | Keppra           |           |

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|--|-------------------------------|--|--|-----------|
|  |                               | mg and 750 mg  |  |           |
| Levofloxacin                               | Tablets                       | 250 mg, 500 mg and 750 mg  | Levaquin                                     |           |
| Levofloxacin                               | Injection                     | 25 mg/mL   | Levaquin                                     |           |
| Levofloxacin                               | Injection                     | 5 mg/mL; 50 mL, 100 mL and 150 mL vials  | Levaquin in Dextrose 5% in Plastic Container |           |
| Levofloxacin                               | Ophthalmic Solution           | 0.5%   | Quixin                                       |           |
| Levonorgestrel and Ethinyl Estradiol       | Tablets                       | 0.15 mg/0.03 mg  | Seasonale                                    | 3/29/2004 |
| Levothyroxine Sodium                       | Tablets                       | 0.025 mg, 0.05 mg, 0.075 mg, 0.088 mg, 0.1 mg, 0.112 mg, 0.125 mg, 0.150 mg, 0.175 mg, 0.2 mg and 0.3 mg | Levoxyl                                      |           |
| Loperamide HCl and Simethicone             | Tablets                       | 2 mg/125 mg  | Imodium Advanced                             |           |
| Loratadine                                 | Tablets                       | 10 mg  | Claritin                                     |           |
| Loratadine                                 | Syrup                         | 1 mg/mL  | Claritin                                     |           |
| Loratadine                                 | Orally Disintegrating Tablets | 10 mg  | Claritin RediTabs                            |           |
| Loratadine/ Pseudoephedrine                | Extended-release Tablets      | 5 mg/120 mg  | Claritin D- 12 hour                          |           |
| Loratadine/ Pseudoephedrine                | Extended-release Tablets      | 10 mg/240 mg   | Claritin D-24 hour                           |           |
| Losartan Potassium and Hydrochlorothiazide | Tablets                       | 50 mg/12.5 mg and 100 mg/25 mg   | Hyzaar                                       | 5/24/2004 |
| Mefloquine Hydrochloride                   | Tablets                       | 250 mg   | Lariam                                       |           |
| Megestrol Acetate                          | Oral Suspension               | 40 mg/mL   | Megace                                       |           |
| Metaxalone                                 | Tablets                       | 400 mg   | Skelaxin                                     |           |
| Metformin Hydrochloride                    | Extended-release Tablets      | 500 mg   | Glucophage XR                                |           |
|  |                               |  |  |           |

|   |                                  |   |                |                  |
|---|----------------------------------|---|----------------|------------------|
| Metformin Hydrochloride                         | Extended-release Tablets         | 750 mg                                      | Glucophage XR  |                  |
| Metoclopramide Hydrochloride                    | Injection                        | 5 mg/mL, 2 mL, 10 mL, 20 mL and 30 mL vials | Reglan         |                  |
| Metoprolol Succinate                            | Extended-release Tablets         | 25 mg, 50 mg, 100 mg and 200 mg             | Toprol XL      |                  |
| Mirtazapine                                     | Tablets                          | 7.5 mg, 15 mg, 30 mg, and 45 mg             | Remeron        |                  |
| Mirtazapine                                     | Orally Disintegrating Tablets    | 15 mg, 30 mg and 45 mg                      | Remeron SolTab |                  |
| Modafinil                                       | Tablets                          | 100 mg and 200 mg                           | Provigil       |                  |
| Moexipril Hydrochloride                         | Tablets                          | 7.5 mg and 15 mg                            | Univasc        |                  |
| Moexipril Hydrochloride and Hydrochlorothiazide | Tablets                          | 7.5mg/12.5mg 15 mg/25 mg and 15 mg/12.5 mg  | Uniretic       | 1/15/2004        |
| Mometasone Furoate                              | Topical Solution (Cream)         | 0.1%  | Elocon         |                  |
| <b>Mometasone Furoate</b>                       | <b>Topical Solution (Lotion)</b> | <b>0.1%</b>                                 | <b>Elocon</b>  | <b>6/10/2004</b> |
| Moxifloxacin Hydrochloride                      | Tablets                          | 400 mg                                      | Avelox         |                  |
| Nabumetone                                      | Tablets                          | 500 mg and 750 mg                           | Relafen        |                  |
| Naproxen Sodium                                 | Extended-release Tablets         | 375 mg (base) and 500 mg (base)             | Naprelan       |                  |
| Nefazodone HCl                                  | Tablets                          | 50 mg, 100 mg, 150 mg 200 mg and 250 mg     | Serzone        |                  |
| Niacin  | Extended-release Tablets         | 500 mg, 750 mg and 1000 mg                  | Niaspan        |                  |
|   |                                  |   |                |                  |

|  |                          |   |                                  |  |
|--|--------------------------|---|----------------------------------|--|
| Nicotine                                 | Transdermal System       | 7 mg/day, 14 mg/day and 21 mg/day                                   | Habitrol                         |  |
| Nicotine Polacrilex                      | Troche/Lozenge           | 2 mg and 4 mg   | Commit                           |  |
| Nifedipine                               | Capsules                 | 10 mg and 20 mg   | Procardia                        |  |
| Nifedipine                               | Extended-release Tablets | 30 mg, 60 mg and 90 mg  | Adalat CC                        |  |
| Nifedipine                               | Extended-release Tablets | 30 mg, 60 mg and 90 mg  | Procardia XL                     |  |
| Nitrofurantoin Monohydrate/Macrocrystals | Capsules                 | 75 mg/25 mg   | Macrobid                         |  |
| Nitroglycerin                            | Transdermal System       | 0.1 mg/hr   | Transderm-Nitro                  |  |
| Nitroglycerin                            | Transdermal System       | 0.1 mg/hr, 0.2 mg/hr, 0.3 mg/hr, 0.4 mg/hr, 0.6 mg/hr and 0.8 mg/hr | Nitro-dur                        |  |
| Nizatidine                               | Capsules                 | 150 mg and 300 mg   | Axid                             |  |
| Norethindrone/ Ethinyl Estradiol         | Tablets                  | 0.5 mg/ 0.035 mg, 0.75 mg/ 0.035 mg and 1 mg /0.035 mg              | Ortho-Novum 7/7/7, 21 and 28 day |  |
| Norethindrone Acetate/Ethinyl Estradiol  | Tablets                  | 1 mg/0.005 mg   | Femhrt                           |  |
| Norethindrone Acetate/Ethinyl Estradiol  | Tablets                  | 1 mg/ 0.02 mg, 1 mg/0.03 mg and 1 mg /0.035 mg                      | Estrostep Fe                     |  |
| Norethindrone Acetate/Ethinyl Estradiol  | Tablets                  | 1 mg/0.02 mg, 1 mg/ 0.03 mg and 1 mg /0.035 mg                      | Estrostep 21                     |  |
| Norgestimate/ Ethinyl Estradiol          | Tablets                  | 0.18 mg /0.035 mg,  | Ortho Tri-Cyclen, 21             |  |

|                                 |                               |   |                                 |  |
|---------------------------------|-------------------------------|---|---------------------------------|--|
|                                 |                               | 0.215 mg /0.035 mg and 0.25 mg /0.035 mg                    | and 28 day                      |  |
| Norgestimate/ Ethinyl Estradiol | Tablets                       | 0.18 mg /0.025 mg, 0.215 mg /0.025 mg and 0.25 mg /0.025 mg | Ortho Tri-Cyclen Lo, 28 day     |  |
| Nortriptyline Hydrochloride     | Capsules                      | 10 mg, 25 mg, 50 mg and 75 mg                               | Pamelor                         |  |
| Octreotide Acetate              | Injection                     | 0.05 mg /mL, 0.1 mg /mL and 0.5 mg/mL, 1 mL vials           | Sandostatin (Preservative-free) |  |
| Octreotide Acetate              | Injection                     | 0.2 mg/mL and 1 mg /mL, 5 mL vials                          | Sandostatin                     |  |
| Ofloxacin                       | Otic Solution                 | 0.3%  | Floxin                          |  |
| Olanzapine                      | Tablets                       | 2.5 mg, 5 mg, 7.5 mg, 10 mg and 15 mg                       | Zyprexa                         |  |
| Olanzapine                      | Tablets                       | 20 mg   | Zyprexa                         |  |
| Olanzapine                      | Orally Disintegrating Tablets | 5 mg, 10 mg, 15 mg and 20 mg                                | Zyprexa Zydis                   |  |
| Omeprazole                      | Delayed-release Capsules      | 10 mg, 20 mg and 40 mg                                      | Prilosec                        |  |
| Ondansetron Hydrochloride       | Tablets                       | 4 mg, 8 mg, 16 mg and 24 mg                                 | Zofran                          |  |
| Ondansetron Hydrochloride       | Orally Disintegrating Tablets | 4 mg and 8 mg   | Zofran ODT                      |  |
| Ondansetron Hydrochloride       | Injection                     | 2 mg/mL, 20 mL vials  | Zofran                          |  |
| Ondansetron Hydrochloride       | Injection                     | 2 mg/mL, 2 mL vials (Preservative-                          | Zofran                          |  |

|                            |                              |  |                                   |           |
|----------------------------|------------------------------|--|-----------------------------------|-----------|
|                            |                              | free)  |                                   |           |
| Ondansetron Hydrochloride  | Injection                    | 0.64 mg/mL,<br>50 mL<br>container<br>(plastic)                     | Zofran in<br>Plastic<br>Container |           |
| Oxazepam                   | Capsules                     | 10 mg, 15 mg<br>and 30 mg  | Serax                             |           |
| Oxybutynin Chloride        | Extended-<br>release Tablets | 5 mg, 10 mg<br>and 15 mg   | Ditropan XL                       |           |
| Oxycodone                  | Extended-<br>release Tablets | 10 mg, 20<br>mg,<br>40 mg, 80 mg<br>and 160 mg                     | Oxycontin                         |           |
| Paclitaxel                 | Injection                    | 6 mg/mL, 5<br>mL, 16.7<br>mL, 25 mL,<br>33.3 mL and<br>50 mL vials | Taxol                             |           |
| Pamidronate Disodium       | For Injection                | 30 mg/vial, 60<br>mg/vial<br>and 90<br>mg/vial                     | Aredia                            |           |
| Pamidronate Disodium       | Injection                    | 30 mg/vial, 60<br>mg/vial<br>and 90<br>mg/vial                     | Aredia                            |           |
| Pantoprazole Sodium        | Delayed-<br>release Tablets  | 20 mg and<br>40 mg   | Protonix                          | 2/02/2004 |
| Paroxetine Hydrochloride   | Tablets                      | 10 mg, 20<br>mg, 30 mg<br>and<br>40 mg                             | Paxil                             |           |
| Paroxetine Hydrochloride   | Capsules                     | 10 mg and 20<br>mg   | Paxil                             |           |
| Pergolide Mesylate         | Tablets                      | 0.05 mg, 0.25<br>mg and 1 mg                                       | Permax                            |           |
| Pioglitazone Hydrochloride | Tablets                      | 15 mg, 30 mg<br>and 45 mg  | Actos                             |           |
| Polyethylene Glycol 3350   | Powder for Oral<br>Solution  | 17g/Scoopful   | Miralax                           |           |
| Potassium Chloride         | Extended-                    | 10 mEq and   | K-Dur                             |           |

|   |                           |  |            |  |
|---|---------------------------|--|------------|--|
|   | release Tablets           | 20 mEq   |            |  |
| Potassium Chloride                          | Extended-release Capsules | 8 mEq and 10 mEq   | Micro K    |  |
| Pravastatin Sodium                          | Tablets                   | 10 mg, 20 mg, 40 mg and 80 mg                              | Pravachol  |  |
| Prazosin Hydrochloride                      | Capsules                  | 1 mg, 2 mg and 5 mg  | Minipress  |  |
| Prednisolone Sodium Phosphate               | Oral Solution             | 5 mg(base)/ 5 mL and 15 mg (base)/ 5 mL                    | Pediapred  |  |
| Propofol                                    | Injection                 | 10 mg/mL ; 20 mL, 50 mL and 100 mL vials and 20 mL syringe | Diprivan   |  |
| Propranolol Hydrochloride                   | Extended-release Capsules | 60 mg, 80 mg, 120 mg and 160 mg                            | Inderal LA |  |
| Quinapril Hydrochloride                     | Tablets                   | 5 mg, 10 mg, 20 mg and 40 mg                               | Accupril   |  |
| Quinapril Hydrochloride/Hydrochlorothiazide | Tablets                   | 10 mg/12.5 mg, 20 mg/12.5 mg and 20mg/25 mg                | Accuretic  |  |
| Rabeprazole Sodium                          | Delayed-release Tablets   | 20 mg  | Aciphex    |  |
| Raloxifene Hydrochloride                    | Tablets                   | 60 mg  | Evista     |  |
| Ramipril                                    | Capsules                  | 1.25 mg, 2.5 mg, 5 mg and 10 mg                            | Altace     |  |
| Ranitidine                                  | Injection                 | 25 mg/mL, 2 mL and 6 mL and 40 mL vials                    | Zantac     |  |
|   |                           |  |            |  |

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|--------------------------|-------------------------------|-------------------------------------|-----------|-----------|
| Ranitidine               | Tablets                       | 75 mg, 150 mg and 300 mg            | Zantac    |           |
| Ranitidine               | Capsules                      | 150 mg and 300 mg                   | Zantac    |           |
| Ranitidine               | Oral Solution                 | 15 mg/mL                            | Zantac    |           |
| Ribavirin                | Capsule                       | 200 mg                              | Rebetol   |           |
| Risedronate Sodium       | Tablets                       | 5 mg, 30 mg and 35 mg               | Actonel   | 4/23/2004 |
| Risperidone              | Oral Solution                 | 1 mg/mL                             | Risperdal |           |
| Risperidone              | Tablets                       | 0.25 mg, 1 mg, 2 mg, 3 mg and 4 mg  | Risperdal |           |
| Risperidone              | Orally Disintegrating Tablets | 1 mg, 0.5 mg and 2 mg               | Risperdal |           |
| Rivastigmine Tartrate    | Capsules                      | 1.5 mg, 3 mg, 4.5 mg and 6 mg       | Exelon    | 4/21/2004 |
| Rofecoxib                | Tablets                       | 12.5 mg, 25 mg and 50 mg            | Vioxx     |           |
| Rosiglitazone Maleate    | Tablets                       | 2 mg, 4 mg and 8 mg                 | Avandia   |           |
| Sertraline Hydrochloride | Tablets                       | 25 mg, 50 mg and 100 mg             | Zoloft    |           |
| Sertraline Hydrochloride | Oral Concentrate              | 20 mg/mL                            | Zoloft    |           |
| Sevoflurane              | Inhalation                    | 100%, 250 mL                        | Ultane    |           |
| Silver Sulfadiazine      | Cream                         | 1%                                  | Silvadene |           |
| Simvastatin              | Tablets                       | 5 mg, 10 mg, 20 mg, 40 mg and 80 mg | Zocor     |           |
| Sumatriptan Succinate    | Tablets                       | 25 mg, 50 mg and 100 mg             | Imitrex   |           |
|                          |                               |                                     |           |           |



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|----------------------------------|---------------------------|--------------------------------|------------|------------|
| Tamoxifen Citrate                | Tablets                   | 10 mg and 20 mg                | Nolvadex   |            |
| Terazosin Hydrochloride          | Capsules                  | 1 mg, 2 mg, 5 mg and 10 mg     | Hytrin     |            |
| Terazosin Hydrochloride          | Tablets                   | 1 mg, 2 mg, 5 mg and 10 mg     | Hytrin     |            |
| Terbinafine Hydrochloride        | Tablets                   | 250 mg                         | Lamisil    |            |
| Terfenadine                      | Tablets                   | 60 mg                          | Seldane    |            |
| Testosterone                     | Gel                       | 1%                             | Androgel   |            |
| Ticlopidine Hydrochloride        | Tablets                   | 250 mg                         | Ticlid     |            |
| Timolol Maleate                  | Ophthalmic Solution       | 0.25% and 0.5%                 | Timoptic   |            |
| Tolterodine Tartrate             | Tablets                   | 1 mg and 2 mg                  | Detrol     |            |
| Topiramate                       | Tablets                   | 25 mg, 100 mg and 200 mg       | Topamax    | 12/26/2001 |
| Torsemide                        | Tablets                   | 5 mg, 10 mg, 20 mg, and 100 mg | Demadex    |            |
| Tramadol Hydrochloride           | Tablets                   | 50 mg                          | Ultram     |            |
| Trazodone Hydrochloride          | Tablets                   | 150 mg                         | Desyrel    |            |
| Tretinoin                        | Cream                     | 0.025%, 0.05% and 0.1%         | Retin-A    |            |
| Tretinoin                        | Gel                       | 0.025%                         | Retin-A    |            |
| Triamterene/ Hydrochlorothiazide | Tablets                   | 37.5 mg/25 mg and 75 mg/50 mg  | Maxzide    |            |
| Valacyclovir Hydrochloride       | Tablets                   | 500 mg and 1 g                 | Valtrex    |            |
| Venlafaxine Hydrochloride        | Extended-release Capsules | 37.5 mg, 75 mg and 150 mg      | Effexor XR |            |
| Vecuronium Bromide               | For Injection             | 10 mg/vial and 20 mg/vial      | Norcuron   |            |
| Verapamil Hydrochloride          | Extended-release Capsules | 120 mg, 180 mg and 240 mg      | Verelan SR |            |
| Verapamil Hydrochloride          | Extended-release Tablets  | 180 mg                         | Isoptin SR |            |

|                         |                          |                                    |           |  |
|-------------------------|--------------------------|------------------------------------|-----------|--|
| Verapamil Hydrochloride | Extended-release Tablets | 240 mg                             | Covera HS |  |
| Vincristine Sulfate     | Injection                | 1 mg/mL, 1 mL, 2 mL and 5 mL vials | Oncovin   |  |
| Zidovudine              | Capsules                 | 100 mg                             | Retrovir  |  |

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Date created: 3/2/2004, updated: 8/16/2004

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