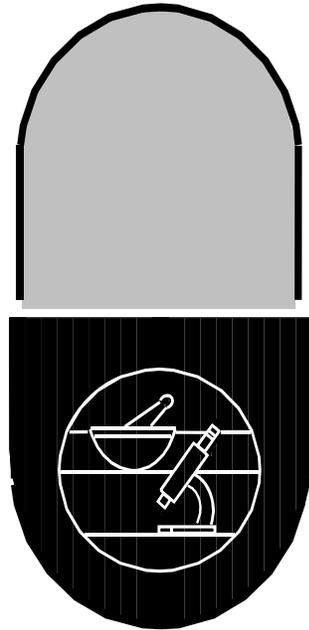


**CUMULATIVE
SUPPLEMENT 05
May 2009**



**APPROVED
DRUG PRODUCTS**

**WITH
THERAPEUTIC EQUIVALENCE EVALUATIONS**

29th EDITION

**Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Generic Drugs**

2009

Prepared By
Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration

**APPROVED DRUG PRODUCTS
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29th EDITION

Cumulative Supplement 5

May 2009

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**APPROVED DRUG PRODUCTS
with
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29th EDITION

**CUMULATIVE SUPPLEMENT 5
May 2009**

1.0 INTRODUCTION

1.1 HOW TO USE THE CUMULATIVE SUPPLEMENT

This Cumulative Supplement is one of a series of monthly updates to the Approved Drug Products with Therapeutic Equivalence Evaluations, 28th Edition (the List). The List is composed of four parts: approved prescription drug products with therapeutic equivalence evaluations; over-the-counter (OTC) drug products that require approved applications as a condition of marketing; drug products with approval under Section 505 of the Act administered by the Center for Biologics Evaluation and Research; and products that have never been marketed, are for exportation, are for military use, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.

The Cumulative Supplement provides, among other things, information on newly approved drugs and, if necessary, revised therapeutic equivalence evaluations and updated patent and exclusivity data. The Addendum contains appropriate drug patent and exclusivity information required of the Agency by the "Drug Price Competition and Patent Term Restoration Act of 1984" for the Prescription, OTC, and Drug Products with Approval under Section 505 of the Act Administered by the Center for Biologics Evaluation and Research Lists.

Because all parts of the publication are subject to changes, additions, or deletions, the List must be used in conjunction with the most current Cumulative Supplement. Users may wish to mark to the left of the ingredient(s) in the List to indicate that changes to that entry appear in the Cumulative Supplement. Drug product information is provided in each Cumulative Supplement for completeness to assist in locating the proper place in the List for the revision.

The presence of any therapeutic equivalence code indicates that the drug product is multisource; the deletion of a therapeutic equivalence code indicates that the drug product has become single source. (An infrequent exception exists when a therapeutic equivalence code is revised. In that case the deletion of the therapeutic equivalence code is followed immediately by the addition of the revised one.)

Products that have never been marketed, are for exportation, are for military use, or have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons, will be flagged in this Cumulative Supplement with the "@" symbol to designate their non-marketed status. All products having a "@" symbol in the 12th Cumulative Supplement of the 29th Edition List will then be added to the "Discontinued Drug Product List" appearing in the 30th Edition. The current edition

Section 2. How To Use The Drug Product Lists describes the layout and usage of the List.

New additions to the Prescription Drug Product List and OTC Drug Product List are indicated by the symbol >A>. The Patent and Exclusivity List new additions are indicated by the symbol >A> to the left of Patent Number or Exclusivity Code. The >A> symbol is then dropped in subsequent Cumulative Supplements for that item.

New deletions to the Prescription Drug Product List and OTC Drug Product List are indicated by the symbol >D> (DELETE) to the left of the line. The information line with the >D> symbol is dropped in subsequent Cumulative Supplements for that item.

The Patent and Exclusivity List is arranged in alphabetical order by active ingredient name(s) and trade name. The trade name will follow the active ingredient name separated by a dash symbol. Also shown is the application number and product number (FDA's internal file number) for reference purposes. All patents with their expiration dates are displayed for each application number. Drug substance and drug product patents are indicated as such with DS or DP in the Patent codes column. Use patents are indicated with the symbol "U" followed by a number representing a specific use. Exclusivity information for a specific drug is indicated by an abbreviation followed by the date upon which the exclusivity expires. Refer to the Exclusivity Terms, Section B, in the Patent and Exclusivity Information Addendum for an explanation of all codes and abbreviations. Refer to Section 1.3 for internet access to the most current list of Patent and Exclusivity terms.

1.2 CUMULATIVE SUPPLEMENT CONTENT

Since February 2005, we have been providing daily Electronic Orange Book (EOB) product information for new generic drug approvals. Daily generic updates provide the consumer with the current list of approved generic products which is important for substitution purposes. Previously, a first-time-generic product approved early in the month would not be published in the Cumulative Supplement (CS) for several weeks.

The CS monthly update publish goal is by the end of the following month's second work week (e.g., November's supplement will be updated by the end of the second full work week in December).

Currently, the monthly PDF CS includes:

- Generic product ANDA (Abbreviated New Drug Approval) approvals as of the date of publication.
- All product changes received and processed as of the date of publication.
 - Refer to CS Section 1.8 Cumulative Supplement Legend for types of changes
 - Discontinued products will be processed as of the date of publication. There will be circumstances where a product is discontinued in one month, however, it will be reported in a different month's CS. For example, the Orange Book Staff received a letter November 7 that the product has been discontinued from manufacturing and marketing. The Orange Book subsequently publishes the October CS on November 14. The product will show in the October CS that it is discontinued even though the date of discontinuance is the day that the Orange Book Staff receives notification (November 7).

- New Drug Application (NDA) approvals (20,000 and 50,000 series) appear in the CS month they were approved.
- Patent information, also updated daily in the EOB, is current to the date of publication.
- Exclusivity information is updated monthly and current to the date of publication.

Every effort is made to ensure the Cumulative Supplement is current and accurate. Applicant holders are requested to inform the FDA Orange Book Staff (OBS) of any changes or corrections. The OBS can be contacted by email at drugproducts@cder.fda.gov. Send Changes by FAX: 240-276-8974; mail to:

FDA/CDER Orange Book Staff
Office of Generic Drugs, HFD-610
7500 Standish Place
Rockville, MD 20855-2773

1.3 APPLICANT NAME CHANGES

It is not practical to identify in the Cumulative Supplement each and every product involved when an applicant transfers its entire line of approved drug products to another applicant, or when an applicant changes its name. Therefore, the cumulation of these transfers and name changes will be identified in this section only. Where only partial lines of approved products are transferred between applicants, each approved product involved will appear as an applicant name change entry in the Cumulative Supplement.

It is also not practical to identify each and every product involved when an applicant name is changed to meet internal publication standards (e.g., MSD or Zenith [Former Abbreviated Names] are changed, respectively, to Merck Sharp Dohme or Zenith Labs [New Abbreviated Names]). When this occurs, each product involved (either currently in the Cumulative Supplement or in the following year's edition) will reflect the new abbreviated name. Consequently, it will not appear as an applicant name change entry in the Cumulative Supplement nor will the cumulation of these name changes appear in this section. The Electronic Orange Book Query, updated monthly, will contain the most current applicant holder name.

| <u>FORMER APPLICANT NAME</u> <u>(FORMER ABBREVIATED NAME)</u> | <u>NEW APPLICANT NAME</u> <u>(NEW ABBREVIATED NAME)</u> |
|--|--|
| DABUR ONCOLOGY PLC (DABUR ONCOLOGY PLC) | FRESENIUS KABI ONCOLOGY PLC (FRESENIUS KABI ONCOL) |
| TORPHARM INC (TORPHARM) | APOTEX INC (APOTEX) |

1.4 AVAILABILITY OF THE EDITION

Since 1997, the Electronic Orange Book Query (EOBQ) <http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm>, has been available on the internet and has become the updated-every-month Orange Book. The Query provides searching of the approved drug list by active ingredient, proprietary name, applicant holder, applicant number or patent number. Product search categories are: prescription, over-the-counter, discontinued drugs. There are links to patent and exclusivity information that may be applicable to each product.

Commencing with the 25th edition, the Annual Edition and monthly Cumulative Supplements have been provided in downloadable Portable Document Format (PDF) at the EOB home page by clicking on Annual Edition. The PDF annual and cumulative supplements duplicate previous paper versions. Over time, there will be an archive for the annuals and each year's December Cumulative Supplement.

The downloaded Annual Edition and Cumulative Supplements are also available in a paper version (Approved Drug Products with Therapeutic Equivalence Evaluations, ADP) from the U.S. Government Printing Office: <http://bookstore.gpo.gov>; toll free 866-512-1800.

There are historical lists of Orange Book cumulative supplement product monthly changes at <http://www.fda.gov/Drugs/InformationOnDrugs/ucm086229.htm>. There are ASCII text files of the Orange Book drug product, patent, and exclusivity data at <http://www.fda.gov/Drugs/InformationOnDrugs/ucm129689.htm>. The drug product text files are provided in eobzip.exe and eobzip.zip format. The files are updated concurrently with the monthly cumulative supplements. The annual Orange Book Edition Appendices A, B, and C in PDF format are updated quarterly. Effective August 18, 2003, patent submissions for publication in the Orange Book and Docket *95S-0117 need to be submitted on form FDA-3542 which may be downloaded from the FDA Forms List, <http://www.fda.gov/opacom/morechoices/fdaforms/default.html>.

The current listing of the Orphan Product Designations and Approvals is available at <http://www.fda.gov/orphan/designat/list.htm>.

1.5 REPORT OF COUNTS FOR THE PRESCRIPTION DRUG PRODUCT LIST

DESCRIPTION OF REPORT

This report provides summary counts derived from the product information in the Prescription Drug Product List and the current Cumulative Supplement. Products included in the counts are domestically marketed drug products approved for both safety and effectiveness under section 505 of the Federal Food, Drug, and Cosmetic Act. Excluded are approved drug products marketed by distributors; those marketed solely abroad; and those now regarded as medical devices, biologics or foods.

The baseline column (Dec 2008) refers to the products in the Prescription Drug Product List. For each three-month period, a column of quarterly data is added which incorporates counts of product activity from the previous quarter(s) with those in the baseline count.

DEFINITIONS

Drug Product

For this report, a drug product is the representation in the Prescription Drug Product List of an active moiety (molecular entity and its salts, esters and derivatives) either as a single ingredient or as a combination product provided in a specific dosage form and strength for a given route of administration with approval for marketing by a firm under a particular generic or trade name.

New Molecular Entity

A new molecular entity is considered an active moiety that has not previously been approved (either as the parent compound or as a salt, ester or derivative of the parent compound) in the United States for use in a drug product either as a single ingredient or as part of a combination.

REPORT OF COUNTS FOR THE PRESCRIPTION DRUG PRODUCT LIST
COUNTS CUMULATIVE BY QUARTER

| <u>CATEGORIES COUNTED</u> | <u>DEC 2008</u> | <u>MAR 2009</u> | <u>JUN 2009</u> | <u>SEPT 2009</u> |
|--|-----------------|-----------------|-----------------|------------------|
| DRUG PRODUCTS LISTED | 12751 | 12910 | | |
| SINGLE SOURCE | 2433 | 2449 | | |
| | (19.1%) | (19.0%) | | |
| MULTISOURCE | 10229 | 10372 | | |
| | (80.2%) | (80.3%) | | |
| THERAPEUTICALLY EQUIVALENT | 10072 | 10216 | | |
| | (79.0%) | (79.1%) | | |
| NOT THERAPEUTICALLY EQUIVALENT EXCEPTIONS ¹ | 157 | 156 | | |
| | (1.2%) | (1.2%) | | |
| | 89 | 89 | | |
| | (0.7%) | (0.7%) | | |
| NEW MOLECULAR ENTITIES APPROVED | 15 | 5 | | |
| NUMBER OF APPLICANTS | 719 | 724 | | |

¹Amino acid-containing products of varying composition (see Introduction, page xx of the List).

1.6 CUMULATIVE SUPPLEMENT LEGEND

The List is sorted by Ingredient(s) and, within each grouping, by the Dosage Form; Route and then by trade name.

The individual product record contains the Therapeutic Equivalence Code, Reference Listed Drug symbol, applicant holder, strength(s), New Drug Application number, product number, and approval date. The last two columns describe the action. The Action Month is the CS month the action occurred. The OB Action is the type of change that has occurred.

New ingredient(s), new dosage form; route(s), new trade names, and new product additions are preceded by >A> during the action month. The change month is the current CS month; the change code for new approvals is NEWA. Following months will display the same information without the >A>.

Changes to currently listed products will list two records. The deleted product record will be preceded by >D>. The product record change addition being made will be preceded by >A>. Following months will display only the >A> record without the >A>. All changes that occur to the product through the Annual year will be listed. The change month and change code will document the change.

The change code and description:

| | |
|------|--|
| NEWA | New drug product approval usually in the supplement month. |
| CAHN | Applicant holder firm name has changed. |
| CAIN | Change. There has been a change in the Ingredient(s) name. All products will be deleted under the old name |

and all products will be added under the changed ingredient(s) name.

| | |
|------|---|
| CDFR | Change. Dosage Form; Route of Administration. |
| CFTG | Change. A first time generic for the innovator product. A TE Code is added. |
| CMFD | Change. The product is moved from the Discontinued Section due to a change in marketing status. |
| CMS1 | Change. Miscellaneous addition to list. |
| CMS2 | Change. Miscellaneous deletion from list. |
| CPOT | Change. Potency amount/unit. |
| CRLD | Change. Reference Listed Drug. |
| CTEC | Change. Therapeutic Equivalence Code. |
| CTNA | Change. Trade Name. |
| DISC | Discontinued. The Rx or OTC listed product is not being marketed and will be moved to the discontinued section in the next edition. |

PRESCRIPTION DRUG PRODUCT LIST - 28TH EDITION

RX DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 5 - May 2009

1-1

ACARBOSE

TABLET; ORAL

ACARBOSE

| | | | | | | | |
|-----|----|------------|-------|------------|--------------|-----|------|
| >A> | AB | IMPAX LABS | 25MG | N78441 001 | May 14, 2009 | May | NEWA |
| >A> | AB | | 50MG | N78441 002 | May 14, 2009 | May | NEWA |
| >A> | AB | | 100MG | N78441 003 | May 14, 2009 | May | NEWA |

ACETAMINOPHEN; CODEINE PHOSPHATE

TABLET; ORAL

ACETAMINOPHEN AND CODEINE PHOSPHATE

@ SANDOZ 300MG;30MG

N81250 001 Jul 16, 1992 Mar DISC

@ 300MG;60MG

N81249 001 Jul 16, 1992 Mar DISC

TYLENOL W/ CODEINE NO. 4

| | | | | | | | |
|----|--|----------------------|------------|------------|--|-----|------|
| AA | | ORTHO MCNEIL JANSSEN | 300MG;60MG | N85055 004 | | Mar | CMFD |
|----|--|----------------------|------------|------------|--|-----|------|

ACETAMINOPHEN; HYDROCODONE BITARTRATE

CAPSULE; ORAL

HYDROCODONE BITARTRATE AND ACETAMINOPHEN

@ MALLINCKRODT 500MG;5MG

N89006 001 Aug 09, 1985 Feb CTNA

ACETAMINOPHEN; OXYCODONE HYDROCHLORIDE

TABLET; ORAL

PERCOCET

| | | | | | | | |
|-----|---|-------------|-------------|------------|--------------|-----|------|
| >D> | + | ENDO PHARMS | 325MG;2.5MG | N40330 001 | Jun 25, 1999 | May | CTEC |
|-----|---|-------------|-------------|------------|--------------|-----|------|

| | | | | | | | |
|-----|----|---|-------------|------------|--------------|-----|------|
| >A> | AA | + | 325MG;2.5MG | N40330 001 | Jun 25, 1999 | May | CTEC |
|-----|----|---|-------------|------------|--------------|-----|------|

ACETAMINOPHEN; PROPOXYPHENE HYDROCHLORIDE

TABLET; ORAL

PROPOXYPHENE HYDROCHLORIDE AND ACETAMINOPHEN

@ SANDOZ 650MG;65MG

N89959 001 Jul 18, 1989 Mar DISC

ACETAMINOPHEN; PROPOXYPHENE NAPSYLATE

TABLET; ORAL

PROPOXYPHENE NAPSYLATE AND ACETAMINOPHEN

@ SANDOZ 650MG;100MG

N70443 001 Jan 23, 1986 Mar DISC

ACETAMINOPHEN; TRAMADOL HYDROCHLORIDE

TABLET; ORAL

TRAMADOL HYDROCHLORIDE AND ACETAMINOPHEN

| | | | | | | | |
|----|--|-------|--------------|------------|--------------|-----|------|
| AB | | MYLAN | 325MG;37.5MG | N77858 001 | Sep 26, 2008 | Apr | CAHN |
|----|--|-------|--------------|------------|--------------|-----|------|

ACETAZOLAMIDE SODIUM

INJECTABLE; INJECTION

ACETAZOLAMIDE SODIUM

@ HOSPIRA EQ 500MG BASE/VIAL

N40108 001 Oct 30, 1995 Apr DISC

ACYCLOVIR SODIUM

INJECTABLE; INJECTION

ACYCLOVIR SODIUM

@ HOSPIRA EQ 500MG BASE/VIAL

N74758 001 Apr 22, 1997 Apr DISC

@ EQ 1GM BASE/VIAL

N74758 002 Apr 22, 1997 Apr DISC

ADENOSINE

INJECTABLE; INJECTION

ADENOSINE

| | | | | | | | |
|-----|----------|---------------------|------------|--------------|--------------|------|------|
| AP | LUITPOLD | 3MG/ML | N90010 001 | Apr 28, 2009 | Apr | NEWA | |
| >A> | AP | STRIDES ARCOLAB LTD | 3MG/ML | N78686 001 | May 13, 2009 | May | NEWA |

ALBUTEROL

AEROSOL, METERED; INHALATION

ALBUTEROL

| | | | | | | |
|--|--------------------|------------|------------|--------------|-----|------|
| | @ ARMSTRONG PHARMS | 0.09MG/INH | N72273 001 | Aug 14, 1996 | Jan | DISC |
|--|--------------------|------------|------------|--------------|-----|------|

ALBUTEROL SULFATE

SOLUTION; INHALATION

ALBUTEROL SULFATE

| | | | | | | |
|----|-------------------|----------------|------------|--------------|-----|------|
| | @ BAUSCH AND LOMB | EQ 0.083% BASE | N75358 001 | Mar 29, 2000 | Apr | DISC |
| AN | HOLOPACK INTL | EQ 0.083% BASE | N77839 001 | Dec 16, 2008 | Jan | CAHN |
| AN | TEVA PARENTERAL | EQ 0.083% BASE | N75343 001 | Nov 09, 1999 | Apr | CAHN |

TABLET; ORAL

ALBUTEROL SULFATE

| | | | | | | |
|--|----------|-------------|------------|--------------|-----|------|
| | @ SANDOZ | EQ 2MG BASE | N72151 001 | Dec 05, 1989 | Mar | DISC |
| | @ | EQ 4MG BASE | N72152 001 | Dec 05, 1989 | Mar | DISC |

ALBUTEROL SULFATE; IPRATROPIUM BROMIDE

SOLUTION; INHALATION

ALBUTEROL SULFATE AND IPRATROPIUM BROMIDE

| | | | | | | |
|----|-----------------|-----------------------|------------|--------------|-----|------|
| AN | TEVA PARENTERAL | EQ 0.083% BASE;0.017% | N76724 001 | Dec 31, 2007 | Apr | CAHN |
|----|-----------------|-----------------------|------------|--------------|-----|------|

ALENDRONATE SODIUM

TABLET; ORAL

ALENDRONATE SODIUM

| | | | | | | |
|----|--------|--------------|------------|--------------|-----|------|
| AB | SANDOZ | EQ 5MG BASE | N75871 001 | Apr 22, 2009 | Apr | NEWA |
| AB | | EQ 10MG BASE | N75871 002 | Apr 22, 2009 | Apr | NEWA |
| AB | | EQ 35MG BASE | N75871 004 | Apr 22, 2009 | Apr | NEWA |
| AB | | EQ 40MG BASE | N75871 003 | Apr 22, 2009 | Apr | NEWA |
| AB | | EQ 70MG BASE | N75871 005 | Apr 22, 2009 | Apr | NEWA |

ALLOPURINOL

TABLET; ORAL

ALLOPURINOL

| | | | | | | |
|--|----------|-------|------------|--------------|-----|------|
| | @ SANDOZ | 100MG | N70268 001 | Dec 31, 1985 | Mar | DISC |
| | @ | 300MG | N70269 001 | Dec 31, 1985 | Mar | DISC |

AMILORIDE HYDROCHLORIDE

TABLET; ORAL

AMILORIDE HYDROCHLORIDE

| | | | | | | | |
|-----|----|---------------------|-----|------------|--------------|-----|------|
| AB | + | PAR PHARM | 5MG | N70346 001 | Jan 22, 1986 | Jan | CTEC |
| AB | | SIGMAPHARM LABS LLC | 5MG | N79133 001 | Jan 30, 2009 | Jan | NEWA |
| | | MIDAMOR | | | | | |
| >D> | | @ PADDOCK LABS | 5MG | N18200 001 | | May | CMFD |
| >A> | AB | | 5MG | N18200 001 | | May | CMFD |

AMILORIDE HYDROCHLORIDE; HYDROCHLOROTHIAZIDE

TABLET; ORAL

AMILORIDE HYDROCHLORIDE AND HYDROCHLOROTHIAZIDE

| | | | | | | |
|--|----------|-----------------------|------------|--------------|-----|------|
| | @ SANDOZ | EQ 5MG ANHYDROUS;50MG | N73357 001 | Nov 27, 1991 | Mar | DISC |
|--|----------|-----------------------|------------|--------------|-----|------|

AMINOCAPROIC ACID

INJECTABLE; INJECTION

AMINOCAPROIC ACID

| | | | | | |
|-----------|----------|------------|--------------|-----|------|
| @ HOSPIRA | 250MG/ML | N70888 001 | Jun 16, 1988 | Apr | DISC |
|-----------|----------|------------|--------------|-----|------|

TABLET; ORAL

AMICAR

| | | | | | |
|----------------|-----|------------|--------------|-----|------|
| XANODYNE PHARM | 1GM | N15197 002 | Jun 24, 2004 | Jan | NEWA |
|----------------|-----|------------|--------------|-----|------|

AMINOPHYLLINE

INJECTABLE; INJECTION

AMINOPHYLLINE IN SODIUM CHLORIDE 0.45%

| | | | | | |
|-----------|-------------|------------|--------------|-----|------|
| @ HOSPIRA | 100MG/100ML | N88147 002 | May 03, 1983 | Apr | DISC |
|-----------|-------------|------------|--------------|-----|------|

| | | | | | |
|---|-------------|------------|--------------|-----|------|
| @ | 200MG/100ML | N88147 003 | May 03, 1983 | Apr | DISC |
|---|-------------|------------|--------------|-----|------|

AMIODARONE HYDROCHLORIDE

TABLET; ORAL

AMIODARONE HYDROCHLORIDE

| | | | | | | |
|----|-------|-------|------------|--------------|-----|------|
| AB | MYLAN | 200MG | N75188 001 | Feb 24, 1999 | Apr | CAHN |
|----|-------|-------|------------|--------------|-----|------|

AMLODIPINE BESYLATE

TABLET; ORAL

AMLODIPINE BESYLATE

| | | | | | | |
|----|-------|---------------|------------|--------------|-----|------|
| AB | ALKEM | EQ 2.5MG BASE | N78925 001 | May 04, 2009 | Apr | NEWA |
|----|-------|---------------|------------|--------------|-----|------|

| | | | | | | |
|----|--|-------------|------------|--------------|-----|------|
| AB | | EQ 5MG BASE | N78925 002 | May 04, 2009 | Apr | NEWA |
|----|--|-------------|------------|--------------|-----|------|

| | | | | | | |
|----|--|--------------|------------|--------------|-----|------|
| AB | | EQ 10MG BASE | N78925 003 | May 04, 2009 | Apr | NEWA |
|----|--|--------------|------------|--------------|-----|------|

| | | | | | | |
|----|-------------------|---------------|------------|--------------|-----|------|
| AB | GLENMARK GENERICS | EQ 2.5MG BASE | N78552 001 | Apr 08, 2009 | Mar | NEWA |
|----|-------------------|---------------|------------|--------------|-----|------|

| | | | | | | |
|----|--|-------------|------------|--------------|-----|------|
| AB | | EQ 5MG BASE | N78552 002 | Apr 08, 2009 | Mar | NEWA |
|----|--|-------------|------------|--------------|-----|------|

| | | | | | | |
|----|--|--------------|------------|--------------|-----|------|
| AB | | EQ 10MG BASE | N78552 003 | Apr 08, 2009 | Mar | NEWA |
|----|--|--------------|------------|--------------|-----|------|

| | | | | | | |
|----|----------------|---------------|------------|--------------|-----|------|
| AB | SYNTHON PHARMS | EQ 2.5MG BASE | N77080 001 | Jun 27, 2007 | Jan | CAHN |
|----|----------------|---------------|------------|--------------|-----|------|

| | | | | | | |
|----|--|-------------|------------|--------------|-----|------|
| AB | | EQ 5MG BASE | N77080 002 | Jun 27, 2007 | Jan | CAHN |
|----|--|-------------|------------|--------------|-----|------|

| | | | | | | |
|----|--|--------------|------------|--------------|-----|------|
| AB | | EQ 10MG BASE | N77080 003 | Jun 27, 2007 | Jan | CAHN |
|----|--|--------------|------------|--------------|-----|------|

AMLODIPINE; HYDROCHLOROTHIAZIDE; VALSARTAN

TABLET; ORAL

EXFORGE HCT

NOVARTIS

| | | | | |
|------------------|------------|--------------|-----|------|
| 5MG;12.5MG;160MG | N22314 001 | Apr 30, 2009 | Apr | NEWA |
|------------------|------------|--------------|-----|------|

| | | | | |
|----------------|------------|--------------|-----|------|
| 5MG;25MG;160MG | N22314 002 | Apr 30, 2009 | Apr | NEWA |
|----------------|------------|--------------|-----|------|

| | | | | |
|-------------------|------------|--------------|-----|------|
| 10MG;12.5MG;160MG | N22314 003 | Apr 30, 2009 | Apr | NEWA |
|-------------------|------------|--------------|-----|------|

| | | | | | |
|---|-----------------|------------|--------------|-----|------|
| + | 10MG;25MG;320MG | N22314 005 | Apr 30, 2009 | Apr | NEWA |
|---|-----------------|------------|--------------|-----|------|

| | | | | |
|-----------------|------------|--------------|-----|------|
| 10MG;25MG;160MG | N22314 004 | Apr 30, 2009 | Apr | NEWA |
|-----------------|------------|--------------|-----|------|

AMOXICILLIN; CLAVULANATE POTASSIUM

TABLET; ORAL

AMOXICILLIN AND CLAVULANATE POTASSIUM

| | | | | | | |
|----|--------|---------------------|------------|--------------|-----|------|
| AB | APOTEX | 250MG;EQ 125MG BASE | N65333 001 | Feb 24, 2009 | Feb | NEWA |
|----|--------|---------------------|------------|--------------|-----|------|

| | | | | | | |
|----|--|---------------------|------------|--------------|-----|------|
| AB | | 500MG;EQ 125MG BASE | N65333 002 | Feb 24, 2009 | Feb | NEWA |
|----|--|---------------------|------------|--------------|-----|------|

APRACLONIDINE HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC

APRACLONIDINE HYDROCHLORIDE

| | | | | | | |
|----|-----------|--------------|------------|--------------|-----|------|
| AT | AKORN INC | EQ 0.5% BASE | N77764 001 | Mar 12, 2009 | Feb | NEWA |
|----|-----------|--------------|------------|--------------|-----|------|

IOPIDINE

| | | | | | | | |
|----|---|-------|--------------|------------|--------------|-----|------|
| AT | + | ALCON | EQ 0.5% BASE | N20258 001 | Jul 30, 1993 | Feb | CFTG |
|----|---|-------|--------------|------------|--------------|-----|------|

ARMODAFINIL

TABLET; ORAL

NUVIGIL

| | | | | | |
|----------|-------|------------|--------------|-----|------|
| CEPHALON | 100MG | N21875 002 | Mar 26, 2009 | Mar | CMFD |
| | 200MG | N21875 005 | Mar 26, 2009 | Mar | NEWA |

ARTEMETHER; LUMEFANTRINE

TABLET; ORAL

COARTEM

| | | | | | |
|----------|------------|------------|--------------|-----|------|
| NOVARTIS | 20MG;120MG | N22268 001 | Apr 07, 2009 | Apr | NEWA |
|----------|------------|------------|--------------|-----|------|

ASPIRIN; BUTALBITAL; CAFFEINE

TABLET; ORAL

BUTALBITAL, ASPIRIN AND CAFFEINE

| | | | | | |
|----------|-----------------|------------|--------------|-----|------|
| @ SANDOZ | 325MG;50MG;40MG | N86398 002 | Apr 06, 1984 | Mar | DISC |
|----------|-----------------|------------|--------------|-----|------|

ASPIRIN; CAFFEINE; ORPHENADRINE CITRATE

TABLET; ORAL

ORPHENGESIC

| | | | | | |
|------------------|-----------------|------------|--------------|-----|------|
| @ SOLCO HLTHCARE | 385MG;30MG;25MG | N75141 001 | May 29, 1998 | Jan | CAHN |
|------------------|-----------------|------------|--------------|-----|------|

ORPHENGESIC FORTE

| | | | | | |
|------------------|-----------------|------------|--------------|-----|------|
| @ SOLCO HLTHCARE | 770MG;60MG;50MG | N75141 002 | May 29, 1998 | Jan | CAHN |
|------------------|-----------------|------------|--------------|-----|------|

ATRACURIUM BESYLATE

INJECTABLE; INJECTION

ATRACURIUM BESYLATE

| | | | | | |
|-----------|---------|------------|--------------|-----|------|
| @ HOSPIRA | 10MG/ML | N74740 001 | Mar 28, 1997 | Jan | DISC |
|-----------|---------|------------|--------------|-----|------|

ATRACURIUM BESYLATE PRESERVATIVE FREE

| | | | | | |
|-----------|---------|------------|--------------|-----|------|
| @ HOSPIRA | 10MG/ML | N74741 001 | Mar 28, 1997 | Jan | DISC |
|-----------|---------|------------|--------------|-----|------|

AZACITIDINE

INJECTABLE; IV-SC

VIDAZA

| | | | | | |
|-----------|------------|------------|--------------|-----|------|
| + CELGENE | 100MG/VIAL | N50794 001 | May 19, 2004 | Mar | CAHN |
|-----------|------------|------------|--------------|-----|------|

AZELASTINE HYDROCHLORIDE

SPRAY, METERED; NASAL

AZELASTINE HYDROCHLORIDE

| | | | | | |
|--------------|-----------------------|------------|--------------|-----|------|
| @ APOTEX INC | EQ 0.125MG BASE/SPRAY | N77954 001 | Apr 30, 2009 | Apr | DISC |
|--------------|-----------------------|------------|--------------|-----|------|

AZITHROMYCIN

INJECTABLE; INJECTION

AZITHROMYCIN

| | | | | | | |
|----|----------------|--------------------|------------|--------------|-----|------|
| AP | SAGENT STRIDES | EQ 500MG BASE/VIAL | N65506 001 | Mar 24, 2009 | Mar | NEWA |
|----|----------------|--------------------|------------|--------------|-----|------|

BACLOFEN

TABLET; ORAL

BACLOFEN

| | | | | | | |
|----|-------|------|------------|--------------|-----|------|
| AB | MYLAN | 10MG | N77181 001 | Jul 29, 2005 | Apr | CAHN |
|----|-------|------|------------|--------------|-----|------|

| | | | | | | |
|----|--|------|------------|--------------|-----|------|
| AB | | 20MG | N77121 002 | Jul 29, 2005 | Apr | CAHN |
|----|--|------|------------|--------------|-----|------|

BENDAMUSTINE HYDROCHLORIDEPOWDER; IV (INFUSION)
TREANDA

| | | | | | | | |
|-----|---|----------|-----------|------------|--------------|-----|------|
| >A> | + | CEPHALON | 25MG/VIAL | N22249 002 | May 01, 2009 | May | NEWA |
|-----|---|----------|-----------|------------|--------------|-----|------|

BENZTROPINE MESYLATEINJECTABLE; INJECTION
COGENTIN

| | | | | | | | |
|--|---|--------------|--------|------------|--|-----|------|
| | + | LUNDBECK INC | 1MG/ML | N12015 001 | | Apr | CAHN |
|--|---|--------------|--------|------------|--|-----|------|

BENZYL ALCOHOL

LOTION; TOPICAL

| | | | | | | | |
|-----|---|-------------------|----|------------|--------------|-----|------|
| >D> | | BENZYL ALCOHOL | | | | | |
| >D> | + | SCIELE PHARMA INC | 5% | N22129 001 | Apr 09, 2009 | May | CTNA |
| | + | | 5% | N22129 001 | Apr 09, 2009 | Apr | NEWA |
| >A> | | ULESFIA | | | | | |
| >A> | + | SCIELE PHARMA INC | 5% | N22129 001 | Apr 09, 2009 | May | CTNA |

BESIFLOXACIN HYDROCHLORIDESUSPENSION/DROPS; OPHTHALMIC
BESIVANCE

| | | | | | | | |
|-----|---|-----------------|--------------|------------|--------------|-----|------|
| >A> | + | BAUSCH AND LOMB | EQ 0.6% BASE | N22308 001 | May 28, 2009 | May | NEWA |
|-----|---|-----------------|--------------|------------|--------------|-----|------|

BETAMETHASONE DIPROPIONATE; CALCIPOTRIENE HYDRATEOINTMENT; TOPICAL
TACLONEX

| | | | | | | | |
|--|---|-----------|---------------|------------|--------------|-----|------|
| | + | LEO PHARM | 0.064%;0.005% | N21852 001 | Jan 09, 2006 | Mar | CAHN |
|--|---|-----------|---------------|------------|--------------|-----|------|

BETAMETHASONE VALERATEAEROSOL, FOAM; TOPICAL
LUXIQ

| | | | | | | | |
|-----|---|------------------|---------------|------------|--------------|-----|------|
| >A> | + | CONNECTICS | EQ 0.12% BASE | N20934 001 | Feb 28, 1999 | May | CAHN |
| >D> | + | STIEFEL LABS INC | EQ 0.12% BASE | N20934 001 | Feb 28, 1999 | May | CAHN |

BETHANECHOL CHLORIDE

TABLET; ORAL

BETHANECHOL CHLORIDE

| | | | | | | | |
|----|--|--------------------|------|------------|--------------|-----|------|
| AA | | SUN PHARM INDS INC | 5MG | N40897 001 | Apr 22, 2009 | Apr | NEWA |
| AA | | | 10MG | N40897 002 | Apr 22, 2009 | Apr | NEWA |
| AA | | | 25MG | N40897 003 | Apr 22, 2009 | Apr | NEWA |
| AA | | | 50MG | N40897 004 | Apr 22, 2009 | Apr | NEWA |

BRIMONIDINE TARTRATESOLUTION/DROPS; OPHTHALMIC
BRIMONIDINE TARTRATE

| | | | | | | | |
|----|--|-----------------|------|------------|--------------|-----|------|
| AT | | TEVA PARENTERAL | 0.2% | N76372 001 | Sep 10, 2004 | Apr | CAHN |
|----|--|-----------------|------|------------|--------------|-----|------|

BROMOCRIPTINE MESYLATE

TABLET; ORAL

CYCLOSET

| | | | | | | | |
|-----|---|-------------|---------------|------------|--------------|-----|------|
| >A> | + | VEROSCIENCE | EQ 0.8MG BASE | N20866 001 | May 05, 2009 | May | NEWA |
|-----|---|-------------|---------------|------------|--------------|-----|------|

BROMPHENIRAMINE MALEATE; DEXTROMETHORPHAN HYDROBROMIDE; PSEUDOEPHEDRINE HYDROCHLORIDE

SYRUP; ORAL

BROMFED-DM

| | | | | | | |
|----|--------------|-----------------------------|------------|--------------|-----|------|
| AA | WOCKHARDT EU | 2MG/5ML; 10MG/5ML; 30MG/5ML | N89681 001 | Dec 22, 1988 | Apr | CAHN |
|----|--------------|-----------------------------|------------|--------------|-----|------|

BUDESONIDE

SUSPENSION; INHALATION

BUDESONIDE

| | | | | | | |
|----|-----------------|------------|------------|--------------|-----|------|
| AN | APOTEX | 0.25MG/2ML | N78202 001 | Mar 30, 2009 | Mar | NEWA |
| AN | | 0.5MG/2ML | N78202 002 | Mar 30, 2009 | Mar | NEWA |
| AN | TEVA PARENTERAL | 0.25MG/2ML | N77519 001 | Nov 18, 2008 | Apr | CAHN |
| AN | | 0.5MG/2ML | N77519 002 | Nov 18, 2008 | Apr | CAHN |

BUPROPION HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL

BUPROPION HYDROCHLORIDE

| | | | | | | |
|-----|-------------|-------|------------|--------------|-----|------|
| AB1 | WATSON LABS | 100MG | N79095 001 | Mar 24, 2009 | Mar | NEWA |
| AB2 | | 150MG | N79094 001 | Mar 24, 2009 | Mar | NEWA |
| AB1 | | 150MG | N79095 002 | Mar 24, 2009 | Mar | NEWA |
| AB1 | | 200MG | N79095 003 | Mar 24, 2009 | Mar | NEWA |

BUSPIRONE HYDROCHLORIDE

TABLET; ORAL

BUSPAR

| | | | | | | |
|----|------------------------|------|------------|--------------|-----|------|
| AB | + BRISTOL MYERS SQUIBB | 15MG | N18731 003 | Apr 22, 1996 | Feb | CRLD |
| | @ | 30MG | N18731 004 | Apr 22, 1996 | Feb | DISC |

BUSPIRONE HYDROCHLORIDE

| | | | | | | |
|----|--------------------|-------|------------|--------------|-----|------|
| AB | DR REDDYS LABS LTD | 5MG | N78246 001 | Feb 27, 2009 | Feb | NEWA |
| AB | | 10MG | N78246 002 | Feb 27, 2009 | Feb | NEWA |
| AB | | 15MG | N78246 003 | Feb 27, 2009 | Feb | NEWA |
| AB | | 30MG | N78246 004 | Feb 27, 2009 | Feb | NEWA |
| AB | MYLAN | 5MG | N75467 001 | Feb 28, 2002 | Apr | CAHN |
| AB | | 7.5MG | N75467 002 | Mar 28, 2001 | Apr | CAHN |
| AB | | 10MG | N75467 003 | Feb 28, 2002 | Apr | CAHN |
| AB | | 15MG | N75467 004 | Feb 28, 2002 | Apr | CAHN |
| | @ SANDOZ | 5MG | N75413 001 | Mar 19, 2002 | Mar | DISC |
| | @ | 10MG | N75413 002 | Mar 19, 2002 | Mar | DISC |
| | @ | 15MG | N75413 003 | Mar 19, 2002 | Mar | DISC |

BUTORPHANOL TARTRATE

INJECTABLE; INJECTION

BUTORPHANOL TARTRATE

| | | | | | | |
|----|--------------------|--------|------------|--------------|-----|------|
| AP | HIKMA FARMACEUTICA | 1MG/ML | N78400 001 | May 01, 2009 | Apr | NEWA |
| AP | | 2MG/ML | N78247 001 | Apr 29, 2009 | Apr | NEWA |
| AP | | 2MG/ML | N78400 002 | May 01, 2009 | Apr | NEWA |

CAFFEINE CITRATE

SOLUTION; INTRAVENOUS

CAFFEINE CITRATE

| | | | | | | |
|----|--------------|------------------------------------|------------|--------------|-----|------|
| AP | PADDOCK LABS | EQ 30MG BASE/3ML (EQ 10MG BASE/ML) | N77233 001 | Sep 21, 2006 | Apr | CAHN |
|----|--------------|------------------------------------|------------|--------------|-----|------|

CALCITONIN, SALMON

SPRAY, METERED; NASAL
CALCITONIN-SALMON

>A> AB MDRNA 200 IU/SPRAY N76979 001 Jun 08, 2009 May NEWA

CALCITRIOL

CAPSULE; ORAL
ROCALTROL

AB VALIDUS PHARMS 0.25UGM N18044 001 Mar CAHN

AB + 0.5UGM N18044 002 Mar CAHN

OINTMENT; TOPICAL

VECTICAL

+ GALDERMA LABS LP 3UGM/GM N22087 001 Jan 23, 2009 Jan NEWA

SOLUTION; ORAL

ROCALTROL

AA + VALIDUS PHARMS 1UGM/ML N21068 001 Nov 20, 1998 Mar CAHN

CARBAMAZEPINE

TABLET; ORAL

CARBAMAZEPINE

AB TORRENT PHARMS 100MG N77272 001 Dec 07, 2005 Apr CAHN

AB 200MG N77272 002 Dec 07, 2005 Apr CAHN

AB 300MG N77272 003 Dec 07, 2005 Apr CAHN

AB 400MG N77272 004 Dec 07, 2005 Apr CAHN

TABLET, CHEWABLE; ORAL

CARBAMAZEPINE

AB TORRENT PHARMS 100MG N75712 001 Jul 05, 2001 Jan CAHN

TABLET, EXTENDED RELEASE; ORAL

CARBAMAZEPINE

AB TARO 100MG N78115 001 Mar 31, 2009 Mar NEWA

AB 200MG N78115 002 Mar 31, 2009 Mar NEWA

AB 400MG N78115 003 Mar 31, 2009 Mar NEWA

TEGRETOL-XR

AB NOVARTIS 100MG N20234 001 Mar 25, 1996 Mar CFTG

AB 200MG N20234 002 Mar 25, 1996 Mar CFTG

AB + 400MG N20234 003 Mar 25, 1996 Mar CFTG

CARBENICILLIN INDANYL SODIUM

TABLET; ORAL

GEOCILLIN

@ PFIZER

EQ 382MG BASE N50435 001 Mar DISC

CARBIDOPA; LEVODOPA

TABLET; ORAL

CARBIDOPA AND LEVODOPA

@ SANDOZ

10MG;100MG N73586 001 Jun 29, 1995 Mar DISC

@

25MG;100MG N73587 001 Jun 29, 1995 Mar DISC

@

25MG;250MG N73620 001 Jun 29, 1995 Mar DISC

TABLET, EXTENDED RELEASE; ORAL

CARBIDOPA AND LEVODOPA

@ KV PHARM

50MG;200MG N76663 001 Jun 24, 2004 Apr DISC

CARBOPLATIN

INJECTABLE; INJECTION

CARBOPLATIN

| | | | | | | | |
|----|---|-------------|------------|------------|--------------|-----|------|
| AP | + | WATSON LABS | 50MG/VIAL | N76162 001 | Oct 14, 2004 | Apr | CAHN |
| AP | + | | 150MG/VIAL | N76162 002 | Oct 14, 2004 | Apr | CAHN |
| AP | + | | 450MG/VIAL | N76162 003 | Oct 14, 2004 | Apr | CAHN |

INJECTABLE; IV (INFUSION)

CARBOPLATIN

| | | | | | | | |
|----|--|-----------------|-------------------------|------------|--------------|-----|------|
| AP | | PHARMACHEMIE BV | EQ 50MG/5ML (10MG/ML) | N77679 001 | Feb 25, 2009 | Feb | NEWA |
| AP | | | EQ 450MG/45ML (10MG/ML) | N77679 003 | Feb 25, 2009 | Feb | NEWA |
| AP | | | EQ 150MG/15ML (10MG/ML) | N77679 002 | Feb 25, 2009 | Feb | NEWA |

CARISOPRODOL

TABLET; ORAL

CARISOPRODOL

@ SANDOZ

350MG

N81025 001 Apr 13, 1989 Mar DISC

CEFAZOLIN SODIUM

INJECTABLE; INJECTION

CEFAZOLIN SODIUM

| | | | | | | | |
|----|--|-------------------|--------------------|------------|--------------|-----|------|
| AP | | CEPHAZONE PHARMA | EQ 500MG BASE/VIAL | N65280 001 | Mar 18, 2009 | Mar | NEWA |
| AP | | | EQ 1GM BASE/VIAL | N65280 002 | Mar 18, 2009 | Mar | NEWA |
| AP | | | EQ 10GM BASE/VIAL | N65295 001 | Mar 18, 2009 | Mar | NEWA |
| AP | | | EQ 20GM BASE/VIAL | N65296 001 | Mar 18, 2009 | Mar | NEWA |
| | | @ GLAXOSMITHKLINE | EQ 1GM BASE/VIAL | N64033 001 | Oct 31, 1993 | Mar | DISC |

CEFTRIAZONE SODIUM

INJECTABLE; IM-IV

CEFTRIAZONE

| | | | | | | | |
|----|---|--------|------------------|------------|--------------|-----|------|
| AP | + | SANDOZ | EQ 2GM BASE/VIAL | N65169 004 | May 09, 2005 | Mar | CRLD |
|----|---|--------|------------------|------------|--------------|-----|------|

CETIRIZINE HYDROCHLORIDE

SYRUP; ORAL

CETIRIZINE HYDROCHLORIDE

| | | | | | | | |
|----|--|--------------------|---------|------------|--------------|-----|------|
| AA | | DR REDDYS LABS LTD | 5MG/5ML | N78870 001 | Apr 27, 2009 | Apr | NEWA |
|----|--|--------------------|---------|------------|--------------|-----|------|

CHLOROTHIAZIDE

TABLET; ORAL

DIURIL

@ LUNDBECK INC

250MG

N11145 004

Apr CAHN

@

500MG

N11145 002

Apr CAHN

CHLOROTHIAZIDE SODIUM

INJECTABLE; INJECTION

DIURIL

+ LUNDBECK INC

EQ 500MG BASE/VIAL

N11145 005

Apr CAHN

CHLORPROPAMIDE

TABLET; ORAL

CHLORPROPAMIDE

@ SANDOZ

100MG

N88725 001 Aug 31, 1984 Mar DISC

@

250MG

N88726 001 Aug 31, 1984 Mar DISC

CHLORZOXAZONE

| | | | | | | | | | |
|----|---------------|-------|--|--------|-----|--------------|-----|------|--|
| | TABLET; ORAL | | | | | | | | |
| | CHLORZOXAZONE | | | | | | | | |
| | @ SANDOZ | 250MG | | N89852 | 001 | May 04, 1988 | Mar | DISC | |
| | @ | 500MG | | N89853 | 001 | May 04, 1988 | Mar | DISC | |
| AA | WATSON LABS | 500MG | | N89859 | 001 | May 04, 1988 | Apr | CAHN | |

CHOLINE FENOFIBRATE

CAPSULE, DELAYED RELEASE; ORAL

| | | | | | | | | | |
|---|-------------|--------------------------|--|--------|-----|--------------|-----|------|--|
| | TRILIPIX | | | | | | | | |
| | ABBOTT LABS | EQ 45MG FENOFIBRIC ACID | | N22224 | 001 | Dec 15, 2008 | Jan | CTNA | |
| + | | EQ 135MG FENOFIBRIC ACID | | N22224 | 002 | Dec 15, 2008 | Jan | CTNA | |

CHYMOPAPAIN

INJECTABLE; INJECTION

| | | | | | | | | | |
|--|---------------|-------------------|--|--------|-----|--------------|-----|------|--|
| | CHYMODIACTIN | | | | | | | | |
| | @ CHART MEDCL | 4,000 UNITS/VIAL | | N18663 | 002 | Aug 21, 1984 | Mar | CAHN | |
| | @ | 10,000 UNITS/VIAL | | N18663 | 001 | Nov 10, 1982 | Mar | CAHN | |

CIMETIDINE

TABLET; ORAL

| | | | | | | | | | |
|--|------------|-------|--|--------|-----|--------------|-----|------|--|
| | CIMETIDINE | | | | | | | | |
| | @ SANDOZ | 200MG | | N74100 | 001 | Jan 31, 1995 | Mar | DISC | |
| | @ | 300MG | | N74100 | 002 | Jan 31, 1995 | Mar | DISC | |
| | @ | 400MG | | N74100 | 003 | Jan 31, 1995 | Mar | DISC | |
| | @ | 800MG | | N74100 | 004 | Jan 31, 1995 | Mar | DISC | |

CIPROFLOXACIN HYDROCHLORIDE

SOLUTION/DROPS; OTIC

| | | | | | | | | | |
|-----|-----------------------|--------------|--|--------|-----|--------------|-----|------|--|
| >A> | CETRAXAL | | | | | | | | |
| >A> | + LABORATORIOS SALVAT | EQ 0.2% BASE | | N21918 | 001 | May 01, 2009 | May | NEWA | |

TABLET; ORAL

| | | | | | | | | | |
|----|-----------------------------|---------------|--|--------|-----|--------------|-----|------|--|
| | CIPROFLOXACIN HYDROCHLORIDE | | | | | | | | |
| AB | MYLAN | EQ 250MG BASE | | N75685 | 002 | Jun 09, 2004 | Mar | CMFD | |
| AB | | EQ 500MG BASE | | N75685 | 003 | Jun 09, 2004 | Mar | CMFD | |
| AB | | EQ 750MG BASE | | N75685 | 001 | Jun 09, 2004 | Mar | CMFD | |
| | @ TEVA | EQ 250MG BASE | | N76136 | 001 | Jun 09, 2004 | Jan | DISC | |
| | @ | EQ 500MG BASE | | N76136 | 002 | Jun 09, 2004 | Jan | DISC | |
| | @ | EQ 750MG BASE | | N76136 | 003 | Jun 09, 2004 | Jan | DISC | |

CITALOPRAM HYDROBROMIDE

TABLET; ORAL

| | | | | | | | | | |
|----|-------------------------|--------------|--|--------|-----|--------------|-----|------|--|
| | CITALOPRAM HYDROBROMIDE | | | | | | | | |
| AB | AMNEAL PHARMS | EQ 10MG BASE | | N77045 | 003 | Apr 29, 2005 | Feb | CAHN | |
| AB | | EQ 20MG BASE | | N77045 | 002 | Apr 29, 2005 | Feb | CAHN | |
| AB | | EQ 40MG BASE | | N77045 | 001 | Apr 29, 2005 | Feb | CAHN | |
| AB | GLENMARK GENERICS | EQ 10MG BASE | | N77654 | 001 | Feb 27, 2009 | Feb | NEWA | |
| AB | | EQ 20MG BASE | | N77654 | 002 | Feb 27, 2009 | Feb | NEWA | |
| AB | | EQ 40MG BASE | | N77654 | 003 | Feb 27, 2009 | Feb | NEWA | |

CLONIDINE HYDROCHLORIDE

TABLET; ORAL

| | | | | | | | | | |
|--|-------------------------|-------|--|--------|-----|--------------|-----|------|--|
| | CLONIDINE HYDROCHLORIDE | | | | | | | | |
| | @ SANDOZ | 0.1MG | | N70887 | 001 | Aug 31, 1988 | Mar | DISC | |
| | @ | 0.2MG | | N70886 | 001 | Aug 31, 1988 | Mar | DISC | |

TABLET; ORAL

CLONIDINE HYDROCHLORIDE

| | | | | | |
|----------|-------|------------|--------------|-----|------|
| @ SANDOZ | 0.3MG | N71294 001 | Aug 31, 1988 | Mar | DISC |
|----------|-------|------------|--------------|-----|------|

CLORAZEPATE DIPOTASSIUM

CAPSULE; ORAL

CLORAZEPATE DIPOTASSIUM

| | | | | | |
|----------|--------|------------|--------------|-----|------|
| @ SANDOZ | 3.75MG | N72219 001 | Aug 26, 1988 | Mar | DISC |
|----------|--------|------------|--------------|-----|------|

TRANXENE

| | | | | | |
|----------------|--------|------------|--|-----|------|
| @ LUNDBECK INC | 3.75MG | N17105 001 | | Apr | CAHN |
|----------------|--------|------------|--|-----|------|

| | | | | | |
|---|-------|------------|--|-----|------|
| @ | 7.5MG | N17105 002 | | Apr | CAHN |
|---|-------|------------|--|-----|------|

| | | | | | |
|---|------|------------|--|-----|------|
| @ | 15MG | N17105 003 | | Apr | CAHN |
|---|------|------------|--|-----|------|

TABLET; ORAL

CLORAZEPATE DIPOTASSIUM

| | | | | | |
|----------|-------|------------|--------------|-----|------|
| @ SANDOZ | 7.5MG | N72513 001 | May 11, 1990 | Mar | DISC |
|----------|-------|------------|--------------|-----|------|

| | | | | | |
|---|------|------------|--------------|-----|------|
| @ | 15MG | N72514 001 | May 11, 1990 | Mar | DISC |
|---|------|------------|--------------|-----|------|

TRANXENE

| | | | | | | |
|----|--------------|--------|------------|--|-----|------|
| AB | LUNDBECK INC | 3.75MG | N17105 006 | | Apr | CAHN |
|----|--------------|--------|------------|--|-----|------|

| | | | | | | |
|----|--|-------|------------|--|-----|------|
| AB | | 7.5MG | N17105 007 | | Apr | CAHN |
|----|--|-------|------------|--|-----|------|

| | | | | | | |
|----|---|------|------------|--|-----|------|
| AB | + | 15MG | N17105 008 | | Apr | CAHN |
|----|---|------|------------|--|-----|------|

>D> TRANXENE SD

| | | | | | | |
|-----|--------------|---------|------------|--|-----|------|
| >D> | LUNDBECK INC | 11.25MG | N17105 005 | | May | DISC |
|-----|--------------|---------|------------|--|-----|------|

| | | | | | | |
|-----|---|---------|------------|--|-----|------|
| >A> | @ | 11.25MG | N17105 005 | | May | DISC |
|-----|---|---------|------------|--|-----|------|

| | | | | | | |
|--|--|---------|------------|--|-----|------|
| | | 11.25MG | N17105 005 | | Apr | CAHN |
|--|--|---------|------------|--|-----|------|

| | | | | | | |
|-----|---|--------|------------|--|-----|------|
| >D> | + | 22.5MG | N17105 004 | | May | DISC |
|-----|---|--------|------------|--|-----|------|

| | | | | | | |
|-----|---|--------|------------|--|-----|------|
| >A> | @ | 22.5MG | N17105 004 | | May | DISC |
|-----|---|--------|------------|--|-----|------|

| | | | | | | |
|--|---|--------|------------|--|-----|------|
| | + | 22.5MG | N17105 004 | | Apr | CAHN |
|--|---|--------|------------|--|-----|------|

CODEINE PHOSPHATE; PSEUDOEPHEDRINE HYDROCHLORIDE; TRIPROLIDINE HYDROCHLORIDE

SYRUP; ORAL

TRIAICIN-C

| | | | | | | |
|---|----------------|------------------------------|------------|--------------|-----|------|
| + | STI PHARMA LLC | 10MG/5ML;30MG/5ML;1.25MG/5ML | N88704 001 | Mar 22, 1985 | Apr | CAHN |
|---|----------------|------------------------------|------------|--------------|-----|------|

COLISTIMETHATE SODIUM

INJECTABLE; INJECTION

COLISTIMETHATE SODIUM

| | | | | | | |
|----|---------|--------------------|------------|--------------|-----|------|
| AP | PADDOCK | EQ 150MG BASE/VIAL | N65177 001 | Mar 19, 2004 | Apr | CTNA |
|----|---------|--------------------|------------|--------------|-----|------|

| | | | | | | |
|----|--------------|--------------------|------------|--------------|-----|------|
| AP | X GEN PHARMS | EQ 150MG BASE/VIAL | N64216 001 | Feb 26, 1999 | Apr | CTNA |
|----|--------------|--------------------|------------|--------------|-----|------|

CROMOLYN SODIUM

SOLUTION; INHALATION

CROMOLYN SODIUM

| | | | | | | | |
|----|---|-----------------|---------|------------|--------------|-----|------|
| AN | + | TEVA PARENTERAL | 10MG/ML | N75271 001 | Jan 18, 2000 | Apr | CAHN |
|----|---|-----------------|---------|------------|--------------|-----|------|

CYANOCOBALAMIN

GEL, METERED; NASAL

NASCOBAL

| | | | | | | |
|---|-----------|-----------|------------|--------------|-----|------|
| @ | PAR PHARM | 0.5MG/INH | N19722 001 | Nov 05, 1996 | Mar | CAHN |
|---|-----------|-----------|------------|--------------|-----|------|

SPRAY, METERED; NASAL

NASCOBAL

| | | | | | | | |
|-----|---|--------------|-------------|------------|--------------|-----|------|
| >A> | + | PAR PHARM CO | 0.5MG/SPRAY | N21642 001 | Jan 31, 2005 | May | CAHN |
|-----|---|--------------|-------------|------------|--------------|-----|------|

| | | | | | | | |
|-----|---|-----------|-------------|------------|--------------|-----|------|
| >D> | + | QOL MEDCL | 0.5MG/SPRAY | N21642 001 | Jan 31, 2005 | May | CAHN |
|-----|---|-----------|-------------|------------|--------------|-----|------|

CYCLOPHOSPHAMIDE

| | | | | | |
|-----------------------|-------------------|------------|------------|--------------|----------|
| INJECTABLE; INJECTION | | | | | |
| CYTOXAN | | | | | |
| | @ BAXTER HLTHCARE | 100MG/VIAL | N12142 001 | Feb | CAHN |
| | @ | 200MG/VIAL | N12142 002 | Feb | CAHN |
| | @ | 500MG/VIAL | N12142 003 | Feb | CAHN |
| | @ | 1GM/VIAL | N12142 004 | Aug 30, 1982 | Feb CAHN |
| | @ | 2GM/VIAL | N12142 005 | Aug 30, 1982 | Feb CAHN |
| LYOPHILIZED CYTOXAN | | | | | |
| | + BAXTER HLTHCARE | 100MG/VIAL | N12142 006 | Dec 05, 1985 | Feb CAHN |
| | + | 200MG/VIAL | N12142 007 | Dec 10, 1985 | Feb CAHN |
| AP | + | 500MG/VIAL | N12142 008 | Jan 04, 1984 | Feb CAHN |
| AP | + | 1GM/VIAL | N12142 010 | Sep 24, 1985 | Feb CAHN |
| AP | + | 2GM/VIAL | N12142 009 | Dec 10, 1984 | Feb CAHN |
| TABLET; ORAL | | | | | |
| CYTOXAN | | | | | |
| | @ BAXTER HLTHCARE | 25MG | N12141 002 | Feb | CAHN |
| | @ | 50MG | N12141 001 | Feb | CAHN |

DACTINOMYCIN

INJECTABLE; INJECTION

COSMEGEN

| | | | | | |
|---|--------------|------------|------------|-----|------|
| + | LUNDBECK INC | 0.5MG/VIAL | N50682 001 | Apr | CAHN |
|---|--------------|------------|------------|-----|------|

DEFEROXAMINE MESYLATE

INJECTABLE; INJECTION

DEFEROXAMINE MESYLATE

| | | | | | |
|----|-------------|------------|------------|--------------|----------|
| AP | WATSON LABS | 500MG/VIAL | N76806 001 | Mar 31, 2006 | Apr CAHN |
| AP | | 2GM/VIAL | N76806 002 | Mar 31, 2006 | Apr CAHN |

DESOGESTREL; ETHINYL ESTRADIOL

TABLET; ORAL-21

DESOGESTREL AND ETHINYL ESTRADIOL

| | | | | | |
|---|---------------------|---------------|------------|--------------|----------|
| @ | DURAMED PHARMS BARR | 0.15MG;0.03MG | N75256 001 | Aug 12, 1999 | Feb DISC |
|---|---------------------|---------------|------------|--------------|----------|

DEXAMETHASONE

ELIXIR; ORAL

DEXAMETHASONE

| | | | | | |
|----|------------------|-----------|------------|-----|------|
| AA | + STI PHARMA LLC | 0.5MG/5ML | N84754 001 | Apr | CAHN |
|----|------------------|-----------|------------|-----|------|

DEXAMETHASONE; TOBRAMYCIN

SUSPENSION/DROPS; OPHTHALMIC

TOBRADEX ST

| | | | | | |
|---|-------|------------|------------|--------------|----------|
| + | ALCON | 0.05%;0.3% | N50818 001 | Feb 13, 2009 | Feb NEWA |
|---|-------|------------|------------|--------------|----------|

DEXLANSOPRAZOLE

CAPSULE, DELAYED RELEASE; ORAL

KAPIDEX

| | | | | | |
|---|---------------|------|------------|--------------|----------|
| | TAKEDA PHARMS | 30MG | N22287 001 | Jan 30, 2009 | Jan NEWA |
| + | | 60MG | N22287 002 | Jan 30, 2009 | Jan NEWA |

DEXTROAMPHETAMINE SULFATE

TABLET; ORAL

DEXTROAMPHETAMINE SULFATE

| | | | | | |
|----|--------|------|------------|--------------|----------|
| AA | + BARR | 10MG | N40361 002 | Jan 31, 2001 | Mar CRLD |
|----|--------|------|------------|--------------|----------|

TABLET; ORAL

DEXTROSTAT

| | | | | |
|---------|------|------------|-----|------|
| @ SHIRE | 5MG | N84051 001 | Mar | DISC |
| @ | 10MG | N84051 002 | Mar | DISC |

DEXTROSE

INJECTABLE; INJECTION

DEXTROSE 60% IN PLASTIC CONTAINER

| | | | | | |
|-----------|------------|------------|--------------|-----|------|
| @ HOSPIRA | 60GM/100ML | N19346 001 | Jan 25, 1985 | Apr | DISC |
|-----------|------------|------------|--------------|-----|------|

DIAZEPAM

TABLET; ORAL

DIAZEPAM

| | | | | | |
|----------|------|------------|--------------|-----|------|
| @ SANDOZ | 2MG | N70302 001 | Dec 20, 1985 | Mar | DISC |
| @ | 5MG | N70303 001 | Dec 20, 1985 | Mar | DISC |
| @ | 10MG | N70304 001 | Dec 20, 1985 | Mar | DISC |

DIETHYLPROPION HYDROCHLORIDE

TABLET; ORAL

DIETHYLPROPION HYDROCHLORIDE

| | | | | | | |
|----|-----------------|------|------------|--------------|-----|------|
| AA | COREPHARMA | 25MG | N40828 001 | Nov 05, 2008 | Feb | CTEC |
| AA | + WATSON PHARMS | 25MG | N11722 002 | | Feb | CTEC |

DIFLUNISAL

TABLET; ORAL

DIFLUNISAL

| | | | | | |
|----------|-------|------------|--------------|-----|------|
| @ SANDOZ | 500MG | N74604 001 | Jun 10, 1996 | Mar | DISC |
| + TEVA | 500MG | N73673 001 | Jul 31, 1992 | Mar | CTEC |

DIGOXIN

INJECTABLE; INJECTION

DIGOXIN

| | | | | | |
|-----------|-----------|------------|--------------|-----|------|
| @ HOSPIRA | 0.25MG/ML | N40206 001 | Aug 28, 1998 | Apr | DISC |
|-----------|-----------|------------|--------------|-----|------|

DILTIAZEM HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL

DILT-CD

| | | | | | | |
|-----|--------|-------|------------|--------------|-----|------|
| AB3 | APOTEX | 300MG | N76151 004 | May 20, 2004 | Apr | CAHN |
|-----|--------|-------|------------|--------------|-----|------|

DIPHENHYDRAMINE HYDROCHLORIDE

CAPSULE; ORAL

DIPHENHYDRAMINE HYDROCHLORIDE

| | | | | | |
|----------------------|------|------------|--------------|-----|------|
| + BARR | 50MG | N80738 001 | | Mar | CRLD |
| @ LNK | 25MG | N87977 001 | Jan 27, 1983 | Mar | DISC |
| @ | 50MG | N87978 001 | Jan 27, 1983 | Mar | DISC |
| @ SANDOZ | 25MG | N80832 001 | | Mar | DISC |
| @ | 50MG | N80832 002 | | Mar | DISC |
| @ VALEANT PHARM INTL | 50MG | N80592 001 | | Mar | DISC |
| @ WATSON LABS | 25MG | N80728 001 | | Mar | DISC |
| @ | 50MG | N80727 001 | | Mar | DISC |

DIPYRIDAMOLE

TABLET; ORAL

DIPYRIDAMOLE

| | | | | | |
|----------|------|------------|--------------|-----|------|
| @ SANDOZ | 25MG | N86944 002 | Apr 16, 1991 | Mar | DISC |
|----------|------|------------|--------------|-----|------|

TABLET; ORAL

DIPYRIDAMOLE

| | | | | | | | |
|---|--------|------|--------|-----|--------------|-----|------|
| @ | SANDOZ | 50MG | N87562 | 001 | Feb 25, 1992 | Mar | DISC |
| @ | | 75MG | N87561 | 001 | Feb 25, 1992 | Mar | DISC |

DIVALPROEX SODIUM

CAPSULE, DELAYED REL PELLETS; ORAL

DEPAKOTE

| | | | | | | | | |
|----|---|--------|------------------------|--------|-----|--------------|-----|------|
| AB | + | ABBOTT | EQ 125MG VALPROIC ACID | N19680 | 001 | Sep 12, 1989 | Jan | CFTG |
|----|---|--------|------------------------|--------|-----|--------------|-----|------|

DIVALPROEX SODIUM

| | | | | | | | | |
|----|--|----------------------|------------------------|--------|-----|--------------|-----|------|
| AB | | DR REDDYS LABS LTD | EQ 125MG VALPROIC ACID | N78979 | 001 | Jan 23, 2009 | Jan | NEWA |
| AB | | ZYDUS PHARMS USA INC | EQ 125MG VALPROIC ACID | N78919 | 001 | Jan 27, 2009 | Jan | NEWA |

TABLET, DELAYED RELEASE; ORAL

DIVALPROEX SODIUM

| | | | | | | | | |
|----|--|----------------------|------------------------|--------|-----|--------------|-----|------|
| AB | | MYLAN | EQ 125MG VALPROIC ACID | N90062 | 001 | Mar 17, 2009 | Mar | NEWA |
| AB | | | EQ 250MG VALPROIC ACID | N90062 | 002 | Mar 17, 2009 | Mar | NEWA |
| AB | | | EQ 500MG VALPROIC ACID | N90062 | 003 | Mar 17, 2009 | Mar | NEWA |
| AB | | ZYDUS PHARMS USA INC | EQ 125MG VALPROIC ACID | N77100 | 001 | Mar 05, 2009 | Feb | NEWA |
| AB | | | EQ 250MG VALPROIC ACID | N77100 | 002 | Mar 05, 2009 | Feb | NEWA |
| AB | | | EQ 500MG VALPROIC ACID | N77100 | 003 | Mar 05, 2009 | Feb | NEWA |

TABLET, EXTENDED RELEASE; ORAL

DEPAKOTE ER

| | | | | | | | | |
|----|---|--------|------------------------|--------|-----|--------------|-----|------|
| AB | | ABBOTT | EQ 250MG VALPROIC ACID | N21168 | 002 | May 31, 2002 | Jan | CFTG |
| AB | + | | EQ 500MG VALPROIC ACID | N21168 | 001 | Aug 04, 2000 | Jan | CFTG |

DIVALPROEX SODIUM

| | | | | | | | | |
|----|--|----------------------|------------------------|--------|-----|--------------|-----|------|
| AB | | ANCHEN PHARMS | EQ 250MG VALPROIC ACID | N78445 | 001 | Feb 26, 2009 | Feb | NEWA |
| AB | | IMPAX LABS | EQ 250MG VALPROIC ACID | N78791 | 001 | May 06, 2009 | Apr | NEWA |
| AB | | MYLAN | EQ 250MG VALPROIC ACID | N77567 | 001 | Jan 29, 2009 | Jan | NEWA |
| AB | | | EQ 500MG VALPROIC ACID | N77567 | 002 | Jan 29, 2009 | Jan | NEWA |
| AB | | WOCKHARDT | EQ 250MG VALPROIC ACID | N78705 | 002 | Feb 10, 2009 | Jan | NEWA |
| AB | | ZYDUS PHARMS USA INC | EQ 250MG VALPROIC ACID | N78239 | 001 | Feb 27, 2009 | Feb | NEWA |

DORZOLAMIDE HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC

DORZOLAMIDE HYDROCHLORIDE

| | | | | | | | | |
|----|--|-------|------------|--------|-----|--------------|-----|------|
| AT | | ALCON | EQ 2% BASE | N78981 | 001 | Apr 13, 2009 | Mar | NEWA |
|----|--|-------|------------|--------|-----|--------------|-----|------|

DOXYCYCLINE

CAPSULE; ORAL

DOXYCYCLINE

| | | | | | | | |
|---|-----------|---------------|--------|-----|--------------|-----|------|
| + | PAR PHARM | EQ 150MG BASE | N65055 | 003 | Jul 15, 2005 | Jan | CRLD |
|---|-----------|---------------|--------|-----|--------------|-----|------|

TABLET; ORAL

DOXYCYCLINE

| | | | | | | | | |
|----|--|--------------|---------------|--------|-----|--------------|-----|------|
| AB | | MUTUAL PHARM | EQ 50MG BASE | N65471 | 001 | Apr 17, 2009 | Mar | NEWA |
| AB | | | EQ 75MG BASE | N65471 | 002 | Apr 17, 2009 | Mar | NEWA |
| AB | | | EQ 100MG BASE | N65471 | 003 | Apr 17, 2009 | Mar | NEWA |

DRONABINOL

CAPSULE; ORAL

DRONABINOL

| | | | | | | | | |
|----|--|------------|-------|--------|-----|--------------|-----|------|
| AB | | SVC PHARMA | 2.5MG | N78292 | 001 | Jun 27, 2008 | Mar | CAHN |
| AB | | | 5MG | N78292 | 002 | Jun 27, 2008 | Mar | CAHN |
| AB | | | 10MG | N78292 | 003 | Jun 27, 2008 | Mar | CAHN |

DROSPIRENONE; ETHINYL ESTRADIOL

| | | | | | | | |
|----|------------------------------------|------------|--------|-----|--------------|-----|------|
| | TABLET; ORAL | | | | | | |
| | DROSPIRENONE AND ETHINYL ESTRADIOL | | | | | | |
| AB | BARR | 3MG;0.02MG | N78515 | 001 | Mar 30, 2009 | Mar | NEWA |
| | YAZ | | | | | | |
| AB | + BAYER HLTHCARE | 3MG;0.02MG | N21676 | 001 | Mar 16, 2006 | Mar | CFTG |

ENALAPRIL MALEATE

TABLET; ORAL

ENALAPRIL MALEATE

@ SANDOZ 2.5MG
 @ 5MG
 @ 10MG
 @ 20MG

N75048 001 Aug 22, 2000 Mar DISC
 N75048 002 Aug 22, 2000 Mar DISC
 N75048 003 Aug 22, 2000 Mar DISC
 N75048 004 Aug 22, 2000 Mar DISC

ENALAPRIL MALEATE; FELODIPINE

TABLET, EXTENDED RELEASE; ORAL

LEXXEL

>D> + ASTRAZENECA 5MG;2.5MG N20668 002 Oct 28, 1998 May DISC
 >A> @ 5MG;2.5MG N20668 002 Oct 28, 1998 May DISC

ENALAPRILAT

INJECTABLE; INJECTION

ENALAPRILAT

AP + HOSPIRA 1.25MG/ML N75458 001 Aug 22, 2000 Feb CRLD
 VASOTEC
 @ BIOVAIL LABS INTL 1.25MG/ML N19309 001 Feb 09, 1988 Feb DISC

EPINEPHRINE BITARTRATE; PRILOCAINE HYDROCHLORIDE

INJECTABLE; INJECTION

CITANEST FORTE DENTAL

+ DENTSPLY PHARM 0.005MG/ML;4% N21383 001 Apr CTNA

EPINEPHRINE; LIDOCAINE HYDROCHLORIDE

INJECTABLE; INJECTION

XYLOCAINE DENTAL WITH EPINEPHRINE

AP + DENTSPLY PHARM 0.01MG/ML;2% N21381 001 Apr CTNA
 AP + 0.02MG/ML;2% N21381 002 Apr CTNA
 XYLOCAINE W/ EPINEPHRINE
 AP + APP PHARMS 0.02MG/ML;2% N06488 005 Apr CMFD

EPOPROSTENOL SODIUM

INJECTABLE; INJECTION

EPOPROSTENOL SODIUM

+ ACTELION EQ 1.5MG BASE/VIAL N22260 001 Jun 27, 2008 Apr CAHN

ERGOCALCIFEROL

CAPSULE; ORAL

ERGOCALCIFEROL

>A> ORIT LABS LLC 50,000 IU N40833 001 May 20, 2009 May NEWA

ERYTHROMYCIN ESTOLATE

SUSPENSION; ORAL

ERYTHROMYCIN ESTOLATE

@ ALPHARMA US PHARMS EQ 125MG BASE/5ML N62353 001 Nov 18, 1982 Apr DISC

SUSPENSION; ORAL

ERYTHROMYCIN ESTOLATE

| | | | | | |
|----------------------|-------------------|------------|--------------|-----|------|
| @ ALPHARMA US PHARMS | EQ 250MG BASE/5ML | N62409 001 | Dec 16, 1982 | Apr | DISC |
|----------------------|-------------------|------------|--------------|-----|------|

ERYTHROMYCIN ETHYLSUCCINATE

SUSPENSION; ORAL

ERYTHROMYCIN ETHYLSUCCINATE

| | | | | | |
|----------------------|-------------------|------------|--|-----|------|
| @ ALPHARMA US PHARMS | EQ 200MG BASE/5ML | N62200 001 | | Apr | DISC |
|----------------------|-------------------|------------|--|-----|------|

| | | | | | |
|---|-------------------|------------|--|-----|------|
| @ | EQ 400MG BASE/5ML | N62200 002 | | Apr | DISC |
|---|-------------------|------------|--|-----|------|

ERYTHROMYCIN ETHYLSUCCINATE; SULFISOXAZOLE ACETYL

GRANULE; ORAL

ERYZOLE

| | | | | | |
|--------|--|------------|--------------|-----|------|
| @ ALRA | EQ 200MG BASE/5ML;EQ 600MG BASE/5ML | N62758 001 | Jun 15, 1988 | Jan | DISC |
|--------|--|------------|--------------|-----|------|

PEDIAZOLE

| | | | | | |
|-------------|--|------------|--|-----|------|
| @ ROSS LABS | EQ 200MG BASE/5ML;EQ 600MG BASE/5ML | N50529 001 | | Jan | DISC |
|-------------|--|------------|--|-----|------|

ERYTHROMYCIN LACTOBIONATE

INJECTABLE; INJECTION

ERYTHROCIN

| | | | | | |
|-----------|------------------|------------|--|-----|------|
| @ HOSPIRA | EQ 1GM BASE/VIAL | N50182 003 | | Feb | DISC |
|-----------|------------------|------------|--|-----|------|

| | | | | | |
|------|------------------|------------|--------------|-----|------|
| AP + | EQ 1GM BASE/VIAL | N62638 002 | Oct 31, 1986 | Feb | CRLD |
|------|------------------|------------|--------------|-----|------|

ESTRADIOL

TABLET; ORAL

INNOFEM

| | | | | | |
|--------------------|-------|------------|--------------|-----|------|
| @ NOVO NORDISK INC | 0.5MG | N40312 001 | Nov 19, 1999 | Apr | DISC |
|--------------------|-------|------------|--------------|-----|------|

| | | | | | |
|---|-----|------------|--------------|-----|------|
| @ | 1MG | N40312 002 | Nov 19, 1999 | Apr | DISC |
|---|-----|------------|--------------|-----|------|

| | | | | | |
|---|-----|------------|--------------|-----|------|
| @ | 2MG | N40312 003 | Nov 19, 1999 | Apr | DISC |
|---|-----|------------|--------------|-----|------|

ETHAMBUTOL HYDROCHLORIDE

TABLET; ORAL

MYAMBUTOL

| | | | | | | |
|----|----------------|-------|------------|--|-----|------|
| AB | STI PHARMA LLC | 100MG | N16320 001 | | Mar | CAHN |
|----|----------------|-------|------------|--|-----|------|

| | | | | | | |
|---|--|-------|------------|--|-----|------|
| @ | | 200MG | N16320 002 | | Mar | CAHN |
|---|--|-------|------------|--|-----|------|

| | | | | | | |
|----|--|-------|------------|--|-----|------|
| AB | | 400MG | N16320 003 | | Mar | CAHN |
|----|--|-------|------------|--|-----|------|

| | | | | | | |
|---|--|-------|------------|--|-----|------|
| @ | | 500MG | N16320 004 | | Mar | CAHN |
|---|--|-------|------------|--|-----|------|

ETHINYL ESTRADIOL; ETHYNODIOL DIACETATE

TABLET; ORAL-21

DEMULEN 1/35-21

| | | | | | |
|-----------------|-------------|------------|--|-----|------|
| @ GD SEARLE LLC | 0.035MG;1MG | N18168 001 | | Apr | DISC |
|-----------------|-------------|------------|--|-----|------|

DEMULEN 1/50-21

| | | | | | |
|-----------------|------------|------------|--|-----|------|
| @ GD SEARLE LLC | 0.05MG;1MG | N16927 001 | | Apr | DISC |
|-----------------|------------|------------|--|-----|------|

ZOVIA 1/35E-21

| | | | | | |
|---------------|-------------|------------|--------------|-----|------|
| @ WATSON LABS | 0.035MG;1MG | N72720 001 | Dec 30, 1991 | Apr | DISC |
|---------------|-------------|------------|--------------|-----|------|

ZOVIA 1/50E-21

| | | | | | |
|---------------|------------|------------|--------------|-----|------|
| @ WATSON LABS | 0.05MG;1MG | N72722 001 | Dec 30, 1991 | Apr | DISC |
|---------------|------------|------------|--------------|-----|------|

TABLET; ORAL-28

DEMULEN 1/35-28

| | | | | | |
|-----------------|-------------|------------|--|-----|------|
| @ GD SEARLE LLC | 0.035MG;1MG | N18160 001 | | Apr | DISC |
|-----------------|-------------|------------|--|-----|------|

DEMULEN 1/50-28

| | | | | | |
|-----------------|------------|------------|--|-----|------|
| @ GD SEARLE LLC | 0.05MG;1MG | N16936 001 | | Apr | DISC |
|-----------------|------------|------------|--|-----|------|

TABLET; ORAL-28
 ZOVIA 1/50E-28
 + WATSON LABS 0.05MG;1MG N72723 001 Dec 30, 1991 Apr CRLD

ETHINYL ESTRADIOL; LEVONORGESTREL

TABLET; ORAL-21
 TRIPHASIL-21
 @ AKRIMAX PHARMS 0.03MG,0.04MG,0.03MG;0.05MG,0.075 N19192 001 Nov 01, 1984 Apr CAHN
 MG,0.125MG

TABLET; ORAL-28
 TRIPHASIL-28
 @ WYETH PHARMS INC 0.03MG,0.04MG,0.03MG;0.05MG,0.075 N19190 001 Nov 01, 1984 Apr DISC
 MG,0.125MG

ETHINYL ESTRADIOL; NORETHINDRONE

TABLET; ORAL-21
 NORETHINDRONE AND ETHINYL ESTRADIOL (7/14)
 WATSON LABS 0.035MG,0.035MG;0.5MG,1MG N71041 001 Sep 24, 1991 Apr CRLD

TABLET; ORAL-28
 NORETHINDRONE AND ETHINYL ESTRADIOL (10/11)
 WATSON LABS 0.035MG,0.035MG;0.5MG,1MG N71044 001 Apr 01, 1988 Apr CTEC

ETHINYL ESTRADIOL; NORETHINDRONE ACETATE

TABLET; ORAL-21
 LOESTRIN 21 1.5/30
 AB WARNER CHILCOTT 0.03MG;1.5MG N17875 001 Apr CRLD

LOESTRIN 21 1/20
 AB WARNER CHILCOTT 0.02MG;1MG N17876 001 Apr CRLD

TABLET; ORAL-28
 LOESTRIN FE 1/20
 AB WARNER CHILCOTT 0.02MG;1MG N17354 001 Apr CRLD

ETHINYL ESTRADIOL; NORGESTREL

TABLET; ORAL-21
 OGESTREL 0.5/50-21
 @ WATSON LABS 0.05MG;0.5MG N75406 001 Dec 15, 1999 Apr DISC

OVRAL
 @ AKRIMAX PHARMS 0.05MG;0.5MG N16672 001 Mar CAHN

ETHOTOIN

TABLET; ORAL
 PEGANONE
 + LUNDBECK INC 250MG N10841 001 Apr CAHN
 @ 500MG N10841 003 Apr CAHN

ETOPOSIDE

CAPSULE; ORAL
 ETOPOSIDE
 + GENPHARM 50MG N75635 001 Sep 19, 2001 Feb CRLD

VEPESID
 @ BRISTOL MYERS SQUIBB 50MG N19557 001 Dec 30, 1986 Feb DISC

EVEROLIMUS

TABLET; ORAL
 AFINITOR
 NOVARTIS 5MG N22334 001 Mar 30, 2009 Mar NEWA

TABLET; ORAL

AFINITOR

| | | | | | | |
|---|----------|------|------------|--------------|-----|------|
| + | NOVARTIS | 10MG | N22334 002 | Mar 30, 2009 | Mar | NEWA |
|---|----------|------|------------|--------------|-----|------|

FAMOTIDINE

TABLET; ORAL

FAMOTIDINE

| | | | | | | | |
|-----|----|-------------|------|------------|--------------|-----|------|
| >A> | AB | ALEMBIC LTD | 20MG | N78916 001 | May 22, 2009 | May | NEWA |
| >A> | AB | | 40MG | N78916 002 | May 22, 2009 | May | NEWA |
| | | @ SANDOZ | 20MG | N75302 001 | Apr 16, 2001 | Mar | DISC |
| | | @ | 40MG | N75302 002 | Apr 16, 2001 | Mar | DISC |

FEBUXOSTAT

TABLET; ORAL

ULORIC

| | | | | | | | |
|---|--|---------------|------|------------|--------------|-----|------|
| | | TAKEDA PHARMS | 40MG | N21856 001 | Feb 13, 2009 | Feb | NEWA |
| + | | | 80MG | N21856 002 | Feb 13, 2009 | Feb | NEWA |

FENOPROFEN CALCIUM

CAPSULE; ORAL

NALFON

| | | | | | | | |
|---|--|------------|---------------|------------|--|-----|------|
| | | @ PEDINOL | EQ 300MG BASE | N17604 002 | | Feb | DISC |
| | | NALFON 200 | | | | | |
| + | | PEDINOL | EQ 200MG BASE | N17604 003 | | Feb | CRLD |

TABLET; ORAL

FENOPROFEN CALCIUM

| | | | | | | | |
|--|--|----------|---------------|------------|--------------|-----|------|
| | | @ SANDOZ | EQ 600MG BASE | N72396 001 | Oct 17, 1988 | Mar | DISC |
|--|--|----------|---------------|------------|--------------|-----|------|

FENTANYL CITRATE

INJECTABLE; INJECTION

SUBLIMAZE PRESERVATIVE FREE

| | | | | | | | | |
|-----|----|---|-----------|-------------------|------------|--|-----|------|
| >A> | AP | + | AKORN | EQ 0.05MG BASE/ML | N16619 001 | | May | CAHN |
| >D> | AP | + | AKORN MFG | EQ 0.05MG BASE/ML | N16619 001 | | May | CAHN |

FLECAINIDE ACETATE

TABLET; ORAL

FLECAINIDE ACETATE

| | | | | | | | |
|--|--|----------|-------|------------|--------------|-----|------|
| | | @ SANDOZ | 50MG | N76030 001 | Oct 28, 2002 | Mar | DISC |
| | | @ | 100MG | N76030 002 | Oct 28, 2002 | Mar | DISC |
| | | @ | 150MG | N76030 003 | Oct 28, 2002 | Mar | DISC |

FLUDARABINE PHOSPHATE

INJECTABLE; INJECTION

FLUDARABINE PHOSPHATE

| | | | | | | | |
|----|--|----------------|-----------|------------|--------------|-----|------|
| AP | | ACTAVIS TOTOWA | 50MG/VIAL | N78610 001 | Feb 11, 2009 | Feb | NEWA |
|----|--|----------------|-----------|------------|--------------|-----|------|

FLUMAZENIL

INJECTABLE; INJECTION

FLUMAZENIL

| | | | | | | | |
|----|--|--------------------|----------------------|------------|--------------|-----|------|
| AP | | HIKMA FARMACEUTICA | 0.5MG/5ML (0.1MG/ML) | N78527 001 | Mar 23, 2009 | Mar | NEWA |
| AP | | | 1MG/10ML (0.1MG/ML) | N78527 002 | Mar 23, 2009 | Mar | NEWA |

FLUOCINOLONE ACETONIDE

OIL; TOPICAL

DERMA-SMOOTHIE/FS

| | | | | | | | |
|---|--|-------------|-------|------------|--------------|-----|------|
| + | | HILL DERMAC | 0.01% | N19452 002 | Nov 09, 2005 | Feb | NEWA |
|---|--|-------------|-------|------------|--------------|-----|------|

FLUOROURACIL

SOLUTION; TOPICAL

FLUOROPLEX

| | | | | |
|----------|----|------------|-----|------|
| @ ELORAC | 1% | N16765 001 | Feb | CAHN |
|----------|----|------------|-----|------|

FLUOXETINE HYDROCHLORIDE

CAPSULE; ORAL

FLUOXETINE HYDROCHLORIDE

| | | | | | | |
|-----|----------------------|--------------|------------|--------------|-----|------|
| AB1 | ALEMBIC LTD | EQ 10MG BASE | N90223 001 | Mar 19, 2009 | Mar | NEWA |
| AB1 | | EQ 20MG BASE | N90223 002 | Mar 19, 2009 | Mar | NEWA |
| AB | | EQ 40MG BASE | N90223 003 | Mar 19, 2009 | Mar | NEWA |
| AB1 | BEIJING DOUBLE CRANE | EQ 10MG BASE | N76165 001 | Feb 01, 2002 | Mar | CAHN |
| AB1 | | EQ 20MG BASE | N76165 002 | Feb 01, 2002 | Mar | CAHN |

SOLUTION; ORAL

FLUOXETINE HYDROCHLORIDE

| | | | | | | |
|----|-----------------|------------------|------------|--------------|-----|------|
| AA | AUROBINDO PHARM | EQ 20MG BASE/5ML | N79209 001 | Mar 20, 2009 | Mar | NEWA |
|----|-----------------|------------------|------------|--------------|-----|------|

TABLET; ORAL

FLUOXETINE HYDROCHLORIDE

| | | | | | | |
|----|-------|--------------|------------|--------------|-----|------|
| AB | MYLAN | EQ 10MG BASE | N75755 001 | Aug 02, 2001 | Apr | CAHN |
| + | | EQ 20MG BASE | N75755 002 | Aug 02, 2001 | Apr | CAHN |

FLURAZEPAM HYDROCHLORIDE

CAPSULE; ORAL

FLURAZEPAM HYDROCHLORIDE

| | | | | | |
|----------|------|------------|--------------|-----|------|
| @ SANDOZ | 15MG | N71716 001 | Jul 31, 1991 | Mar | DISC |
| @ | 30MG | N71717 001 | Jul 31, 1991 | Mar | DISC |

FLURBIPROFEN

TABLET; ORAL

FLURBIPROFEN

| | | | | | |
|----------|-------|------------|--------------|-----|------|
| @ SANDOZ | 50MG | N74448 001 | Jul 28, 1995 | Mar | DISC |
| @ | 100MG | N74448 002 | Jul 28, 1995 | Mar | DISC |

FLUVOXAMINE MALEATE

TABLET; ORAL

FLUVOXAMINE MALEATE

| | | | | | |
|---------------|-------|------------|--------------|-----|------|
| @ IVAX PHARMS | 25MG | N75898 001 | Mar 12, 2001 | Mar | DISC |
| @ | 50MG | N75898 002 | Mar 12, 2001 | Mar | DISC |
| @ | 100MG | N75898 003 | Mar 12, 2001 | Mar | DISC |

FOMEPIZOLE

INJECTABLE; INJECTION

FOMEPIZOLE

| | | | | | | |
|----|-------------|----------------------|------------|--------------|-----|------|
| AP | GENERAMEDIX | 1.5GM/1.5ML (1GM/ML) | N79033 001 | Apr 07, 2009 | Mar | NEWA |
|----|-------------|----------------------|------------|--------------|-----|------|

FOSINOPRIL SODIUM

TABLET; ORAL

FOSINOPRIL SODIUM

| | | | | | |
|----------|------|------------|--------------|-----|------|
| @ SANDOZ | 10MG | N76188 001 | Oct 08, 2004 | Mar | DISC |
| @ | 20MG | N76188 002 | Oct 08, 2004 | Mar | DISC |
| @ | 40MG | N76188 003 | Oct 08, 2004 | Mar | DISC |

FOSINOPRIL SODIUM; HYDROCHLOROTHIAZIDE

TABLET; ORAL

MONOPRIL-HCT

@ BRISTOL MYERS SQUIBB 10MG;12.5MG

N20286 002 Nov 30, 1994 Feb DISC

@ 20MG;12.5MG

N20286 001 Nov 30, 1994 Feb DISC

GALANTAMINE HYDROBROMIDE

CAPSULE, EXTENDED RELEASE; ORAL

GALANTAMINE HYDROBROMIDE

>A> AB IMPAX LABS EQ 8MG BASE

N78484 001 May 27, 2009 May NEWA

>A> AB EQ 16MG BASE

N78484 002 May 27, 2009 May NEWA

>A> AB EQ 24MG BASE

N78484 003 May 27, 2009 May NEWA

SOLUTION; ORAL

GALANTAMINE HYDROBROMIDE

AA ROXANE 4MG/ML

N78185 001 Jan 30, 2009 Jan NEWA

RAZADYNE

AA + ORTHO MCNEIL JANSSEN 4MG/ML

N21224 001 Jun 22, 2001 Jan CFTG

TABLET; ORAL

GALANTAMINE HYDROBROMIDE

AB BEJING YABAO EQ 4MG BASE

N77604 001 Feb 06, 2009 Apr CAHN

AB EQ 8MG BASE

N77604 002 Feb 06, 2009 Apr CAHN

AB EQ 12MG BASE

N77604 003 Feb 06, 2009 Apr CAHN

>A> AB MYLAN EQ 4MG BASE

N77590 001 May 29, 2009 May NEWA

AB EQ 4MG BASE

N77603 001 Aug 28, 2008 Apr CAHN

>A> AB EQ 8MG BASE

N77590 002 May 29, 2009 May NEWA

AB EQ 8MG BASE

N77603 002 Aug 28, 2008 Apr CAHN

>A> AB EQ 12MG BASE

N77590 003 May 29, 2009 May NEWA

AB EQ 12MG BASE

N77603 003 Aug 28, 2008 Apr CAHN

AB PAR PHARM EQ 4MG BASE

N77604 001 Feb 06, 2009 Jan NEWA

AB EQ 8MG BASE

N77604 002 Feb 06, 2009 Jan NEWA

AB EQ 12MG BASE

N77604 003 Feb 06, 2009 Jan NEWA

AB ROXANE EQ 4MG BASE

N77608 001 Feb 11, 2009 Jan NEWA

AB EQ 8MG BASE

N77608 002 Feb 11, 2009 Jan NEWA

AB EQ 12MG BASE

N77608 003 Feb 11, 2009 Jan NEWA

GLIMEPIRIDE; PIOGLITAZONE HYDROCHLORIDE

TABLET; ORAL

DUETACT

>D> TAKEDA GLOBAL 2MG;30MG

N21925 001 Jul 28, 2006 May CRLD

>A> + 2MG;30MG

N21925 001 Jul 28, 2006 May CRLD

>D> + 4MG;30MG

N21925 002 Jul 28, 2006 May CRLD

>A> 4MG;30MG

N21925 002 Jul 28, 2006 May CRLD

GLYBURIDE

TABLET; ORAL

GLYBURIDE

AB + TEVA 5MG

N74388 003 Aug 29, 1995 Mar CRLD

MICRONASE

@ PHARMACIA AND UPJOHN 1.25MG

N17498 001 May 01, 1984 Mar DISC

@ 2.5MG

N17498 002 May 01, 1984 Mar DISC

@ 5MG

N17498 003 May 01, 1984 Mar DISC

GLYBURIDE; METFORMIN HYDROCHLORIDE

TABLET; ORAL

GLUCOVANCE

| | | | | | | | |
|---------------------------------------|----|----------------------|--------------|------------|--------------|-----|------|
| >D> | AB | BRISTOL MYERS SQUIBB | 2.5MG;500MG | N21178 002 | Jul 31, 2000 | May | CRLD |
| >A> | AB | + | 2.5MG;500MG | N21178 002 | Jul 31, 2000 | May | CRLD |
| >D> | AB | + | 5MG;500MG | N21178 003 | Jul 31, 2000 | May | CRLD |
| >A> | AB | | 5MG;500MG | N21178 003 | Jul 31, 2000 | May | CRLD |
| GLYBURIDE AND METFORMIN HYDROCHLORIDE | | | | | | | |
| >A> | AB | DR REDDYS LABS INC | 1.25MG;250MG | N79009 001 | Jun 03, 2009 | May | NEWA |
| >A> | AB | | 2.5MG;500MG | N79009 002 | Jun 03, 2009 | May | NEWA |
| >A> | AB | | 5MG;500MG | N79009 003 | Jun 03, 2009 | May | NEWA |

GLYCOPYRROLATE

TABLET; ORAL

GLYCOPYRROLATE

| | | | | | | | |
|----|--|-----------|-----|------------|--------------|-----|------|
| AA | | WEST WARD | 1MG | N40836 001 | Mar 05, 2009 | Feb | NEWA |
| AA | | | 2MG | N40836 002 | Mar 05, 2009 | Feb | NEWA |

GRANISETRON HYDROCHLORIDE

INJECTABLE; INJECTION

GRANISETRON HYDROCHLORIDE

| | | | | | | | |
|----|--|--------|--|------------|--------------|-----|------|
| AP | | SANDOZ | EQ 0.1MG BASE/ML (EQ 0.1MG BASE/ML) | N78534 001 | Apr 30, 2009 | Apr | NEWA |
| AP | | | EQ 1MG BASE/ML (EQ 1MG BASE/ML) | N78531 001 | Apr 30, 2009 | Apr | NEWA |
| AP | | | EQ 4MG BASE/4ML (EQ 1MG BASE/ML) | N78531 002 | Apr 30, 2009 | Apr | NEWA |

TABLET; ORAL

GRANISETRON HYDROCHLORIDE

| | | | | | | | |
|----|--|--------------------|-------------|------------|--------------|-----|------|
| AB | | DR REDDYS LABS LTD | EQ 1MG BASE | N78846 001 | Feb 27, 2009 | Feb | NEWA |
|----|--|--------------------|-------------|------------|--------------|-----|------|

HALOPERIDOL DECANOATE

INJECTABLE; INJECTION

HALOPERIDOL DECANOATE

| | | | | | | | |
|--|---|--------|------------------|------------|--------------|-----|------|
| | @ | SANDOZ | EQ 50MG BASE/ML | N76463 001 | Jun 24, 2005 | Apr | DISC |
| | @ | | EQ 100MG BASE/ML | N76463 002 | Jun 24, 2005 | Apr | DISC |

HALOPERIDOL LACTATE

INJECTABLE; INJECTION

HALOPERIDOL

| | | | | | | | |
|--|---|--------|----------------|------------|--------------|-----|------|
| | @ | SANDOZ | EQ 5MG BASE/ML | N76464 001 | Sep 29, 2004 | Apr | DISC |
|--|---|--------|----------------|------------|--------------|-----|------|

HISTRELIN ACETATE

IMPLANT; SUBCUTANEOUS

SUPPRELIN LA

| | | | | | | | |
|--------|--|-------------|------|------------|--------------|-----|------|
| + | | ENDO PHARM | 50MG | N22058 001 | May 03, 2007 | Apr | CAHN |
| VANTAS | | | | | | | |
| + | | ENDO PHARM | 50MG | N21732 001 | Oct 12, 2004 | Apr | CAHN |
| + | | ENDO PHARMS | 50MG | N21732 001 | Oct 12, 2004 | Mar | CAHN |

HOMATROPINE METHYLBROMIDE; HYDROCODONE BITARTRATE

SYRUP; ORAL

HYCODAN

| | | | | | | | |
|--|---|-------------|-------------------|------------|--------------|-----|------|
| | @ | ENDO PHARMS | 1.5MG/5ML;5MG/5ML | N05213 002 | Jul 26, 1988 | Feb | DISC |
|--|---|-------------|-------------------|------------|--------------|-----|------|

HYDROCODONE BITARTRATE AND HOMATROPINE METHYLBROMIDE

| | | | | | | | |
|----|---|----------------|-------------------|------------|--------------|-----|------|
| AA | + | HI TECH PHARMA | 1.5MG/5ML;5MG/5ML | N40613 001 | Feb 08, 2008 | Feb | CRLD |
|----|---|----------------|-------------------|------------|--------------|-----|------|

TABLET; ORAL

| | | | | | | | | |
|----|---------------|-----------|--|--------|-----|--------------|-----|------|
| | HYCODAN | | | | | | | |
| | @ ENDO PHARMS | 1.5MG;5MG | | N05213 | 001 | Jul 26, 1988 | Feb | DISC |
| | TUSSIGON | | | | | | | |
| AA | + KING PHARMS | 1.5MG;5MG | | N88508 | 001 | Jul 30, 1985 | Feb | CRLD |

HYDRALAZINE HYDROCHLORIDE

INJECTABLE; INJECTION

| | | | | | | | | |
|----|---------------------------|---------|--|--------|-----|--------------|-----|------|
| | HYDRALAZINE HYDROCHLORIDE | | | | | | | |
| AP | AKORN | 20MG/ML | | N40730 | 001 | Apr 21, 2009 | Mar | NEWA |

TABLET; ORAL

| | | | | | | | | |
|-----|---------------------------|---------------------|-------|--------|-----|--------------|-----|------|
| | HYDRALAZINE HYDROCHLORIDE | | | | | | | |
| >A> | AA | GLENMARK PHARMS LTD | 10MG | N90527 | 001 | May 27, 2009 | May | NEWA |
| >A> | AA | | 25MG | N90527 | 002 | May 27, 2009 | May | NEWA |
| >A> | AA | | 50MG | N90527 | 003 | May 27, 2009 | May | NEWA |
| >A> | AA | | 100MG | N90527 | 004 | May 27, 2009 | May | NEWA |
| | @ SANDOZ | | 10MG | N83241 | 001 | | Mar | DISC |
| | @ | | 25MG | N83560 | 001 | | Mar | DISC |
| | @ | | 50MG | N83561 | 001 | | Mar | DISC |

HYDROCHLOROTHIAZIDE

CAPSULE; ORAL

| | | | | | | | | |
|----|---------------------|--------|--|--------|-----|--------------|-----|------|
| | HYDROCHLOROTHIAZIDE | | | | | | | |
| AB | IPCA LABS LTD | 12.5MG | | N79237 | 001 | Apr 02, 2009 | Mar | NEWA |

SOLUTION; ORAL

| | | | | | | | | |
|--|---------------------|----------|--|--------|-----|--------------|-----|------|
| | HYDROCHLOROTHIAZIDE | | | | | | | |
| | @ ROXANE | 50MG/5ML | | N88587 | 001 | Jul 02, 1984 | Mar | DISC |

TABLET; ORAL

| | | | | | | | | |
|--|---------------------|------|--|--------|-----|--------------|-----|------|
| | HYDROCHLOROTHIAZIDE | | | | | | | |
| | @ SANDOZ | 25MG | | N87565 | 001 | Mar 09, 1982 | Mar | DISC |
| | @ | 50MG | | N84912 | 001 | | Mar | DISC |

HYDROCHLOROTHIAZIDE; PROPRANOLOL HYDROCHLORIDE

TABLET; ORAL

| | | | | | | | | |
|--|---|-----------|--|--------|-----|--------------|-----|------|
| | PROPRANOLOL HYDROCHLORIDE AND HYDROCHLOROTHIAZIDE | | | | | | | |
| | @ SANDOZ | 25MG;40MG | | N71060 | 001 | Aug 26, 1987 | Mar | DISC |
| | @ | 25MG;80MG | | N71061 | 001 | Aug 26, 1987 | Mar | DISC |

HYDROCHLOROTHIAZIDE; QUINAPRIL HYDROCHLORIDE

TABLET; ORAL

| | | | | | | | | |
|----|---|---------------------|--|--------|-----|--------------|-----|------|
| | QUINAPRIL HYDROCHLORIDE AND HYDROCHLOROTHIAZIDE | | | | | | | |
| AB | RANBAXY | 12.5MG;EQ 10MG BASE | | N78211 | 001 | Mar 04, 2009 | Feb | NEWA |
| AB | | 12.5MG;EQ 20MG BASE | | N78211 | 002 | Mar 04, 2009 | Feb | NEWA |
| AB | | 25MG;EQ 20MG BASE | | N78211 | 003 | Mar 04, 2009 | Feb | NEWA |

HYDROCHLOROTHIAZIDE; SPIRONOLACTONE

TABLET; ORAL

| | | | | | | | | |
|--|--|-----------|--|--------|-----|--|-----|------|
| | SPIRONOLACTONE AND HYDROCHLOROTHIAZIDE | | | | | | | |
| | @ SANDOZ | 25MG;25MG | | N86881 | 001 | | Mar | DISC |

HYDROCORTISONE ACETATE; OXYTETRACYCLINE HYDROCHLORIDE

SUSPENSION; OPHTHALMIC

| | | | | | | | | |
|--|---------------|---------------------|--|--------|-----|--|-----|------|
| | TERRA-CORTRIL | | | | | | | |
| | @ PFIZER | 1.5%;EQ 5MG BASE/ML | | N61016 | 001 | | Feb | DISC |

HYDROCORTISONE ACETATE; PRAMOXINE HYDROCHLORIDE

AEROSOL, METERED; TOPICAL

PROCTOFOAM HC

| | | | | | |
|----|---------|-------|------------|-----|------|
| BX | UCB INC | 1%;1% | N86195 001 | Apr | CAHN |
|----|---------|-------|------------|-----|------|

HYDROCORTISONE ACETATE; UREA

CREAM; TOPICAL

CARMOL HC

| | | | | | |
|----|--------------|--------|------------|-----|------|
| AT | + NYCOMED US | 1%;10% | N80505 001 | Apr | CAHN |
|----|--------------|--------|------------|-----|------|

HYDROMORPHONE HYDROCHLORIDE

INJECTABLE; INJECTION

DILAUDID

| | | | | | | |
|-----|--------------------|--------|------------|--------------|-----|------|
| >D> | PURDUE PHARM PRODS | 1MG/ML | N19034 003 | Apr 30, 2009 | May | CMFD |
| >A> | + | 1MG/ML | N19034 003 | Apr 30, 2009 | May | CMFD |
| | | 1MG/ML | N19034 003 | Apr 30, 2009 | Apr | NEWA |
| >D> | | 2MG/ML | N19034 004 | Apr 30, 2009 | May | CRLD |
| >A> | + | 2MG/ML | N19034 004 | Apr 30, 2009 | May | CRLD |
| | | 2MG/ML | N19034 004 | Apr 30, 2009 | Apr | NEWA |
| >D> | | 4MG/ML | N19034 005 | Apr 30, 2009 | May | CRLD |
| >A> | + | 4MG/ML | N19034 005 | Apr 30, 2009 | May | CRLD |
| | | 4MG/ML | N19034 005 | Apr 30, 2009 | Apr | NEWA |

TABLET; ORAL

HYDROMORPHONE HYDROCHLORIDE

| | | | | | | |
|-----|-----------|-----|------------|--------------|-----|------|
| >A> | AB ROXANE | 4MG | N74597 003 | May 29, 2009 | May | NEWA |
|-----|-----------|-----|------------|--------------|-----|------|

HYDROXYUREA

CAPSULE; ORAL

HYDROXYUREA

| | | | | | | |
|----|------|-------|------------|--------------|-----|------|
| AB | BARR | 500MG | N75143 001 | Oct 16, 1998 | Feb | CMFD |
|----|------|-------|------------|--------------|-----|------|

HYDROXYZINE HYDROCHLORIDE

TABLET; ORAL

HYDROXYZINE HYDROCHLORIDE

| | | | | | | |
|---|--------|------|------------|--------------|-----|------|
| @ | SANDOZ | 10MG | N87869 001 | Dec 20, 1982 | Mar | DISC |
| @ | | 25MG | N87870 001 | Dec 20, 1982 | Mar | DISC |
| @ | | 50MG | N87871 001 | Dec 20, 1982 | Mar | DISC |

HYDROXYZINE PAMOATE

CAPSULE; ORAL

HYDROXYZINE PAMOATE

| | | | | | | |
|---|--------|-------------|------------|--------------|-----|------|
| @ | SANDOZ | EQ 25MG HCL | N81127 001 | Jun 28, 1991 | Mar | DISC |
|---|--------|-------------|------------|--------------|-----|------|

IBUPROFEN

TABLET; ORAL

IBUPROFEN

| | | | | | | |
|----|----------------|-------|------------|--------------|-----|------|
| AB | + DR REDDYS LA | 800MG | N75682 003 | Nov 14, 2001 | Feb | CRLD |
| | @ SANDOZ | 300MG | N70734 001 | Jun 12, 1986 | Mar | DISC |
| | @ | 400MG | N70735 001 | Jun 12, 1986 | Mar | DISC |
| | @ | 600MG | N70736 001 | Jun 12, 1986 | Mar | DISC |
| | @ | 800MG | N72169 001 | Dec 11, 1987 | Mar | DISC |
| AB | SHASUN USA | 400MG | N78329 001 | Feb 05, 2009 | Jan | NEWA |
| AB | | 600MG | N78329 002 | Feb 05, 2009 | Jan | NEWA |
| AB | | 800MG | N78329 003 | Feb 05, 2009 | Jan | NEWA |

TABLET; ORAL

MOTRIN

| | | | | |
|-------------------|-------|------------|--------------|----------|
| @ MCNEIL CONSUMER | 300MG | N17463 003 | Apr | DISC |
| @ | 400MG | N17463 002 | Feb | DISC |
| @ | 600MG | N17463 004 | Feb | DISC |
| @ | 800MG | N17463 005 | May 22, 1985 | Feb DISC |

IBUPROFEN LYSINE

INJECTABLE; INTRAVENOUS

NEOPROFEN

| | | | | |
|----------------|---------------------------------------|------------|--------------|----------|
| + LUNDBECK INC | EQ 20MG BASE/2ML (EQ 10MG BASE/ML) | N21903 001 | Apr 13, 2006 | Apr CAHN |
|----------------|---------------------------------------|------------|--------------|----------|

IFOSFAMIDE

INJECTABLE; INJECTION

IFEX

| | | | | |
|-------------------|----------|------------|--------------|----------|
| @ BAXTER HLTHCARE | 1GM/VIAL | N19763 001 | Dec 30, 1988 | Feb CAHN |
| @ | 3GM/VIAL | N19763 002 | Dec 30, 1988 | Feb CAHN |

IFOSFAMIDE; MESNA

INJECTABLE; INJECTION

IFEX/MESNEX KIT

| | | | | |
|-------------------|-------------------|------------|--------------|----------|
| + BAXTER HLTHCARE | 1GM/VIAL;100MG/ML | N19763 003 | Oct 10, 1992 | Feb CAHN |
| + | 3GM/VIAL;100MG/ML | N19763 004 | Oct 10, 1992 | Feb CAHN |

>A> ILOPERIDONE

>A> TABLET; ORAL

>A> FANAPT

| | | | | |
|----------------------|------|------------|--------------|----------|
| >A> VANDA PHARMS INC | 1MG | N22192 001 | May 06, 2009 | May NEWA |
| >A> | 2MG | N22192 002 | May 06, 2009 | May NEWA |
| >A> | 4MG | N22192 003 | May 06, 2009 | May NEWA |
| >A> | 6MG | N22192 004 | May 06, 2009 | May NEWA |
| >A> | 8MG | N22192 005 | May 06, 2009 | May NEWA |
| >A> | 10MG | N22192 006 | May 06, 2009 | May NEWA |
| >A> + | 12MG | N22192 007 | May 06, 2009 | May NEWA |

INDOMETHACIN

CAPSULE, EXTENDED RELEASE; ORAL

INDOCIN SR

| | | | | |
|-------------|------|------------|--------------|----------|
| AB + SANDOZ | 75MG | N74464 001 | May 28, 1998 | Feb CTEC |
|-------------|------|------------|--------------|----------|

INDOMETHACIN

| | | | | |
|----------------|------|------------|--------------|----------|
| AB AVANTHI INC | 75MG | N79175 001 | Mar 06, 2009 | Feb NEWA |
|----------------|------|------------|--------------|----------|

SUSPENSION; ORAL

INDOCIN

| | | | | |
|----------------|----------|------------|--------------|----------|
| + IROKO PHARMS | 25MG/5ML | N18332 001 | Oct 10, 1985 | Mar CAHN |
|----------------|----------|------------|--------------|----------|

INDOMETHACIN SODIUM

INJECTABLE; INJECTION

INDOCIN

| | | | | |
|-------------------|------------------|------------|--------------|----------|
| AP + LUNDBECK INC | EQ 1MG BASE/VIAL | N18878 001 | Jan 30, 1985 | Apr CAHN |
|-------------------|------------------|------------|--------------|----------|

INSULIN GLULISINE RECOMBINANT

INJECTABLE; SUBCUTANEOUS

APIDRA SOLOSTAR

| | | | | |
|-------------------|---------------|------------|--------------|----------|
| SANOFI AVENTIS US | 300 UNITS/3ML | N21629 003 | Feb 24, 2009 | Feb NEWA |
|-------------------|---------------|------------|--------------|----------|

IPRATROPIUM BROMIDE

SOLUTION; INHALATION

IPRATROPIUM BROMIDE

| | | | | | | |
|----|-----------------|-------|------------|--------------|-----|------|
| AN | TEVA PARENTERAL | 0.02% | N75313 001 | Feb 07, 2000 | Apr | CAHN |
|----|-----------------|-------|------------|--------------|-----|------|

IRINOTECAN HYDROCHLORIDE

INJECTABLE; INJECTION

IRINOTECAN HYDROCHLORIDE

| | | | | | | |
|----|-------------|---------------------|------------|--------------|-----|------|
| AP | PHARMAFORCE | 40MG/2ML (20MG/ML) | N90016 001 | Jan 28, 2009 | Mar | NEWA |
| AP | | 40MG/2ML(20MG/ML) | N90016 001 | Jan 28, 2009 | Jan | NEWA |
| AP | | 100MG/5ML (20MG/ML) | N90016 002 | Jan 28, 2009 | Mar | NEWA |
| AP | | 100MG/5ML(20MG/ML) | N90016 002 | Jan 28, 2009 | Jan | NEWA |

ISOSORBIDE DINITRATE

TABLET; SUBLINGUAL

ISOSORBIDE DINITRATE

| | | | | | | |
|---|--------|-------|------------|--------------|-----|------|
| @ | SANDOZ | 2.5MG | N86225 001 | Feb 19, 1988 | Mar | DISC |
| @ | | 5MG | N86222 001 | Feb 19, 1988 | Mar | DISC |

KETOCONAZOLE

GEL; TOPICAL

XOLEGEL

| | | | | | | |
|---|------------------|----|------------|--------------|-----|------|
| + | STIEFEL LABS INC | 2% | N21946 001 | Jul 28, 2006 | Jan | CAHN |
|---|------------------|----|------------|--------------|-----|------|

KETOPROFEN

CAPSULE; ORAL

KETOPROFEN

| | | | | | | |
|---|--------|------|------------|--------------|-----|------|
| @ | SANDOZ | 50MG | N74024 001 | Dec 29, 1995 | Mar | DISC |
| @ | | 75MG | N74024 002 | Dec 29, 1995 | Mar | DISC |

LAMOTRIGINE

TABLET; ORAL

LAMOTRIGINE

| | | | | | | |
|----|--------------------|-------|------------|--------------|-----|------|
| AB | APOTEX INC | 25MG | N78625 001 | Jan 27, 2009 | Jan | NEWA |
| AB | | 100MG | N78625 002 | Jan 27, 2009 | Jan | NEWA |
| AB | | 150MG | N78625 003 | Jan 27, 2009 | Jan | NEWA |
| AB | | 200MG | N78625 004 | Jan 27, 2009 | Jan | NEWA |
| AB | AUROBINDO PHARMA | 25MG | N78956 001 | Jan 27, 2009 | Jan | NEWA |
| AB | | 100MG | N78956 002 | Jan 27, 2009 | Jan | NEWA |
| AB | | 150MG | N78956 003 | Jan 27, 2009 | Jan | NEWA |
| AB | | 200MG | N78956 004 | Jan 27, 2009 | Jan | NEWA |
| AB | CADISTA PHARMS | 25MG | N79132 001 | Jan 27, 2009 | Jan | NEWA |
| AB | | 100MG | N79132 002 | Jan 27, 2009 | Jan | NEWA |
| AB | | 150MG | N79132 003 | Jan 27, 2009 | Jan | NEWA |
| AB | | 200MG | N79132 004 | Jan 27, 2009 | Jan | NEWA |
| AB | DR REDDYS LABS LTD | 25MG | N76708 001 | Jan 27, 2009 | Jan | NEWA |
| AB | | 100MG | N76708 002 | Jan 27, 2009 | Jan | NEWA |
| AB | | 150MG | N76708 003 | Jan 27, 2009 | Jan | NEWA |
| AB | | 200MG | N76708 004 | Jan 27, 2009 | Jan | NEWA |
| AB | GENPHARM ULC | 25MG | N77428 001 | Jan 27, 2009 | Jan | NEWA |
| AB | | 100MG | N77428 002 | Jan 27, 2009 | Jan | NEWA |
| AB | | 150MG | N77428 003 | Jan 27, 2009 | Jan | NEWA |
| AB | | 200MG | N77428 004 | Jan 27, 2009 | Jan | NEWA |
| AB | MATRIX LABS LTD | 25MG | N78443 001 | Feb 11, 2009 | Jan | NEWA |
| AB | | 100MG | N78443 002 | Feb 11, 2009 | Jan | NEWA |

TABLET; ORAL

LAMOTRIGINE

| | | | | | | |
|----|------------------|-------|------------|--------------|-----|------|
| AB | MATRIX LABS LTD | 150MG | N78443 003 | Feb 11, 2009 | Jan | NEWA |
| AB | | 200MG | N78443 004 | Feb 11, 2009 | Jan | NEWA |
| AB | MYLAN | 25MG | N77420 001 | Jan 27, 2009 | Jan | NEWA |
| AB | | 100MG | N77420 002 | Jan 27, 2009 | Jan | NEWA |
| AB | | 150MG | N77420 003 | Jan 27, 2009 | Jan | NEWA |
| AB | | 200MG | N77420 004 | Jan 27, 2009 | Jan | NEWA |
| AB | ROXANE | 25MG | N77392 001 | Jan 27, 2009 | Jan | NEWA |
| AB | | 100MG | N77392 002 | Jan 27, 2009 | Jan | NEWA |
| AB | | 150MG | N77392 003 | Jan 27, 2009 | Jan | NEWA |
| AB | | 200MG | N77392 004 | Jan 27, 2009 | Jan | NEWA |
| AB | SANDOZ | 25MG | N78645 001 | Jan 27, 2009 | Jan | NEWA |
| AB | | 100MG | N78645 002 | Jan 27, 2009 | Jan | NEWA |
| AB | | 150MG | N78645 003 | Jan 27, 2009 | Jan | NEWA |
| AB | | 200MG | N78645 004 | Jan 27, 2009 | Jan | NEWA |
| AB | TARO PHARM INDS | 25MG | N78525 001 | Jan 27, 2009 | Jan | NEWA |
| AB | | 100MG | N78525 002 | Jan 27, 2009 | Jan | NEWA |
| AB | | 150MG | N78525 003 | Jan 27, 2009 | Jan | NEWA |
| AB | | 200MG | N78525 004 | Jan 27, 2009 | Jan | NEWA |
| AB | TORRENT PHARMS | 25MG | N78947 001 | Jan 27, 2009 | Jan | NEWA |
| AB | | 100MG | N78947 002 | Jan 27, 2009 | Jan | NEWA |
| AB | | 150MG | N78947 003 | Jan 27, 2009 | Jan | NEWA |
| AB | | 200MG | N78947 004 | Jan 27, 2009 | Jan | NEWA |
| AB | UPSHER SMITH | 25MG | N78310 001 | Feb 04, 2009 | Jan | NEWA |
| AB | | 100MG | N78310 002 | Feb 04, 2009 | Jan | NEWA |
| AB | | 150MG | N78310 003 | Feb 04, 2009 | Jan | NEWA |
| AB | | 200MG | N78310 004 | Feb 04, 2009 | Jan | NEWA |
| AB | WOCKHARDT | 25MG | N78982 001 | Jan 27, 2009 | Jan | NEWA |
| AB | | 100MG | N78982 002 | Jan 27, 2009 | Jan | NEWA |
| AB | | 150MG | N78982 003 | Jan 27, 2009 | Jan | NEWA |
| AB | | 200MG | N78982 004 | Jan 27, 2009 | Jan | NEWA |
| AB | ZYDUS PHARMS USA | 25MG | N77633 001 | Jan 27, 2009 | Jan | NEWA |
| | | 50MG | N77633 002 | Jan 27, 2009 | Jan | NEWA |
| AB | | 100MG | N77633 003 | Jan 27, 2009 | Jan | NEWA |
| AB | | 150MG | N77633 004 | Jan 27, 2009 | Jan | NEWA |
| AB | | 200MG | N77633 005 | Jan 27, 2009 | Jan | NEWA |
| AB | | 250MG | N77633 006 | Jan 27, 2009 | Jan | NEWA |

TABLET, CHEWABLE; ORAL

LAMOTRIGINE

| | | | | | | |
|----|-------------------|------|------------|--------------|-----|------|
| AB | GLENMARK GENERICS | 5MG | N79099 001 | Feb 19, 2009 | Feb | NEWA |
| AB | | 25MG | N79099 002 | Feb 19, 2009 | Feb | NEWA |
| AB | TARO | 5MG | N79204 001 | Feb 04, 2009 | Jan | NEWA |
| AB | | 25MG | N79204 002 | Feb 04, 2009 | Jan | NEWA |

>A> TABLET, EXTENDED RELEASE; ORAL

>A> LAMICTAL XR

| | | | | | | |
|-----|--------------------|-------|------------|--------------|-----|------|
| >A> | SMITHKLINE BEECHAM | 25MG | N22115 001 | May 29, 2009 | May | NEWA |
| >A> | | 50MG | N22115 002 | May 29, 2009 | May | NEWA |
| >A> | | 100MG | N22115 003 | May 29, 2009 | May | NEWA |
| >A> | + | 200MG | N22115 004 | May 29, 2009 | May | NEWA |

>A> TABLET, ORALLY DISINTEGRATING; ORAL

>A> LAMICTAL ODT

| | | | | | | |
|-----|--------------------|-------|------------|--------------|-----|------|
| >A> | SMITHKLINE BEECHAM | 25MG | N22251 001 | May 08, 2009 | May | NEWA |
| >A> | | 50MG | N22251 002 | May 08, 2009 | May | NEWA |
| >A> | | 100MG | N22251 003 | May 08, 2009 | May | NEWA |
| >A> | + | 200MG | N22251 004 | May 08, 2009 | May | NEWA |

LANSOPRAZOLE

| | | | | | | | |
|-----|--|---------------------------------------|-------------|--------|-----|--------------|----------|
| >D> | | FOR SUSPENSION, DELAYED RELEASE; ORAL | | | | | |
| >D> | | PREVACID | | | | | |
| >D> | | TAKEDA PHARMS NA | 15MG/PACKET | N21281 | 001 | May 03, 2001 | May DISC |
| >A> | | @ | 15MG/PACKET | N21281 | 001 | May 03, 2001 | May DISC |
| >D> | | + | 30MG/PACKET | N21281 | 002 | May 03, 2001 | May DISC |
| >A> | | @ | 30MG/PACKET | N21281 | 002 | May 03, 2001 | May DISC |

LEUCOVORIN CALCIUM

| | | | | | | | |
|-----|----|--------------------|-------------|--------|-----|--------------|----------|
| | | TABLET; ORAL | | | | | |
| | | LEUCOVORIN CALCIUM | | | | | |
| >D> | BX | XANODYNE PHARM | EQ 5MG BASE | N18459 | 001 | Jan 30, 1986 | May DISC |
| >A> | | @ | EQ 5MG BASE | N18459 | 001 | Jan 30, 1986 | May DISC |

LEUPROLIDE ACETATE

| | | | | | | | |
|----|--|-----------------------|-----------|--------|-----|--------------|----------|
| | | INJECTABLE; INJECTION | | | | | |
| | | LEUPROLIDE ACETATE | | | | | |
| AP | | SUN PHARMA GLOBAL | 1MG/0.2ML | N78885 | 001 | Mar 09, 2009 | Feb NEWA |

LEVALBUTEROL HYDROCHLORIDE

| | | | | | | | |
|----|---|----------------------------|---------------|--------|-----|--------------|----------|
| | | SOLUTION; INHALATION | | | | | |
| | | LEVALBUTEROL HYDROCHLORIDE | | | | | |
| AN | | DEY | EQ 0.25% BASE | N78309 | 001 | Mar 20, 2009 | Mar NEWA |
| | | XOPENEX | | | | | |
| AN | + | SEPRACOR | EQ 0.25% BASE | N20837 | 004 | Jul 18, 2003 | Mar CFTG |

LEVETIRACETAM

| | | | | | | | |
|----|--|----------------------|----------|--------|-----|--------------|----------|
| | | SOLUTION; ORAL | | | | | |
| | | LEVETIRACETAM | | | | | |
| AA | | SILARX | 100MG/ML | N90263 | 001 | Apr 03, 2009 | Mar NEWA |
| AA | | TARO | 100MG/ML | N78774 | 001 | Feb 10, 2009 | Jan NEWA |
| | | TABLET; ORAL | | | | | |
| | | LEVETIRACETAM | | | | | |
| AB | | APOTEX INC | 250MG | N78869 | 001 | Mar 13, 2009 | Mar NEWA |
| AB | | | 500MG | N78869 | 002 | Mar 13, 2009 | Mar NEWA |
| AB | | | 750MG | N78869 | 003 | Mar 13, 2009 | Mar NEWA |
| AB | | | 1GM | N78869 | 004 | Mar 13, 2009 | Mar NEWA |
| AB | | CIPLA LTD | 250MG | N77319 | 001 | Mar 20, 2009 | Mar NEWA |
| AB | | | 500MG | N77319 | 002 | Mar 20, 2009 | Mar NEWA |
| AB | | | 750MG | N77319 | 003 | Mar 20, 2009 | Mar NEWA |
| AB | | GENPHARM ULC | 250MG | N78731 | 001 | Feb 10, 2009 | Jan NEWA |
| AB | | | 500MG | N78731 | 002 | Feb 10, 2009 | Jan NEWA |
| AB | | | 750MG | N78731 | 003 | Feb 10, 2009 | Jan NEWA |
| AB | | | 1GM | N78731 | 004 | Feb 10, 2009 | Jan NEWA |
| AB | | SOLCO HLTHCARE | 250MG | N78106 | 001 | Feb 10, 2009 | Jan NEWA |
| AB | | | 500MG | N78106 | 002 | Feb 10, 2009 | Jan NEWA |
| AB | | | 750MG | N78106 | 003 | Feb 10, 2009 | Jan NEWA |
| AB | | | 1GM | N78106 | 004 | Feb 10, 2009 | Jan NEWA |
| AB | | WATSON LABS FLORIDA | 250MG | N77408 | 001 | Mar 02, 2009 | Feb NEWA |
| AB | | | 500MG | N77408 | 002 | Mar 02, 2009 | Feb NEWA |
| AB | | | 750MG | N77408 | 003 | Mar 02, 2009 | Feb NEWA |
| AB | | ZYDUS PHARMS USA INC | 250MG | N78918 | 001 | Apr 29, 2009 | Apr NEWA |
| AB | | | 1GM | N78918 | 002 | Apr 29, 2009 | Apr NEWA |

TABLET, EXTENDED RELEASE; ORAL

| | | | | | | | |
|-----------|---------|-------|------------|--------------|-----|------|--|
| KEPPRA XR | | | | | | | |
| | UCB INC | 500MG | N22285 001 | Sep 12, 2008 | Feb | CRLD | |
| + | | 750MG | N22285 002 | Feb 12, 2009 | Feb | NEWA | |

LEVOFLOXACIN

TABLET; ORAL

| | | | | | | | |
|--------------|----------------------|-------|------------|--------------|-----|------|--|
| LEVAQUIN | | | | | | | |
| AB | ORTHO MCNEIL JANSSEN | 250MG | N20634 001 | Dec 20, 1996 | Apr | CFTG | |
| AB | | 500MG | N20634 002 | Dec 20, 1996 | Apr | CFTG | |
| AB | + | 750MG | N20634 003 | Sep 08, 2000 | Apr | CFTG | |
| LEVOFLOXACIN | | | | | | | |
| AB | LUPIN | 250MG | N78424 001 | May 13, 2009 | Apr | NEWA | |
| AB | | 500MG | N78424 002 | May 13, 2009 | Apr | NEWA | |
| AB | | 750MG | N78424 003 | May 13, 2009 | Apr | NEWA | |

LEVOTHYROXINE SODIUM**

**Refer to Annual Edition Preface Section 1.8 Levothyroxine Sodium for amplifying information

TABLET; ORAL

| | | | | | | | |
|----------------------|------------|---------|------------|--------------|-----|------|--|
| LEVOTHYROXINE SODIUM | | | | | | | |
| AB2, AB3 | MERCK KGAA | 0.025MG | N76752 001 | Jun 16, 2005 | Apr | CAHN | |
| AB2, AB3 | | 0.05MG | N76752 002 | Jun 16, 2005 | Apr | CAHN | |
| AB2, AB3 | | 0.075MG | N76752 003 | Jun 16, 2005 | Apr | CAHN | |
| AB2, AB3 | | 0.088MG | N76752 004 | Jun 16, 2005 | Apr | CAHN | |
| AB2, AB3 | | 0.1MG | N76752 005 | Jun 16, 2005 | Apr | CAHN | |
| AB2, AB3 | | 0.112MG | N76752 006 | Jun 16, 2005 | Apr | CAHN | |
| AB2, AB3 | | 0.125MG | N76752 007 | Jun 16, 2005 | Apr | CAHN | |
| AB2, AB3 | | 0.15MG | N76752 008 | Jun 16, 2005 | Apr | CAHN | |
| AB2, AB3 | | 0.175MG | N76752 009 | Jun 16, 2005 | Apr | CAHN | |
| AB2, AB3 | | 0.2MG | N76752 010 | Jun 16, 2005 | Apr | CAHN | |
| AB2, AB3 | | 0.3MG | N76752 011 | Jun 16, 2005 | Apr | CAHN | |

LIDOCAINE HYDROCHLORIDE

INJECTABLE; INJECTION

LIDOCAINE HYDROCHLORIDE IN PLASTIC CONTAINER

| | | | | | | | |
|------------------|---------------------|---------|------------|--------------|--------------|------|------|
| | @ HOSPIRA | 10% | N88367 001 | Jul 31, 1984 | Apr | DISC | |
| XYLOCAINE | | | | | | | |
| AP | + APP PHARMS | 2% | N06488 002 | | Apr | CMFD | |
| XYLOCAINE DENTAL | | | | | | | |
| AP | + DENTSPLY PHARM | 2% | N21380 001 | | Apr | CTNA | |
| >D> | SYSTEM; INTRADERMAL | | | | | | |
| >D> | ZINGO | | | | | | |
| >D> | + | ANESIVA | 0.5MG | N22114 001 | Aug 16, 2007 | May | DISC |
| >A> | @ | | 0.5MG | N22114 001 | Aug 16, 2007 | May | DISC |

LINDANE

LOTION; TOPICAL

LINDANE

| | | | | | | | |
|--|---------------|----|------------|--|-----|------|--|
| | @ OLTA PHARMS | 1% | N87313 001 | | Apr | CAHN | |
|--|---------------|----|------------|--|-----|------|--|

| | | | | | | |
|--------------------------------------|---|-------------------|-----------------|------------|--------------|----------|
| SHAMPOO; TOPICAL | | | | | | |
| LINDANE | | | | | | |
| AT | + | OLTA PHARMS | 1% | N87266 001 | | Jan CAHN |
| <u>LIOTHYRONINE SODIUM</u> | | | | | | |
| TABLET; ORAL | | | | | | |
| CYTOMEL | | | | | | |
| AB | | KING PHARMS | EQ 0.005MG BASE | N10379 001 | | Mar CFTG |
| AB | | | EQ 0.025MG BASE | N10379 002 | | Mar CTEC |
| AB | + | | EQ 0.05MG BASE | N10379 003 | | Mar CTEC |
| LIOTHYRONINE SODIUM | | | | | | |
| AB | | COASTAL PHARMS | EQ 0.005MG BASE | N90097 001 | Mar 20, 2009 | Mar NEWA |
| AB | | | EQ 0.025MG BASE | N90097 002 | Mar 20, 2009 | Mar NEWA |
| AB | | | EQ 0.05MG BASE | N90097 003 | Mar 20, 2009 | Mar NEWA |
| <u>LITHIUM CARBONATE</u> | | | | | | |
| CAPSULE; ORAL | | | | | | |
| LITHIUM CARBONATE | | | | | | |
| AB | | GLENMARK GENERICS | 150MG | N79139 001 | Feb 03, 2009 | Jan NEWA |
| AB | | | 300MG | N79139 002 | Feb 03, 2009 | Jan NEWA |
| AB | | | 600MG | N79139 003 | Feb 03, 2009 | Jan NEWA |
| <u>LOPERAMIDE HYDROCHLORIDE</u> | | | | | | |
| CAPSULE; ORAL | | | | | | |
| LOPERAMIDE HYDROCHLORIDE | | | | | | |
| | | @ SANDOZ | 2MG | N72993 001 | Aug 28, 1992 | Mar DISC |
| <u>LORAZEPAM</u> | | | | | | |
| CONCENTRATE; ORAL | | | | | | |
| LORAZEPAM | | | | | | |
| AA | | PADDOCK LABS | 2MG/ML | N79244 001 | Apr 28, 2009 | Apr NEWA |
| LORAZEPAM INTENSOL | | | | | | |
| AA | + | ROXANE | 2MG/ML | N72755 001 | Jun 28, 1991 | Apr CFTG |
| SOLUTION; ORAL | | | | | | |
| LORAZEPAM | | | | | | |
| | | @ ROXANE | 0.5MG/5ML | N74648 001 | Mar 18, 1997 | Mar DISC |
| <u>MALATHION</u> | | | | | | |
| LOTION; TOPICAL | | | | | | |
| MALATHION | | | | | | |
| AT | | SYNERX PHARMA | 0.5% | N78743 001 | Mar 06, 2009 | Feb NEWA |
| OVIDE | | | | | | |
| AT | + | TARO PHARMS NORTH | 0.5% | N18613 001 | Aug 02, 1982 | Feb CFTG |
| <u>MECHLORETHAMINE HYDROCHLORIDE</u> | | | | | | |
| INJECTABLE; INJECTION | | | | | | |
| MUSTARGEN | | | | | | |
| | + | LUNDBECK INC | 10MG/VIAL | N06695 001 | | Apr CAHN |
| <u>MECLIZINE HYDROCHLORIDE</u> | | | | | | |
| TABLET; ORAL | | | | | | |
| ANTIVERT | | | | | | |
| AA | + | PFIZER | 12.5MG | N10721 006 | | Jan CAHN |
| AA | + | | 25MG | N10721 004 | | Jan CAHN |
| AA | + | | 50MG | N10721 001 | Jan 20, 1982 | Jan CAHN |

MECLOFENAMATE SODIUM

CAPSULE; ORAL

MECLOFENAMATE SODIUM

| | | | | | |
|----------|---------------|------------|--------------|-----|------|
| @ SANDOZ | EQ 50MG BASE | N72262 001 | Nov 29, 1988 | Mar | DISC |
| @ | EQ 100MG BASE | N72263 001 | Nov 29, 1988 | Mar | DISC |

MEDROXYPROGESTERONE ACETATE

INJECTABLE; INJECTION

MEDROXYPROGESTERONE ACETATE

| | | | | | | | |
|-----|----|--------|----------|------------|--------------|-----|------|
| >A> | AB | SANDOZ | 150MG/ML | N78711 001 | May 20, 2009 | May | NEWA |
|-----|----|--------|----------|------------|--------------|-----|------|

MELOXICAM

TABLET; ORAL

MELOXICAM

| | | | | | | | |
|-----|----|---------------------|-------|------------|--------------|-----|------|
| AB | | BEJING YABAO | 7.5MG | N77933 001 | Jul 19, 2006 | Apr | CAHN |
| AB | | | 15MG | N77933 002 | Jul 19, 2006 | Apr | CAHN |
| >A> | AB | STRIDES ARCOLAB LTD | 7.5MG | N77928 001 | May 13, 2009 | May | NEWA |
| >A> | AB | | 15MG | N77928 002 | May 13, 2009 | May | NEWA |

MEPROBAMATE

TABLET; ORAL

MEPROBAMATE

| | | | | | | | |
|----|--|-------------|-------|------------|--------------|-----|------|
| AA | | ALEMBIC LTD | 200MG | N90122 001 | Feb 18, 2009 | Feb | NEWA |
| AA | | | 400MG | N90122 002 | Feb 18, 2009 | Feb | NEWA |
| | | @ IVC INDS | 400MG | N84153 001 | | Apr | CAHN |

MEQUINOL; TRETINOIN

SOLUTION; TOPICAL

SOLAGE

| | | | | | | | |
|---|--|------------------|----------|------------|--------------|-----|------|
| + | | STIEFEL LABS INC | 2%;0.01% | N20922 001 | Dec 10, 1999 | Jan | CAHN |
|---|--|------------------|----------|------------|--------------|-----|------|

MESALAMINE

TABLET, DELAYED RELEASE; ORAL

| | | | | | | | |
|-----|---|--------------------|-------|------------|--------------|-----|------|
| >A> | | ASACOL | | | | | |
| >A> | + | PROCTER AND GAMBLE | 800MG | N21830 001 | May 29, 2008 | May | CTNA |
| >D> | | MESALAMINE | | | | | |
| >D> | + | PROCTOR AND GAMBLE | 800MG | N21830 001 | May 29, 2008 | May | CTNA |

MESTRANOL; NORETHINDRONE

TABLET; ORAL-21

NORETHIN 1/50M-21

| | | | | | | |
|---|-------------|------------|------------|--------------|-----|------|
| @ | WATSON LABS | 0.05MG;1MG | N71539 001 | Apr 12, 1988 | Apr | DISC |
|---|-------------|------------|------------|--------------|-----|------|

NORETHINDRONE AND MESTRANOL

| | | | | | | |
|---|-------------|------------|------------|--------------|-----|------|
| @ | WATSON LABS | 0.05MG;1MG | N70758 001 | Jul 01, 1988 | Apr | DISC |
|---|-------------|------------|------------|--------------|-----|------|

NORINYL 1+50 21-DAY

| | | | | | | |
|---|-------------|------------|------------|--|-----|------|
| @ | WATSON LABS | 0.05MG;1MG | N13625 002 | | Apr | DISC |
|---|-------------|------------|------------|--|-----|------|

TABLET; ORAL-28

NORETHIN 1/50M-28

| | | | | | | |
|---|-------------|------------|------------|--------------|-----|------|
| @ | WATSON LABS | 0.05MG;1MG | N71540 001 | Apr 12, 1988 | Apr | DISC |
|---|-------------|------------|------------|--------------|-----|------|

NORETHINDRONE AND MESTRANOL

| | | | | | | |
|---|-------------|------------|------------|--------------|-----|------|
| @ | WATSON LABS | 0.05MG;1MG | N70759 001 | Jul 01, 1988 | Apr | DISC |
|---|-------------|------------|------------|--------------|-----|------|

NORINYL 1+50 28-DAY

| | | | | | | |
|---|-------------|------------|------------|--|-----|------|
| + | WATSON LABS | 0.05MG;1MG | N16659 001 | | Apr | CRLD |
|---|-------------|------------|------------|--|-----|------|

ORTHO-NOVUM 1/50 28

| | | | | | | |
|---|----------------------|------------|------------|--|-----|------|
| @ | ORTHO MCNEIL JANSSEN | 0.05MG;1MG | N16709 001 | | Apr | DISC |
|---|----------------------|------------|------------|--|-----|------|

METAPROTERENOL SULFATE

SOLUTION; INHALATION

ALUPENT

| | | | | | | |
|---|----------------------|------|------------|--------------|-----|------|
| @ | BOEHRINGER INGELHEIM | 0.4% | N18761 002 | Oct 10, 1986 | Feb | DISC |
| @ | | 0.6% | N18761 001 | Jun 30, 1983 | Feb | DISC |

METFORMIN HYDROCHLORIDE

TABLET; ORAL

METFORMIN HYDROCHLORIDE

| | | | | | | |
|----|-----------------|-------|------------|--------------|-----|------|
| AB | ALVOGEN | 500MG | N76033 001 | Jan 24, 2002 | Jan | CAHN |
| AB | | 850MG | N76033 002 | Jan 24, 2002 | Jan | CAHN |
| AB | | 1GM | N76033 003 | Jan 24, 2002 | Jan | CAHN |
| AB | PROVIDENT PHARM | 500MG | N77853 001 | Jul 28, 2006 | Apr | CAHN |
| AB | | 850MG | N77853 002 | Jul 28, 2006 | Apr | CAHN |
| AB | | 1GM | N77853 003 | Jul 28, 2006 | Apr | CAHN |

TABLET, EXTENDED RELEASE; ORAL

METFORMIN HYDROCHLORIDE

| | | | | | | |
|---|--------|-------|------------|--------------|-----|------|
| @ | SANDOZ | 500MG | N76223 001 | Dec 14, 2004 | Mar | DISC |
|---|--------|-------|------------|--------------|-----|------|

METFORMIN HYDROCHLORIDE; PIOGLITAZONE HYDROCHLORIDE

>A> TABLET, EXTENDED RELEASE; ORAL

>A> ACTOPLUS MET XR

| | | | | | | |
|-----|---------------|------------------|------------|--------------|-----|------|
| >A> | TAKEDA GLOBAL | 1GM;EQ 15MG BASE | N22024 001 | May 12, 2009 | May | NEWA |
| >A> | + | 1GM;EQ 30MG BASE | N22024 002 | May 12, 2009 | May | NEWA |

METHAMPHETAMINE HYDROCHLORIDE

TABLET; ORAL

DESOXYN

| | | | | | | |
|---|--------------|-----|------------|--|-----|------|
| + | LUNDBECK INC | 5MG | N05378 002 | | Apr | CAHN |
|---|--------------|-----|------------|--|-----|------|

TABLET, EXTENDED RELEASE; ORAL

DESOXYN

| | | | | | | |
|---|--------------|------|------------|--|-----|------|
| @ | LUNDBECK INC | 5MG | N05378 004 | | Apr | CAHN |
| @ | | 10MG | N05378 003 | | Apr | CAHN |
| @ | | 15MG | N05378 005 | | Apr | CAHN |

METHIMAZOLE

TABLET; ORAL

METHIMAZOLE

| | | | | | | | | |
|-----|----|---|----------|------|------------|--------------|-----|------|
| >D> | AB | + | GENPHARM | 10MG | N40350 002 | Mar 29, 2000 | May | CRLD |
| >A> | AB | | | 10MG | N40350 002 | Mar 29, 2000 | May | CRLD |

METHOCARBAMOL

TABLET; ORAL

METHOCARBAMOL

| | | | | | | |
|---|----------------|-------|------------|--|-----|------|
| @ | SOLCO HLTHCARE | 500MG | N86989 001 | | Jan | CAHN |
| @ | | 750MG | N86988 001 | | Jan | CAHN |

METHOTREXATE SODIUM

INJECTABLE; INJECTION

METHOTREXATE SODIUM PRESERVATIVE FREE

| | | | | | | |
|----|---------------|--------------------------------------|------------|--------------|-----|------|
| AP | EBEWE PARENTA | EQ 50MG BASE/2ML (EQ 25MG BASE/ML) | N90039 001 | Mar 31, 2009 | Mar | NEWA |
| AP | | EQ 250MG BASE/10ML (EQ 25MG BASE/ML) | N90039 002 | Mar 31, 2009 | Mar | NEWA |
| AP | | EQ 1GM BASE/40ML (EQ 25MG BASE/ML) | N90029 001 | Mar 31, 2009 | Mar | NEWA |

METHYCLOTHIAZIDE

TABLET; ORAL

ENDURON

| | | | | | |
|--------|-------|------------|--|-----|------|
| ABBOTT | 2.5MG | N12524 001 | | Mar | CTEC |
|--------|-------|------------|--|-----|------|

METHYCLOTHIAZIDE

| | | | | | |
|----------|-------|------------|--------------|-----|------|
| @ SANDOZ | 2.5MG | N89835 001 | Aug 18, 1988 | Mar | DISC |
|----------|-------|------------|--------------|-----|------|

| | | | | | |
|---|-----|------------|--------------|-----|------|
| @ | 5MG | N89837 001 | Aug 18, 1988 | Mar | DISC |
|---|-----|------------|--------------|-----|------|

METHYLDOPA

TABLET; ORAL

METHYLDOPA

| | | | | | |
|----------|-------|------------|--------------|-----|------|
| @ SANDOZ | 125MG | N71700 001 | Mar 02, 1988 | Mar | DISC |
|----------|-------|------------|--------------|-----|------|

| | | | | | |
|---|-------|------------|--------------|-----|------|
| @ | 250MG | N18934 001 | Jun 29, 1984 | Mar | DISC |
|---|-------|------------|--------------|-----|------|

| | | | | | |
|---|-------|------------|--------------|-----|------|
| @ | 500MG | N18934 002 | Jun 29, 1984 | Mar | DISC |
|---|-------|------------|--------------|-----|------|

METHYLPREDNISOLONE ACETATE

INJECTABLE; INJECTION

METHYLPREDNISOLONE ACETATE

| | | | | | | |
|----|--------|---------|------------|--------------|-----|------|
| AB | SANDOZ | 40MG/ML | N40719 001 | Jan 29, 2009 | Jan | NEWA |
|----|--------|---------|------------|--------------|-----|------|

| | | | | | | |
|----|--|---------|------------|--------------|-----|------|
| AB | | 40MG/ML | N40794 001 | Mar 05, 2009 | Feb | NEWA |
|----|--|---------|------------|--------------|-----|------|

| | | | | | | |
|----|--|---------|------------|--------------|-----|------|
| AB | | 80MG/ML | N40719 002 | Jan 29, 2009 | Jan | NEWA |
|----|--|---------|------------|--------------|-----|------|

| | | | | | | |
|----|--|---------|------------|--------------|-----|------|
| AB | | 80MG/ML | N40794 002 | Mar 05, 2009 | Feb | NEWA |
|----|--|---------|------------|--------------|-----|------|

METOCLOPRAMIDE HYDROCHLORIDE

SOLUTION; ORAL

METOCLOPRAMIDE HYDROCHLORIDE

| | | | | | | |
|----|------------|-----------------|------------|--------------|-----|------|
| AA | VISTAPHARM | EQ 5MG BASE/5ML | N75051 001 | Jan 26, 2001 | Mar | CMFD |
|----|------------|-----------------|------------|--------------|-----|------|

TABLET; ORAL

METOCLOPRAMIDE HYDROCHLORIDE

| | | | | | |
|----------|-------------|------------|--------------|-----|------|
| @ SANDOZ | EQ 5MG BASE | N74478 001 | Oct 05, 1995 | Mar | DISC |
|----------|-------------|------------|--------------|-----|------|

| | | | | | |
|---|--------------|------------|--------------|-----|------|
| @ | EQ 10MG BASE | N72215 001 | Jan 30, 1990 | Mar | DISC |
|---|--------------|------------|--------------|-----|------|

METOPROLOL TARTRATE

TABLET; ORAL

METOPROLOL TARTRATE

| | | | | | |
|------------------|------|------------|--------------|-----|------|
| @ SOLCO HLTHCARE | 50MG | N74453 001 | Apr 27, 1995 | Jan | CAHN |
|------------------|------|------------|--------------|-----|------|

| | | | | | |
|---|-------|------------|--------------|-----|------|
| @ | 100MG | N74453 002 | Apr 27, 1995 | Jan | CAHN |
|---|-------|------------|--------------|-----|------|

METRONIDAZOLE

TABLET; ORAL

METRONIDAZOLE

| | | | | | | |
|----|-------------|-------|------------|--------------|-----|------|
| AB | ALEMBIC LTD | 250MG | N79067 001 | Mar 13, 2009 | Mar | NEWA |
|----|-------------|-------|------------|--------------|-----|------|

| | | | | | | |
|----|--|-------|------------|--------------|-----|------|
| AB | | 500MG | N79067 002 | Mar 13, 2009 | Mar | NEWA |
|----|--|-------|------------|--------------|-----|------|

| | | | | | |
|----------|-------|------------|--------------|-----|------|
| @ SANDOZ | 250MG | N18740 001 | Oct 22, 1982 | Mar | DISC |
|----------|-------|------------|--------------|-----|------|

| | | | | | |
|---|-------|------------|--------------|-----|------|
| @ | 500MG | N18740 002 | Oct 22, 1982 | Mar | DISC |
|---|-------|------------|--------------|-----|------|

MEXILETINE HYDROCHLORIDE

CAPSULE; ORAL

MEXILETINE HYDROCHLORIDE

| | | | | | |
|----------|-------|------------|--------------|-----|------|
| @ SANDOZ | 150MG | N74450 001 | May 16, 1996 | Mar | DISC |
|----------|-------|------------|--------------|-----|------|

| | | | | | |
|---|-------|------------|--------------|-----|------|
| @ | 200MG | N74450 002 | May 16, 1996 | Mar | DISC |
|---|-------|------------|--------------|-----|------|

| | | | | | |
|---|-------|------------|--------------|-----|------|
| @ | 250MG | N74450 003 | May 16, 1996 | Mar | DISC |
|---|-------|------------|--------------|-----|------|

MICONAZOLE NITRATE; PETROLATUM, WHITE; ZINC OXIDE

OINTMENT; TOPICAL

VUSION

| | | | | | | |
|---|------------------|------------------|------------|--------------|-----|------|
| + | STIEFEL LABS INC | 0.25%;81.35%;15% | N21026 001 | Feb 16, 2006 | Jan | CAHN |
|---|------------------|------------------|------------|--------------|-----|------|

MILNACIPRAN HYDROCHLORIDE

TABLET; ORAL

SAVELLA

| | | | | | | |
|---|--------------------|--------|------------|--------------|-----|------|
| | CYPRESS BIOSCIENCE | 12.5MG | N22256 001 | Jan 14, 2009 | Jan | NEWA |
| | | 25MG | N22256 002 | Jan 14, 2009 | Jan | NEWA |
| | | 50MG | N22256 003 | Jan 14, 2009 | Jan | NEWA |
| + | | 100MG | N22256 004 | Jan 14, 2009 | Jan | NEWA |

MINOCYCLINE HYDROCHLORIDE

INJECTABLE; INJECTION

MINOCIN

| | | | | | | |
|-----|--------------------|--------------------|------------|--|-----|------|
| >D> | @ TRIAX PHARMS LLC | EQ 100MG BASE/VIAL | N50444 001 | | May | CMFD |
| >A> | + | EQ 100MG BASE/VIAL | N50444 001 | | May | CMFD |

TABLET, EXTENDED RELEASE; ORAL

MINOCYCLINE HYDROCHLORIDE

| | | | | | | |
|----|----------------|---------------|------------|--------------|-----|------|
| AB | BARR | EQ 45MG BASE | N65485 001 | Mar 17, 2009 | Mar | NEWA |
| AB | | EQ 90MG BASE | N65485 002 | Mar 17, 2009 | Mar | NEWA |
| AB | | EQ 135MG BASE | N65485 003 | Mar 17, 2009 | Mar | NEWA |
| AB | IMPAX LABS INC | EQ 45MG BASE | N90024 001 | Feb 03, 2009 | Jan | NEWA |
| AB | | EQ 90MG BASE | N90024 002 | Feb 03, 2009 | Jan | NEWA |
| AB | | EQ 135MG BASE | N90024 003 | Feb 03, 2009 | Jan | NEWA |
| | SOLODYN | | | | | |
| AB | MEDICIS | EQ 45MG BASE | N50808 001 | May 08, 2006 | Jan | CFTG |
| AB | | EQ 90MG BASE | N50808 002 | May 08, 2006 | Jan | CFTG |
| AB | + | EQ 135MG BASE | N50808 003 | May 08, 2006 | Jan | CFTG |

MITOXANTRONE HYDROCHLORIDE

INJECTABLE; INJECTION

MITOXANTRONE HYDROCHLORIDE

| | | | | | | |
|----|-------------|------------------------------------|------------|--------------|-----|------|
| AP | GENERAMEDIX | EQ 20MG BASE/10ML (EQ 2MG BASE/ML) | N78980 001 | Apr 13, 2009 | Mar | NEWA |
| AP | | EQ 30MG BASE/15ML (EQ 2MG BASE/ML) | N78980 002 | Apr 13, 2009 | Mar | NEWA |

MIVACURIUM CHLORIDE

INJECTABLE; INJECTION

MIVACURIUM CHLORIDE

| | | | | | | |
|---|---------------|----------------|------------|--------------|-----|------|
| + | EBEWE PARENTA | EQ 2MG BASE/ML | N78562 001 | Apr 30, 2009 | Apr | NEWA |
|---|---------------|----------------|------------|--------------|-----|------|

MORPHINE SULFATE

CAPSULE, EXTENDED RELEASE; ORAL

KADIAN

| | | | | | | |
|---|-------------------|------|------------|--------------|-----|------|
| + | ACTAVIS ELIZABETH | 10MG | N20616 008 | Apr 20, 2007 | Feb | CRLD |
| + | | 80MG | N20616 006 | Oct 27, 2006 | Feb | CRLD |

TABLET, EXTENDED RELEASE; ORAL

MORPHINE SULFATE

| | | | | | | |
|--|---------------|-------|------------|--------------|-----|------|
| | @ AB GENERICS | 15MG | N74862 001 | Jul 07, 1998 | Apr | DISC |
| | @ | 30MG | N74862 002 | Jul 07, 1998 | Apr | DISC |
| | @ | 60MG | N74862 003 | Jul 07, 1998 | Apr | DISC |
| | @ | 100MG | N74769 001 | Jul 02, 1998 | Apr | DISC |

TABLET, EXTENDED RELEASE; ORAL

MORPHINE SULFATE

| | | | | | |
|---------------|-------|------------|--------------|-----|------|
| @ AB GENERICS | 200MG | N74769 002 | Jul 02, 1998 | Apr | DISC |
|---------------|-------|------------|--------------|-----|------|

MYCOPHENOLATE MOFETIL

CAPSULE; ORAL

MYCOPHENOLATE MOFETIL

| | | | | | | |
|----|----------------------|-------|------------|--------------|-----|------|
| AB | ACCORD HLTHCARE INC | 250MG | N90253 001 | May 04, 2009 | Apr | NEWA |
| AB | APOTEX CORP | 250MG | N90419 001 | Apr 22, 2009 | Apr | NEWA |
| AB | MYLAN | 250MG | N65520 001 | May 04, 2009 | Apr | NEWA |
| AB | TEVA PHARMS | 250MG | N65491 001 | May 06, 2009 | Apr | NEWA |
| AB | ZYDUS PHARMS USA INC | 250MG | N65433 001 | May 04, 2009 | Apr | NEWA |

TABLET; ORAL

MYCOPHENOLATE MOFETIL

| | | | | | | |
|----|----------------------|-------|------------|--------------|-----|------|
| AB | ACCORD HLTHCARE | 500MG | N65416 001 | May 04, 2009 | Apr | NEWA |
| AB | APOTEX | 500MG | N90499 001 | Apr 22, 2009 | Apr | NEWA |
| AB | MYLAN | 500MG | N65521 001 | May 04, 2009 | Apr | NEWA |
| AB | TEVA PHARMS | 500MG | N65457 001 | May 04, 2009 | Apr | NEWA |
| AB | ZYDUS PHARMS USA INC | 500MG | N65477 001 | May 04, 2009 | Apr | NEWA |

NABUMETONE

TABLET; ORAL

NABUMETONE

| | | | | | | |
|----|-------------------|-------|------------|--------------|-----|------|
| AB | ACTAVIS ELIZABETH | 500MG | N79093 001 | Feb 27, 2009 | Feb | NEWA |
| AB | | 750MG | N79093 002 | Feb 27, 2009 | Feb | NEWA |
| | @ SANDOZ | 500MG | N75590 001 | Feb 25, 2002 | Mar | DISC |
| | @ | 750MG | N75590 002 | Feb 25, 2002 | Mar | DISC |

NALTREXONE HYDROCHLORIDE

TABLET; ORAL

NALTREXONE HYDROCHLORIDE

| | | | | | | |
|-----|----------------|-------|------------|--------------|-----|------|
| >D> | + MALLINCKRODT | 100MG | N76264 003 | Mar 22, 2002 | May | CRLD |
| >A> | | 100MG | N76264 003 | Mar 22, 2002 | May | CRLD |

NAPROXEN SODIUM

TABLET, EXTENDED RELEASE; ORAL

NAPRELAN

| | | | | | | |
|---|------------|---------------|------------|--------------|-----|------|
| + | STAT TRADE | EQ 375MG BASE | N20353 001 | Jan 05, 1996 | Mar | CTEC |
| + | | EQ 500MG BASE | N20353 002 | Jan 05, 1996 | Mar | CTEC |

NAPROXEN SODIUM

| | | | | | | |
|---|---------------------|---------------|------------|--------------|-----|------|
| @ | WATSON LABS FLORIDA | EQ 375MG BASE | N75416 002 | Apr 23, 2003 | Mar | DISC |
| @ | | EQ 500MG BASE | N75416 001 | Aug 27, 2002 | Mar | DISC |

NIFEDIPINE

CAPSULE; ORAL

PROCARDIA

| | | | | | | |
|----|----------|------|------------|--------------|-----|------|
| AB | + PFIZER | 10MG | N18482 001 | | Apr | CRLD |
| | @ | 20MG | N18482 002 | Jul 24, 1986 | Apr | DISC |

NIMODIPINE

CAPSULE; ORAL

NIMODIPINE

| | | | | | | |
|----|----------------|------|------------|--------------|-----|------|
| AB | + BARR | 30MG | N77811 001 | May 02, 2007 | Mar | CRLD |
| | NIMOTOP | | | | | |
| | @ BAYER PHARMS | 30MG | N18869 001 | Dec 28, 1988 | Feb | DISC |

NITISINONE

CAPSULE; ORAL

ORFADIN

| | | | | | | |
|---|----------|------|------------|--------------|-----|------|
| | RARE DIS | 2MG | N21232 001 | Jan 18, 2002 | Mar | CAHN |
| | | 5MG | N21232 002 | Jan 18, 2002 | Mar | CAHN |
| + | | 10MG | N21232 003 | Jan 18, 2002 | Mar | CAHN |

NITROFURANTOIN, MACROCRYSTALLINE

CAPSULE; ORAL

NITROFURANTOIN

| | | | | | | |
|--|----------|-------|------------|--------------|-----|------|
| | @ SANDOZ | 25MG | N74336 001 | Jan 25, 1995 | Mar | DISC |
| | @ | 50MG | N74336 002 | Jan 25, 1995 | Mar | DISC |
| | @ | 100MG | N74336 003 | Jan 25, 1995 | Mar | DISC |

OFLOXACIN

SOLUTION/DROPS; OPHTHALMIC

OFLOXACIN

| | | | | | | |
|----|---------|------|------------|--------------|-----|------|
| AT | FDC LTD | 0.3% | N78559 001 | Feb 25, 2009 | Feb | NEWA |
|----|---------|------|------------|--------------|-----|------|

TABLET; ORAL

FLOXIN

| | | | | | | |
|--|------------------------|-------|------------|--------------|-----|------|
| | @ ORTHO MCNEIL JANSSEN | 200MG | N19735 001 | Dec 28, 1990 | Mar | DISC |
| | @ | 300MG | N19735 002 | Dec 28, 1990 | Mar | DISC |
| | @ | 400MG | N19735 003 | Dec 28, 1990 | Mar | DISC |

OLSALAZINE SODIUM

CAPSULE; ORAL

DIPENTUM

| | | | | | | |
|---|--------------|-------|------------|--------------|-----|------|
| + | ALAVEN PHARM | 250MG | N19715 001 | Jul 31, 1990 | Apr | CAHN |
|---|--------------|-------|------------|--------------|-----|------|

OMEPRAZOLE

CAPSULE, DELAYED REL PELLETS; ORAL

OMEPRAZOLE

| | | | | | | |
|----|--------------------|------|------------|--------------|-----|------|
| AB | DR REDDYS LABS | 40MG | N78490 001 | Apr 17, 2009 | Mar | NEWA |
| AB | DR REDDYS LABS LTD | 10MG | N78693 001 | Mar 16, 2009 | Mar | NEWA |
| AB | | 20MG | N78693 002 | Mar 16, 2009 | Mar | NEWA |
| AB | KREMERS URBAN DEV | 40MG | N75410 003 | Jan 23, 2009 | Jan | NEWA |

OMEPRAZOLE MAGNESIUM

CAPSULE, DELAYED RELEASE; ORAL

OMEPRAZOLE MAGNESIUM

| | | | | | | |
|-----|--------------------|------|------------|--------------|-----|------|
| >A> | DR REDDYS LABS LTD | 20MG | N78878 001 | Jun 05, 2009 | May | NEWA |
|-----|--------------------|------|------------|--------------|-----|------|

ONDANSETRON HYDROCHLORIDE

INJECTABLE; INJECTION

ONDANSETRON HYDROCHLORIDE AND DEXTROSE IN PLASTIC CONTAINER

| | | | | | | |
|----|--------------|-------------------|------------|--------------|-----|------|
| AP | BEDFORD LABS | EQ 0.64MG BASE/ML | N78291 001 | Apr 13, 2009 | Mar | NEWA |
|----|--------------|-------------------|------------|--------------|-----|------|

OXACILLIN SODIUM

INJECTABLE; INJECTION

OXACILLIN SODIUM

| | | | | | | |
|--|---------------|--------------------|------------|--------------|-----|------|
| | @ WATSON LABS | EQ 250MG BASE/VIAL | N62856 001 | Oct 26, 1988 | Apr | DISC |
| | @ | EQ 500MG BASE/VIAL | N62856 002 | Oct 26, 1988 | Apr | DISC |
| | @ | EQ 1GM BASE/VIAL | N62856 003 | Oct 26, 1988 | Apr | DISC |
| | @ | EQ 2GM BASE/VIAL | N62856 004 | Oct 26, 1988 | Apr | DISC |
| | @ | EQ 4GM BASE/VIAL | N62856 005 | Oct 26, 1988 | Apr | DISC |

OXAPROZIN

TABLET; ORAL

OXAPROZIN

| | | | | | |
|----------|-------|------------|--------------|-----|------|
| @ SANDOZ | 600MG | N75850 001 | Apr 27, 2001 | Mar | DISC |
|----------|-------|------------|--------------|-----|------|

OXYBUTYNIN CHLORIDE

GEL; TRANSDERMAL

GELNIQUE

| | | | | | |
|---------------|-------------------|------------|--------------|-----|------|
| + WATSON LABS | 10%(100MG/PACKET) | N22204 001 | Jan 27, 2009 | Mar | CTNA |
|---------------|-------------------|------------|--------------|-----|------|

OXYBUTYNIN CHLORIDE

| | | | | | |
|---------------|-------------------|------------|--------------|-----|------|
| + WATSON LABS | 10%(100MG/PACKET) | N22204 001 | Jan 27, 2009 | Jan | NEWA |
|---------------|-------------------|------------|--------------|-----|------|

TABLET, EXTENDED RELEASE; ORAL

OXYBUTYNIN CHLORIDE

| | | | | | | |
|----|----------------|------|------------|--------------|-----|------|
| AB | OSMOTICA PHARM | 5MG | N78503 001 | Feb 04, 2009 | Jan | NEWA |
| AB | | 10MG | N78503 002 | Feb 04, 2009 | Jan | NEWA |
| AB | | 15MG | N78503 003 | Feb 04, 2009 | Jan | NEWA |

OXYCODONE HYDROCHLORIDE

TABLET; ORAL

OXYCODONE HYDROCHLORIDE

| | | | | | | |
|----|--------------------|------|------------|--------------|-----|------|
| AB | SUN PHARM INDS INC | 5MG | N90659 001 | Apr 10, 2009 | Mar | NEWA |
| AB | | 15MG | N90659 002 | Apr 10, 2009 | Mar | NEWA |
| AB | | 30MG | N90659 003 | Apr 10, 2009 | Mar | NEWA |
| AB | VINTAGE PHARMS | 5MG | N77712 003 | Mar 02, 2009 | Mar | NEWA |

ROXICODONE

| | | | | | | |
|--------|-----------------|-----|------------|--------------|-----|------|
| >A> AB | XANODYNE PHARMS | 5MG | N21011 003 | May 15, 2009 | May | NEWA |
|--------|-----------------|-----|------------|--------------|-----|------|

PAMIDRONATE DISODIUM

INJECTABLE; INJECTION

PAMIDRONATE DISODIUM

| | | | | | | |
|----|-------------|-----------|------------|--------------|-----|------|
| AP | GENERAMEDIX | 30MG/VIAL | N78300 001 | Mar 10, 2009 | Feb | NEWA |
| AP | | 90MG/VIAL | N78300 002 | Mar 10, 2009 | Feb | NEWA |

PANCRELIPASE (AMYLASE;LIPASE;PROTEASE)

CAPSULE; ORAL

CREON

SOLVAY

| | | | | | |
|---|--|------------|--------------|-----|------|
| | 30,000USP UNITS;6,000USP UNITS;19,000USP UNITS | N20725 001 | Apr 30, 2009 | Apr | NEWA |
| | 60,000USP UNITS;12,000USP UNITS;38,000USP UNITS | N20725 002 | Apr 30, 2009 | Apr | NEWA |
| + | 120,000USP UNITS;24,000USP UNITS;76,000USP UNITS | N20725 003 | Apr 30, 2009 | Apr | NEWA |

PANCURONIUM BROMIDE

INJECTABLE; INJECTION

PANCURONIUM BROMIDE

@ HOSPIRA

2MG/ML

| | | | |
|------------|--------------|-----|------|
| N72321 001 | Jan 19, 1989 | Apr | DISC |
|------------|--------------|-----|------|

PANTOPRAZOLE SODIUM

TABLET, DELAYED RELEASE; ORAL

PANTOPRAZOLE SODIUM

| | | | | | | |
|----|---------------|--------------|------------|--------------|-----|------|
| AB | KUDCO IRELAND | EQ 20MG BASE | N78281 001 | Mar 17, 2009 | Mar | NEWA |
| AB | | EQ 40MG BASE | N78281 002 | Mar 17, 2009 | Mar | NEWA |

PENICILLIN V POTASSIUM

FOR SOLUTION; ORAL

PENICILLIN-VK

| | | | | | | | |
|----|---|-------------|-------------------|------------|--|-----|------|
| AA | + | TEVA | EQ 250MG BASE/5ML | N60456 002 | | Apr | CRLD |
| | | VEETIDS | | | | | |
| | | @ APOTHECON | EQ 125MG BASE/5ML | N61410 001 | | Mar | DISC |
| | | @ | EQ 250MG BASE/5ML | N61410 002 | | Mar | DISC |

PENTAMIDINE ISETHIONATE

FOR SOLUTION; INHALATION

NEBUPENT

| | | | | | | | |
|-----|--|------------|------------|------------|--------------|-----|------|
| >D> | | APP PHARMS | 600MG/VIAL | N19887 002 | Mar 22, 1996 | May | DISC |
| >A> | | @ | 600MG/VIAL | N19887 002 | Mar 22, 1996 | May | DISC |

PHENDIMETRAZINE TARTRATE

| | | | | | | | |
|-----|---|--------------------------|------|------------|--|-----|------|
| >D> | | CAPSULE; ORAL | | | | | |
| >D> | | PHENDIMETRAZINE TARTRATE | | | | | |
| >D> | + | SANDOZ | 35MG | N85695 001 | | May | DISC |
| >A> | | @ | 35MG | N85695 001 | | May | DISC |

PHENYTOIN

SUSPENSION; ORAL

PHENYTOIN

| | | | | | | | |
|----|--|--------------|-----------|------------|--------------|-----|------|
| AB | | WOCKHARDT EU | 125MG/5ML | N40420 001 | Apr 19, 2002 | Apr | CAHN |
|----|--|--------------|-----------|------------|--------------|-----|------|

PHENYTOIN SODIUM

CAPSULE; ORAL

PROMPT PHENYTOIN SODIUM

@ IVAX PHARMS

100MG PROMPT

N80259 001

Jan DISC

PILOCARPINE HYDROCHLORIDE

TABLET; ORAL

PILOCARPINE HYDROCHLORIDE

| | | | | | | | |
|----|--|---------|-------|------------|--------------|-----|------|
| AB | | LANNETT | 7.5MG | N77220 002 | May 06, 2009 | Apr | NEWA |
|----|--|---------|-------|------------|--------------|-----|------|

PINDOLOL

TABLET; ORAL

PINDOLOL

@ SANDOZ

5MG

N73608 001 Mar 29, 1993 Mar DISC

@

10MG

N73609 001 Mar 29, 1993 Mar DISC

POLYETHYLENE GLYCOL 3350

FOR SOLUTION; ORAL

POLYETHYLENE GLYCOL 3350

| | | | | | | | |
|----|--|---------------|---------------|------------|--------------|-----|------|
| AA | | GAVIS PHARMS | 17GM/SCOOPFUL | N77736 001 | May 26, 2006 | Jan | CAHN |
| | | @ TEVA PHARMS | 17GM/SCOOPFUL | N77445 001 | May 04, 2006 | Jan | DISC |

POLYETHYLENE GLYCOL 3350; POTASSIUM CHLORIDE; SODIUM BICARBONATE; SODIUM CHLORIDE

FOR SOLUTION; ORAL

PEG-3350; POTASSIUM CHLORIDE; SODIUM BICARBONATE; SODIUM CHLORIDE

| | | | | | | | |
|-----|----|----------------|--|------------|--------------|-----|------|
| >A> | AA | NOVEL LABS INC | 420GM/BOT;1.48GM/BOT;5.72GM/BOT;1 1.2GM/BOT | N90019 001 | May 27, 2009 | May | NEWA |
|-----|----|----------------|--|------------|--------------|-----|------|

POLYETHYLENE GLYCOL 3350; POTASSIUM CHLORIDE; SODIUM BICARBONATE; SODIUM CHLORIDE; SODIUM SULFATE ANHYDROUS

FOR SOLUTION; ORAL

GOLYTELY

| | | | | | | | | |
|-----|----|---|---------------------------|---|------------|--------------|-----|------|
| >D> | AA | + | BRAINTREE | 227.1GM/PACKET;2.82GM/PACKET;6.36 GM/PACKET;5.53GM/PACKET;21.5GM/PACKET | N19011 002 | Jun 02, 1992 | May | CTEC |
| >A> | | + | | 227.1GM/PACKET;2.82GM/PACKET;6.36 GM/PACKET;5.53GM/PACKET;21.5GM/PACKET | N19011 002 | Jun 02, 1992 | May | CTEC |
| >D> | | + | | 236GM/BOT;2.97GM/BOT;6.74GM/BOT;5.86GM/BOT;22.74GM/BOT | N19011 001 | Jul 13, 1984 | May | CFTG |
| >A> | AA | + | | 236GM/BOT;2.97GM/BOT;6.74GM/BOT;5.86GM/BOT;22.74GM/BOT | N19011 001 | Jul 13, 1984 | May | CFTG |
| | | + | | 236GM/BOT;2.97GM/BOT;6.74GM/BOT;5.86GM/BOT;22.74GM/BOT | N19011 001 | Jul 13, 1984 | Mar | CTEC |
| >A> | | | PEG 3350 AND ELECTROLYTES | | | | | |
| >A> | AA | | NOVEL LABS INC | 236GM/BOT;2.97GM/BOT;6.74GM/BOT;5.86GM/BOT;22.74GM/BOT | N90231 001 | Jun 01, 2009 | May | NEWA |
| >A> | AA | | | 240GM/BOT;2.98GM/BOT;6.72GM/BOT;5.84GM/BOT;22.72GM/BOT | N90186 001 | Jun 01, 2009 | May | NEWA |

FOR SUSPENSION; ORAL

CO-LAV

@ BOCA PHARMA

240GM/BOT;2.98GM/BOT;6.72GM/BOT;5.84GM/BOT;22.72GM/BOT

N73428 001 Jan 28, 1992 Mar DISC

GO-EVAC

@ BOCA PHARMA

236GM/BOT;2.97GM/BOT;6.74GM/BOT;5.86GM/BOT;22.74GM/BOT

N73433 001 Apr 28, 1992 Mar DISC

POTASSIUM CHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL

MICRO-K

@ KV PHARM

8MEQ

N18238 001

Feb DISC

MICRO-K 10

@ KV PHARM

10MEQ

N18238 002 May 14, 1984 Feb DISC

POTASSIUM CHLORIDE

@ KV PHARM

10MEQ

N70980 001 Feb 17, 1987 Feb DISC

WATSON LABS FLORIDA

8MEQ

N77419 001 Jun 02, 2008 Feb CTEC

+

10MEQ

N77419 002 Jun 02, 2008 Feb CRLD

INJECTABLE; INJECTION

POTASSIUM CHLORIDE

@ HOSPIRA

1.5MEQ/ML

N83345 001

Apr DISC

TABLET, EXTENDED RELEASE; ORAL

POTASSIUM CHLORIDE

| | | | | | | | | |
|-----|----|---|---------------------|-------|------------|--------------|-----|------|
| >D> | AB | + | WATSON LABS FLORIDA | 10MEQ | N75604 001 | Apr 10, 2002 | May | CRLD |
| >A> | AB | | | 10MEQ | N75604 001 | Apr 10, 2002 | May | CRLD |
| | AB | + | | 10MEQ | N75604 001 | Apr 10, 2002 | Jan | CRLD |

PRAZOSIN HYDROCHLORIDE

CAPSULE; ORAL

PRAZOSIN HYDROCHLORIDE

@ SANDOZ

EQ 1MG BASE

N72576 001 May 16, 1989 Mar DISC

@

EQ 2MG BASE

N72577 001 May 16, 1989 Mar DISC

@

EQ 5MG BASE

N72578 001 May 16, 1989 Mar DISC

PREDNISOLONE SODIUM PHOSPHATE

SOLUTION; ORAL

PREDNISOLONE SODIUM PHOSPHATE

| | | | | | | | | |
|-----|----|--|---------------|------------------|------------|--------------|-----|------|
| | AA | | AMNEAL PHARMS | EQ 15MG BASE/5ML | N78345 001 | Mar 10, 2009 | Feb | NEWA |
| >A> | AA | | VINTAGE | EQ 15MG BASE/5ML | N79010 001 | May 26, 2009 | May | NEWA |

SOLUTION/DROPS; OPHTHALMIC

PREDNISOLONE SODIUM PHOSPHATE

| | | | | | |
|-------------------|--------------------|------------|--------------|-----|------|
| @ BAUSCH AND LOMB | EQ 0.11% PHOSPHATE | N40065 001 | Jul 29, 1994 | Apr | DISC |
|-------------------|--------------------|------------|--------------|-----|------|

PREDNISONE

TABLET; ORAL

PREDNISONE

| | | | | | |
|----------|------|------------|--------------|-----|------|
| @ SANDOZ | 10MG | N89983 001 | Jan 12, 1989 | Mar | DISC |
|----------|------|------------|--------------|-----|------|

| | | | | | |
|---|------|------------|--------------|-----|------|
| @ | 50MG | N89984 001 | Jan 12, 1989 | Mar | DISC |
|---|------|------------|--------------|-----|------|

PRILOCAINE HYDROCHLORIDE

INJECTABLE; INJECTION

CITANEST PLAIN DENTAL

| | | | | | |
|------------------|----|------------|--|-----|------|
| + DENTSPLY PHARM | 4% | N21382 001 | | Apr | CTNA |
|------------------|----|------------|--|-----|------|

PROMETHAZINE HYDROCHLORIDE

SYRUP; ORAL

PROMETHAZINE HYDROCHLORIDE

| | | | | | |
|-----------------------|------------|------------|--------------|-----|------|
| AA SUN PHARM INDS INC | 6.25MG/5ML | N40891 001 | Mar 13, 2009 | Mar | NEWA |
|-----------------------|------------|------------|--------------|-----|------|

TABLET; ORAL

PROMETHAZINE HYDROCHLORIDE

| | | | | | |
|---------------|--------|------------|--------------|-----|------|
| >A> AB SANDOZ | 12.5MG | N84176 002 | May 22, 2009 | May | NEWA |
|---------------|--------|------------|--------------|-----|------|

PROPOXYPHENE HYDROCHLORIDE

CAPSULE; ORAL

DOLENE

| | | | | | |
|------------------------|------|------------|--|-----|------|
| AA HERITAGE PHARMS INC | 65MG | N80530 001 | | Mar | CMFD |
|------------------------|------|------------|--|-----|------|

PROPRANOLOL HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL

PROPRANOLOL HYDROCHLORIDE

| | | | | | |
|-----------------|------|------------|--------------|-----|------|
| AB UPSHER SMITH | 60MG | N78311 001 | Mar 06, 2009 | Feb | NEWA |
|-----------------|------|------------|--------------|-----|------|

| | | | | | |
|----|------|------------|--------------|-----|------|
| AB | 80MG | N78311 002 | Mar 06, 2009 | Feb | NEWA |
|----|------|------------|--------------|-----|------|

| | | | | | |
|----|-------|------------|--------------|-----|------|
| AB | 120MG | N78311 003 | Mar 06, 2009 | Feb | NEWA |
|----|-------|------------|--------------|-----|------|

| | | | | | |
|----|-------|------------|--------------|-----|------|
| AB | 160MG | N78311 004 | Mar 06, 2009 | Feb | NEWA |
|----|-------|------------|--------------|-----|------|

TABLET; ORAL

PROPRANOLOL HYDROCHLORIDE

| | | | | | |
|----------|------|------------|--------------|-----|------|
| @ SANDOZ | 10MG | N70663 001 | Jun 13, 1986 | Mar | DISC |
|----------|------|------------|--------------|-----|------|

| | | | | | |
|---|------|------------|--------------|-----|------|
| @ | 20MG | N70664 001 | Jun 13, 1986 | Mar | DISC |
|---|------|------------|--------------|-----|------|

| | | | | | |
|---|------|------------|--------------|-----|------|
| @ | 40MG | N70665 001 | Jun 13, 1986 | Mar | DISC |
|---|------|------------|--------------|-----|------|

| | | | | | |
|---|------|------------|--------------|-----|------|
| @ | 60MG | N70666 001 | Oct 10, 1986 | Mar | DISC |
|---|------|------------|--------------|-----|------|

| | | | | | |
|---|------|------------|--------------|-----|------|
| @ | 80MG | N70667 001 | Jun 13, 1986 | Mar | DISC |
|---|------|------------|--------------|-----|------|

PSEUDOEPHEDRINE HYDROCHLORIDE; TRIPROLIDINE HYDROCHLORIDE

TABLET; ORAL

CORPHED

| | | | | | |
|----------|------------|------------|--------------|-----|------|
| @ SANDOZ | 60MG;2.5MG | N88602 001 | Apr 11, 1985 | Mar | DISC |
|----------|------------|------------|--------------|-----|------|

PSEUDOEPHEDRINE HYDROCHLORIDE AND TRIPROLIDINE HYDROCHLORIDE

| | | | | | |
|----------|------------|------------|--------------|-----|------|
| + SANDOZ | 60MG;2.5MG | N88193 001 | May 17, 1983 | Mar | CTEC |
|----------|------------|------------|--------------|-----|------|

RAMIPRIL

CAPSULE; ORAL

RAMIPRIL

| | | | | | |
|------------|-----|------------|--------------|-----|------|
| AB RANBAXY | 5MG | N78849 001 | Mar 06, 2009 | Feb | NEWA |
|------------|-----|------------|--------------|-----|------|

| | | | | | |
|----|------|------------|--------------|-----|------|
| AB | 10MG | N78849 002 | Mar 06, 2009 | Feb | NEWA |
|----|------|------------|--------------|-----|------|

RANITIDINE HYDROCHLORIDE

INJECTABLE; INJECTION

RANITIDINE HYDROCHLORIDE

| | | | | | |
|-----------|-----------------|------------|--------------|-----|------|
| @ BEDFORD | EQ 25MG BASE/ML | N74764 001 | Nov 19, 2004 | Apr | DISC |
|-----------|-----------------|------------|--------------|-----|------|

SYRUP; ORAL

RANITIDINE HYDROCHLORIDE

| | | | | | | | |
|-----|---------------|--------------------|-----------------|--------------|--------------|------|------|
| AA | AMNEAL PHARMS | EQ 15MG BASE/ML | N78312 001 | Sep 02, 2008 | Feb | CTNA | |
| >A> | AA | DR REDDYS LABS LTD | EQ 15MG BASE/ML | N90102 001 | May 26, 2009 | May | NEWA |
| >A> | AA | WOCKHARDT | EQ 15MG BASE/ML | N79211 001 | May 26, 2009 | May | NEWA |
| AA | | EQ 15MG BASE/ML | N79212 001 | Feb 23, 2009 | Feb | NEWA | |

RISEDRONATE SODIUM

TABLET; ORAL

ACTONEL

| | | | | | | |
|-----|--------------------|------|------------|--------------|-----|------|
| >D> | PROCTER AND GAMBLE | 75MG | N20835 004 | Apr 16, 2007 | May | DISC |
| >A> | @ | 75MG | N20835 004 | Apr 16, 2007 | May | DISC |

RISPERIDONE

SOLUTION; ORAL

RISPERDAL

| | | | | | | | |
|----|---|----------------------|--------|------------|--------------|-----|------|
| AA | + | ORTHO MCNEIL JANSSEN | 1MG/ML | N20588 001 | Jun 10, 1996 | Jan | CFTG |
|----|---|----------------------|--------|------------|--------------|-----|------|

RISPERIDONE

| | | | | | | | |
|----|--|------|--------|------------|--------------|-----|------|
| AA | | TEVA | 1MG/ML | N76440 001 | Jan 30, 2009 | Jan | NEWA |
|----|--|------|--------|------------|--------------|-----|------|

TABLET; ORAL

RISPERIDONE

| | | | | | | | |
|-----|----|------------------|--------|------------|--------------|-----|------|
| AB | | CADISTA PHARMS | 0.25MG | N78828 001 | Mar 23, 2009 | Mar | NEWA |
| AB | | | 0.5MG | N78828 002 | Mar 23, 2009 | Mar | NEWA |
| AB | | | 1MG | N78828 003 | Mar 23, 2009 | Mar | NEWA |
| AB | | | 2MG | N78828 004 | Mar 23, 2009 | Mar | NEWA |
| AB | | | 3MG | N78828 005 | Mar 23, 2009 | Mar | NEWA |
| AB | | | 4MG | N78828 006 | Mar 23, 2009 | Mar | NEWA |
| >A> | AB | WEST WARD PHARMS | 0.25MG | N78740 001 | May 29, 2009 | May | NEWA |
| >A> | AB | | 0.5MG | N78740 002 | May 29, 2009 | May | NEWA |
| >A> | AB | | 1MG | N78740 003 | May 29, 2009 | May | NEWA |
| >A> | AB | | 2MG | N78740 004 | May 29, 2009 | May | NEWA |
| >A> | AB | | 3MG | N78740 005 | May 29, 2009 | May | NEWA |
| >A> | AB | | 4MG | N78740 006 | May 29, 2009 | May | NEWA |

TABLET, ORALLY DISINTEGRATING; ORAL

RISPERDAL

| | | | | | | | |
|----|--|----------------------|-------|------------|--------------|-----|------|
| AB | | ORTHO MCNEIL JANSSEN | 0.5MG | N21444 001 | Apr 02, 2003 | Feb | CFTG |
| AB | | | 2MG | N21444 003 | Apr 02, 2003 | Feb | CFTG |
| AB | | | 3MG | N21444 004 | Dec 23, 2004 | Apr | CFTG |
| AB | | | 4MG | N21444 005 | Dec 23, 2004 | Apr | CFTG |

RISPERIDONE

| | | | | | | | |
|----|--|--------------------|--------|------------|--------------|-----|------|
| AB | | DR REDDYS LABS LTD | 0.5MG | N77328 001 | Feb 24, 2009 | Feb | NEWA |
| AB | | | 2MG | N77328 003 | Feb 24, 2009 | Feb | NEWA |
| | | KALI LABS | 0.25MG | N77494 001 | Apr 30, 2009 | Apr | NEWA |
| AB | | | 0.5MG | N77494 002 | Apr 30, 2009 | Apr | NEWA |
| AB | | | 2MG | N77494 004 | Apr 30, 2009 | Apr | NEWA |
| AB | | | 3MG | N77494 005 | Apr 30, 2009 | Apr | NEWA |
| AB | | | 4MG | N77494 006 | Apr 30, 2009 | Apr | NEWA |
| AB | | ZYDUS PHARMS USA | 0.5MG | N78516 001 | May 01, 2009 | Apr | NEWA |
| AB | | | 2MG | N78516 003 | May 01, 2009 | Apr | NEWA |

RITODRINE HYDROCHLORIDE

INJECTABLE; INJECTION

RITODRINE HYDROCHLORIDE

| | | | | | | |
|---|---|------------|------------|--------------|-----|------|
| @ | HOSPIRA | 10MG/ML | N71618 001 | Feb 28, 1991 | Apr | DISC |
| @ | | 15MG/ML | N71619 001 | Feb 28, 1991 | Apr | DISC |
| | RITODRINE HYDROCHLORIDE IN DEXTROSE 5% IN PLASTIC CONTAINER | | | | | |
| @ | HOSPIRA | 30MG/100ML | N71438 001 | Jan 22, 1991 | Apr | DISC |

ROPINIROLE HYDROCHLORIDE

TABLET; ORAL

ROPINIROLE HYDROCHLORIDE

| | | | | | | |
|-----|----------------------|----------------|------------|--------------|-----|------|
| AB | HUAHAI US INC | EQ 0.25MG BASE | N78110 001 | May 05, 2008 | Apr | CAHN |
| AB | | EQ 0.5MG BASE | N78110 002 | May 05, 2008 | Apr | CAHN |
| AB | | EQ 1MG BASE | N78110 003 | May 05, 2008 | Apr | CAHN |
| AB | | EQ 2MG BASE | N78110 004 | May 05, 2008 | Apr | CAHN |
| AB | | EQ 3MG BASE | N78110 005 | May 05, 2008 | Apr | CAHN |
| AB | | EQ 4MG BASE | N78110 006 | May 05, 2008 | Apr | CAHN |
| >A> | ZYDUS PHARMS USA INC | EQ 0.25MG BASE | N90411 001 | Jun 01, 2009 | May | NEWA |
| >A> | | EQ 0.5MG BASE | N90411 002 | Jun 01, 2009 | May | NEWA |
| >A> | | EQ 1MG BASE | N90411 003 | Jun 01, 2009 | May | NEWA |
| >A> | | EQ 2MG BASE | N90411 004 | Jun 01, 2009 | May | NEWA |
| >A> | | EQ 3MG BASE | N90411 005 | Jun 01, 2009 | May | NEWA |
| >A> | | EQ 4MG BASE | N90411 006 | Jun 01, 2009 | May | NEWA |
| >A> | | EQ 5MG BASE | N90411 007 | Jun 01, 2009 | May | NEWA |

TABLET, EXTENDED RELEASE; ORAL

REQUIP XL

| | | | | | | |
|--|--------------------|-------------|------------|--------------|-----|------|
| | SMITHKLINE BEECHAM | EQ 6MG BASE | N22008 006 | Apr 10, 2009 | Apr | NEWA |
|--|--------------------|-------------|------------|--------------|-----|------|

SAMARIUM SM 153 LEXIDRONAM PENTASODIUM

INJECTABLE; INJECTION

QUADRAMET

| | | | | | | | |
|-----|---|-----------------|----------|------------|--------------|-----|------|
| >D> | + | CYTOGEN | 50mCi/ML | N20570 001 | Mar 28, 1997 | May | CAHN |
| >A> | + | EUSA PHARMA USA | 50mCi/ML | N20570 001 | Mar 28, 1997 | May | CAHN |

SELEGILINE HYDROCHLORIDE

TABLET; ORAL

SELEGILINE HYDROCHLORIDE

| | | | | | | |
|---|-------------|-----|------------|--------------|-----|------|
| @ | ENDO PHARMS | 5MG | N74565 001 | Aug 02, 1996 | Apr | DISC |
| @ | SIEGFRIED | 5MG | N74672 001 | Apr 01, 1997 | Apr | DISC |

SERTRALINE HYDROCHLORIDE

TABLET; ORAL

SERTRALINE HYDROCHLORIDE

| | | | | | | |
|----|------------------|---------------|------------|--------------|-----|------|
| AB | AUSTARPHARMA LLC | EQ 25MG BASE | N78677 001 | Mar 04, 2009 | Feb | NEWA |
| AB | | EQ 50MG BASE | N78677 002 | Mar 04, 2009 | Feb | NEWA |
| AB | | EQ 100MG BASE | N78677 003 | Mar 04, 2009 | Feb | NEWA |

SIMVASTATIN

TABLET; ORAL

SIMVASTATIN

| | | | | | | |
|----|-------|-----|------------|--------------|-----|------|
| AB | LUPIN | 5MG | N78103 005 | Apr 14, 2009 | Mar | NEWA |
|----|-------|-----|------------|--------------|-----|------|

| | | | | |
|-----|---------------------------------------|-------------|------------|-----------------------|
| >D> | <u>SODIUM PHOSPHATE, P-32</u> | | | |
| >D> | SOLUTION; INJECTION, ORAL | | | |
| >D> | SODIUM PHOSPHATE P 32 | | | |
| >D> | MALLINCKRODT | 0.67mCi/ML | N11777 001 | May DISC |
| >A> | @ | 0.67mCi/ML | N11777 001 | May DISC |
| | <u>SODIUM POLYSTYRENE SULFONATE</u> | | | |
| | POWDER; ORAL, RECTAL | | | |
| | KALEXATE | | | |
| AA | KVK TECH | 454GM/BOT | N40905 001 | Mar 30, 2009 Mar NEWA |
| | <u>SOMATROPIN RECOMBINANT</u> | | | |
| | INJECTABLE; INJECTION | | | |
| | NORDITROPIN NORDIFLEX | | | |
| | NOVO NORDISK INC | 30MG/3ML | N21148 007 | Mar 10, 2009 Mar NEWA |
| | <u>STANZOLOL</u> | | | |
| | TABLET; ORAL | | | |
| | WINSTROL | | | |
| | @ LUNDBECK INC | 2MG | N12885 001 | May 14, 1984 Mar CAHN |
| | <u>STAVUDINE</u> | | | |
| | FOR SOLUTION; ORAL | | | |
| | STAVUDINE | | | |
| AA | CIPLA LTD | 1MG/ML | N78030 001 | Mar 20, 2009 Mar NEWA |
| | <u>SUCCIMER</u> | | | |
| | CAPSULE; ORAL | | | |
| | CHEMET | | | |
| | + LUNDBECK INC | 100MG | N19998 002 | Jan 30, 1991 Mar CAHN |
| | <u>SULFACETAMIDE SODIUM</u> | | | |
| | LOTION; TOPICAL | | | |
| | SULFACETAMIDE SODIUM | | | |
| AB | PERRIGO CO TENNESSEE | 10% | N78649 001 | Mar 23, 2009 Mar NEWA |
| >A> | AB | TARO | N78668 001 | May 20, 2009 May NEWA |
| | SOLUTION/DROPS; OPHTHALMIC | | | |
| | SULF-10 | | | |
| | @ NOVARTIS | 10% | N80025 001 | Apr DISC |
| | SULFACETAMIDE SODIUM | | | |
| | @ ALCON | 30% | N89068 001 | May 05, 1987 Apr DISC |
| | <u>SULFAMETHOXAZOLE; TRIMETHOPRIM</u> | | | |
| | TABLET; ORAL | | | |
| | SULFAMETHOPRIM | | | |
| AB | PAR PHARM | 400MG;80MG | N70022 001 | Feb 15, 1985 Mar CMFD |
| | SULFAMETHOPRIM-DS | | | |
| AB | PAR PHARM | 800MG;160MG | N70032 001 | Feb 15, 1985 Mar CMFD |
| | SULFAMETHOXAZOLE AND TRIMETHOPRIM | | | |
| | @ SANDOZ | 800MG;160MG | N70890 001 | Nov 13, 1986 Mar DISC |
| | <u>SULINDAC</u> | | | |
| | TABLET; ORAL | | | |
| | SULINDAC | | | |
| | @ SANDOZ | 150MG | N72712 001 | Aug 30, 1991 Mar DISC |

TABLET; ORAL

SULINDAC

@ SANDOZ

200MG

N72713 001 Aug 30, 1991 Mar DISC

SUMATRIPTAN SUCCINATE

INJECTABLE; SUBCUTANEOUS

IMITREX

| | | | | | | | |
|----|---|-----------------|--|------------|--------------|-----|------|
| AP | + | GLAXOSMITHKLINE | EQ 6MG BASE/0.5ML (EQ 12MG BASE/ML) | N20080 001 | Dec 28, 1992 | Jan | CFTG |
|----|---|-----------------|--|------------|--------------|-----|------|

SUMATRIPTAN SUCCINATE

| | | | | | | | |
|----|--|-----------------|--|------------|--------------|-----|------|
| AP | | APP PHARMS | EQ 6MG BASE/0.5ML (EQ 12MG BASE/ML) | N79242 001 | Mar 02, 2009 | Feb | NEWA |
| AP | | BEDFORD | EQ 6MG BASE/0.5ML (EQ 12MG BASE/ML) | N79123 001 | Feb 06, 2009 | Jan | NEWA |
| AP | | SANDOZ | EQ 4MG BASE/0.5ML (EQ 8MG BASE/ML) | N78067 002 | Feb 06, 2009 | Jan | NEWA |
| AP | | | EQ 6MG BASE/0.5ML (EQ 12MG BASE/ML) | N78067 001 | Feb 06, 2009 | Jan | NEWA |
| AP | | TEVA PARENTERAL | EQ 4MG BASE/0.5ML (EQ 8MG BASE/ML) | N78318 001 | Feb 06, 2009 | Jan | NEWA |
| AP | | | EQ 6MG BASE/0.5ML (EQ 12MG BASE/ML) | N78318 002 | Feb 06, 2009 | Jan | NEWA |
| AP | | | EQ 6MG BASE/0.5ML (EQ 12MG BASE/ML) | N77907 001 | Feb 06, 2009 | Jan | NEWA |
| AP | | WOCKHARDT | EQ 6MG BASE/0.5ML (EQ 12MG BASE/ML) | N78593 001 | Feb 06, 2009 | Jan | NEWA |

TABLET; ORAL

IMITREX

| | | | | | | | |
|----|---|-----------------|---------------|------------|--------------|-----|------|
| AB | | GLAXOSMITHKLINE | EQ 25MG BASE | N20132 002 | Jun 01, 1995 | Jan | CFTG |
| AB | | | EQ 50MG BASE | N20132 003 | Jun 01, 1995 | Jan | CFTG |
| AB | + | | EQ 100MG BASE | N20132 001 | Jun 01, 1995 | Jan | CFTG |

SUMATRIPTAN SUCCINATE

| | | | | | | | |
|----|--|---------|---------------|------------|--------------|-----|------|
| AB | | RANBAXY | EQ 100MG BASE | N76572 001 | Feb 09, 2009 | Jan | NEWA |
| AB | | TEVA | EQ 25MG BASE | N76840 001 | Feb 09, 2009 | Jan | NEWA |
| AB | | | EQ 50MG BASE | N76840 002 | Feb 09, 2009 | Jan | NEWA |
| AB | | | EQ 100MG BASE | N76840 003 | Feb 09, 2009 | Jan | NEWA |

SUNITINIB MALATE

CAPSULE; ORAL

SUTENT

CPPI CV

EQ 37.5MG BASE

N21938 004 Mar 31, 2009 Mar NEWA

TADALAFIL

TABLET; ORAL

ADCIRCA

>A>

+ ELI LILLY CO

20MG

N22332 001 May 22, 2009 May NEWA

>A>

TAMOXIFEN CITRATE

TABLET; ORAL

TAMOXIFEN CITRATE

@ ROXANE

EQ 10MG BASE

N76027 001 Feb 20, 2003 Mar DISC

@

EQ 20MG BASE

N76027 002 Feb 20, 2003 Mar DISC

TECHNETIUM TC-99M BICISATE KIT

INJECTABLE; INJECTION

NEUROLITE

LANTHEUS MEDCL

N/A

N20256 001 Nov 23, 1994 Apr CPOT

TECHNETIUM TC-99M MEDRONATE KIT

INJECTABLE; INJECTION

DRAXIMAGE MDP-10

| | | | | | | |
|---|---------------------------|-----|------------|--------------|-----|------|
| + | DRAXIMAGE | N/A | N18035 001 | | Apr | CTEC |
| | DRAXIMAGE MDP-25 | | | | | |
| | @ DRAXIMAGE | N/A | N18035 002 | Feb 27, 2004 | Apr | DISC |
| | TECHNETIUM TC 99M MPI MDP | | | | | |
| | @ GE HEALTHCARE | N/A | N18141 002 | Jun 12, 1989 | Apr | DISC |
| | @ | N/A | N18141 001 | | Apr | DISC |

TECHNETIUM TC-99M SESTAMIBI KIT

INJECTABLE; INJECTION

TECHNETIUM TC 99M SESTAMIBI

| | | | | | | |
|----|---------------------|-----|------------|--------------|-----|------|
| AP | CARDINAL HEALTH 414 | N/A | N78809 001 | Apr 28, 2009 | Apr | NEWA |
| AP | DRAXIMAGE | N/A | N78806 001 | Apr 29, 2009 | Apr | NEWA |

TELIVUDINE

SOLUTION; ORAL

TYZEKA

| | | | | | | |
|---|----------|-----------|------------|--------------|-----|------|
| + | NOVARTIS | 100MG/5ML | N22154 001 | Apr 28, 2009 | Apr | NEWA |
|---|----------|-----------|------------|--------------|-----|------|

TEMAZEPAM

CAPSULE; ORAL

TEMAZEPAM

| | | | | | | |
|---|----------------|------|------------|--------------|-----|------|
| @ | NOVEL LABS INC | 30MG | N71457 001 | Apr 21, 1987 | Mar | CAHN |
|---|----------------|------|------------|--------------|-----|------|

TEMOZOLOMIDE

POWDER; INTRAVENOUS

TEMODAR

| | | | | | | |
|---|----------|------------|------------|--------------|-----|------|
| + | SCHERING | 100MG/VIAL | N22277 001 | Feb 27, 2009 | Feb | NEWA |
|---|----------|------------|------------|--------------|-----|------|

TERAZOSIN HYDROCHLORIDE

CAPSULE; ORAL

TERAZOSIN HYDROCHLORIDE

| | | | | | | | |
|-----|----|-------------|--------------|------------|--------------|-----|------|
| >D> | @ | IVAX PHARMS | EQ 1MG BASE | N75614 002 | Jan 30, 2001 | May | CMFD |
| >A> | AB | | EQ 1MG BASE | N75614 002 | Jan 30, 2001 | May | CMFD |
| >D> | @ | | EQ 2MG BASE | N75614 001 | Jan 30, 2001 | May | CMFD |
| >A> | AB | | EQ 2MG BASE | N75614 001 | Jan 30, 2001 | May | CMFD |
| >D> | @ | | EQ 5MG BASE | N75614 003 | Jan 30, 2001 | May | CMFD |
| >A> | AB | | EQ 5MG BASE | N75614 003 | Jan 30, 2001 | May | CMFD |
| >D> | @ | | EQ 10MG BASE | N75614 004 | Jan 30, 2001 | May | CMFD |
| >A> | AB | | EQ 10MG BASE | N75614 004 | Jan 30, 2001 | May | CMFD |

TABLET; ORAL

HYTRIN

ABBOTT

| | | | | | | |
|---|--|--------------|------------|--------------|-----|------|
| + | | EQ 1MG BASE | N19057 001 | Aug 07, 1987 | Mar | CTEC |
| | | EQ 2MG BASE | N19057 002 | Aug 07, 1987 | Mar | CTEC |
| | | EQ 5MG BASE | N19057 003 | Aug 07, 1987 | Mar | CTEC |
| | | EQ 10MG BASE | N19057 004 | Aug 07, 1987 | Mar | CTEC |

TERAZOSIN HYDROCHLORIDE

| | | | | | | |
|---|--------|--------------|------------|--------------|-----|------|
| @ | SANDOZ | EQ 1MG BASE | N74315 001 | Dec 31, 1998 | Mar | DISC |
| @ | | EQ 2MG BASE | N74315 002 | Dec 31, 1998 | Mar | DISC |
| @ | | EQ 5MG BASE | N74315 003 | Dec 31, 1998 | Mar | DISC |
| @ | | EQ 10MG BASE | N74315 004 | Dec 31, 1998 | Mar | DISC |

TERBUTALINE SULFATE

| | | | | | | | |
|-----|-----------------------|--------------------|--------|------------|--------------|-----|------|
| | INJECTABLE; INJECTION | | | | | | |
| | TERBUTALINE SULFATE | | | | | | |
| >A> | AP | HIKMA FARMACEUTICA | 1MG/ML | N78630 001 | May 20, 2009 | May | NEWA |

TERIPARATIDE RECOMBINANT HUMAN

| | | | | | | | |
|--|--------------------------|-------------------------|--|------------|--------------|-----|------|
| | INJECTABLE; SUBCUTANEOUS | | | | | | |
| | FORTEO | | | | | | |
| | LILLY | 0.6MG/2.4ML (0.25MG/ML) | | N21318 002 | Jun 25, 2008 | Feb | NEWA |
| | + | 0.75MG/3ML (0.25MG/ML) | | N21318 001 | Nov 26, 2002 | Feb | CPOT |

TESTOSTERONE

| | | | | | | | |
|----|------------------|-------------------|--|------------|--------------|-----|------|
| | GEL; TRANSDERMAL | | | | | | |
| | ANDROGEL | | | | | | |
| | UNIMED PHARMS | 1% (2.5GM/PACKET) | | N21015 001 | Feb 28, 2000 | Mar | CTEC |
| BX | + | 1% (5GM/PACKET) | | N21015 002 | Feb 28, 2000 | Mar | CTEC |
| | TESTOSTERONE | | | | | | |
| | @ WATSON LABS | 1% (5GM/PACKET) | | N76737 002 | Jan 27, 2006 | Mar | DISC |
| | @ | 1% (2.5GM/PACKET) | | N76737 001 | Jan 27, 2006 | Mar | DISC |

TESTOSTERONE ENANTHATE

| | | | | | | | |
|----|-----------------------|-------------|----------|------------|--|-----|------|
| | INJECTABLE; INJECTION | | | | | | |
| | DELATESTRYL | | | | | | |
| AO | + | ENDO PHARM | 200MG/ML | N09165 003 | | Apr | CAHN |
| | @ | | 200MG/ML | N09165 001 | | Apr | CAHN |
| AO | + | ENDO PHARMS | 200MG/ML | N09165 003 | | Mar | CAHN |
| | @ | | 200MG/ML | N09165 001 | | Mar | CAHN |

TETRAHYDROZOLINE HYDROCHLORIDE

| | | | | | | | |
|--|-----------------|------------|-------|------------|--|-----|------|
| | SOLUTION; NASAL | | | | | | |
| | TYZINE | | | | | | |
| | + | NYCOMED US | 0.05% | N86576 002 | | Apr | CAHN |
| | | | 0.1% | N86576 001 | | Apr | CAHN |
| | SPRAY; NASAL | | | | | | |
| | TYZINE | | | | | | |
| | + | NYCOMED US | 0.1% | N86576 003 | | Apr | CAHN |

THEOPHYLLINE

| | | | | | | | |
|----|----------------|----------------|-----------|------------|--------------|-----|------|
| | ELIXIR; ORAL | | | | | | |
| | THEOPHYLLINE | | | | | | |
| AA | | PRECISION DOSE | 80MG/15ML | N85863 001 | | Apr | CAHN |
| | SOLUTION; ORAL | | | | | | |
| | THEOPHYLLINE | | | | | | |
| | @ ROXANE | | 80MG/15ML | N87449 001 | Sep 15, 1983 | Mar | DISC |

TIMOLOL MALEATE

| | | | | | | | |
|----|----------------------------|------|---------------|------------|--------------|-----|------|
| | SOLUTION/DROPS; OPHTHALMIC | | | | | | |
| | TIMOPTIC | | | | | | |
| AT | + | ATON | EQ 0.25% BASE | N18086 001 | | Feb | CAHN |
| AT | + | | EQ 0.5% BASE | N18086 002 | | Feb | CAHN |
| | TIMOPTIC IN OCUDOSE | | | | | | |
| | + | ATON | EQ 0.25% BASE | N19463 001 | Nov 05, 1986 | Feb | CAHN |
| | + | | EQ 0.5% BASE | N19463 002 | Nov 05, 1986 | Feb | CAHN |

SOLUTION, GEL FORMING/DROPS; OPHTHALMIC

TIMOPTIC-XE

| | | | | | | | |
|----|---|------|---------------|------------|--------------|-----|------|
| AB | + | ATON | EQ 0.25% BASE | N20330 001 | Nov 04, 1993 | Feb | CAHN |
| AB | + | | EQ 0.5% BASE | N20330 002 | Nov 04, 1993 | Feb | CAHN |

TABLET; ORAL

TIMOLOL MALEATE

| | | | | | | | |
|--|---|----------|------|------------|--------------|-----|------|
| | | MYLAN | 5MG | N72666 001 | Jun 08, 1990 | Mar | CTEC |
| | | | 10MG | N72667 001 | Jun 08, 1990 | Mar | CTEC |
| | + | | 20MG | N72668 001 | Jun 08, 1990 | Mar | CTEC |
| | | @ SANDOZ | 5MG | N72550 001 | Apr 13, 1989 | Mar | DISC |
| | | @ | 10MG | N72551 001 | Apr 13, 1989 | Mar | DISC |
| | | @ | 20MG | N72552 001 | Apr 13, 1989 | Mar | DISC |

TOLAZAMIDE

TABLET; ORAL

TOLAZAMIDE

| | | | | | | | |
|--|--|-------------|-------|------------|--------------|-----|------|
| | | IVAX PHARMS | 100MG | N18894 001 | Nov 02, 1984 | Mar | CTEC |
| | | @ SANDOZ | 100MG | N71633 001 | Dec 09, 1987 | Mar | DISC |
| | | @ | 250MG | N70289 001 | Mar 13, 1986 | Mar | DISC |
| | | @ | 500MG | N70290 001 | Mar 13, 1986 | Mar | DISC |

TOLBUTAMIDE

TABLET; ORAL

TOLBUTAMIDE

| | | | | | | | |
|--|--|----------|-------|------------|--|-----|------|
| | | @ SANDOZ | 500MG | N86574 001 | | Mar | DISC |
|--|--|----------|-------|------------|--|-----|------|

TOLMETIN SODIUM

TABLET; ORAL

TOLMETIN SODIUM

| | | | | | | | |
|--|--|----------|---------------|------------|--------------|-----|------|
| | | @ SANDOZ | EQ 200MG BASE | N73588 001 | Jul 31, 1992 | Mar | DISC |
| | | @ | EQ 600MG BASE | N74002 001 | Sep 27, 1993 | Mar | DISC |

>A> TOLVAPTAN

>A> TABLET; ORAL

>A> SAMSCA

| | | | | | | | |
|-----|---|----------------------|------|------------|--------------|-----|------|
| >A> | | OTSUKA AMERICA PHARM | 15MG | N22275 001 | May 19, 2009 | May | NEWA |
| >A> | + | | 30MG | N22275 002 | May 19, 2009 | May | NEWA |
| >A> | | @ | 60MG | N22275 003 | May 19, 2009 | May | DISC |

TOPIRAMATE

CAPSULE; ORAL

TOPAMAX

| | | | | | | | |
|----|---|----------------------|------|------------|--------------|-----|------|
| AB | | ORTHO MCNEIL JANSSEN | 15MG | N20844 001 | Oct 26, 1998 | Mar | CFTG |
| AB | + | | 25MG | N20844 002 | Oct 26, 1998 | Mar | CFTG |

TOPIRAMATE

| | | | | | | | |
|----|--|-----------------|------|------------|--------------|-----|------|
| AB | | BARR | 15MG | N76448 001 | Apr 15, 2009 | Mar | NEWA |
| AB | | | 25MG | N76448 002 | Apr 15, 2009 | Mar | NEWA |
| AB | | COBALT LABS INC | 15MG | N77868 001 | Apr 15, 2009 | Mar | NEWA |
| AB | | | 25MG | N77868 002 | Apr 15, 2009 | Mar | NEWA |
| AB | | TEVA | 15MG | N76575 001 | Apr 17, 2009 | Mar | NEWA |
| AB | | | 25MG | N76575 002 | Apr 17, 2009 | Mar | NEWA |

TABLET; ORAL

TOPAMAX

| | | | | | | | |
|----|---|----------------------|-------|------------|--------------|-----|------|
| AB | + | ORTHO MCNEIL JANSSEN | 25MG | N20505 004 | Dec 24, 1996 | Mar | CFTG |
| AB | | | 50MG | N20505 005 | Dec 24, 1996 | Mar | CFTG |
| AB | | | 100MG | N20505 001 | Dec 24, 1996 | Mar | CFTG |

TABLET; ORAL

| | | | | | |
|------------|----------------------|-------|------------|--------------|----------|
| TOPAMAX | | | | | |
| AB | ORTHO MCNEIL JANSSEN | 200MG | N20505 002 | Dec 24, 1996 | Mar CFTG |
| TOPIRAMATE | | | | | |
| AB | APOTEX INC | 25MG | N77733 001 | Mar 27, 2009 | Mar NEWA |
| AB | | 50MG | N77733 002 | Mar 27, 2009 | Mar NEWA |
| AB | | 100MG | N77733 003 | Mar 27, 2009 | Mar NEWA |
| AB | | 200MG | N77733 004 | Mar 27, 2009 | Mar NEWA |
| AB | AUROBINDO PHARMA | 25MG | N78462 001 | Mar 27, 2009 | Mar NEWA |
| AB | | 50MG | N78462 002 | Mar 27, 2009 | Mar NEWA |
| AB | | 100MG | N78462 003 | Mar 27, 2009 | Mar NEWA |
| AB | | 200MG | N78462 004 | Mar 27, 2009 | Mar NEWA |
| AB | BARR | 25MG | N76315 001 | Mar 27, 2009 | Mar NEWA |
| AB | | 100MG | N76315 002 | Mar 27, 2009 | Mar NEWA |
| AB | | 200MG | N76315 003 | Mar 27, 2009 | Mar NEWA |
| AB | CIPLA LTD | 25MG | N76343 001 | Mar 27, 2009 | Mar NEWA |
| AB | | 50MG | N76343 002 | Mar 27, 2009 | Mar NEWA |
| AB | | 100MG | N76343 003 | Mar 27, 2009 | Mar NEWA |
| AB | | 200MG | N76343 004 | Mar 27, 2009 | Mar NEWA |
| AB | COBALT LABS INC | 25MG | N77643 001 | Mar 27, 2009 | Mar NEWA |
| AB | | 50MG | N77643 002 | Mar 27, 2009 | Mar NEWA |
| AB | | 100MG | N77643 003 | Mar 27, 2009 | Mar NEWA |
| AB | | 200MG | N77643 004 | Mar 27, 2009 | Mar NEWA |
| AB | GLENMARK GENERICS | 25MG | N77627 001 | Mar 27, 2009 | Mar NEWA |
| AB | | 50MG | N77627 002 | Mar 27, 2009 | Mar NEWA |
| AB | | 100MG | N77627 003 | Mar 27, 2009 | Mar NEWA |
| AB | | 200MG | N77627 004 | Mar 27, 2009 | Mar NEWA |
| AB | INVAGEN PHARMS | 25MG | N79162 001 | Mar 27, 2009 | Mar NEWA |
| AB | | 50MG | N79162 002 | Mar 27, 2009 | Mar NEWA |
| AB | | 100MG | N79162 003 | Mar 27, 2009 | Mar NEWA |
| AB | | 200MG | N79162 004 | Mar 27, 2009 | Mar NEWA |
| AB | MYLAN | 25MG | N76314 001 | Mar 27, 2009 | Mar NEWA |
| AB | | 50MG | N76314 002 | Mar 27, 2009 | Mar NEWA |
| AB | | 100MG | N76314 003 | Mar 27, 2009 | Mar NEWA |
| AB | | 200MG | N76314 004 | Mar 27, 2009 | Mar NEWA |
| AB | PAR PHARM | 25MG | N76311 001 | Mar 27, 2009 | Mar NEWA |
| AB | | 50MG | N76311 002 | Mar 27, 2009 | Mar NEWA |
| AB | | 100MG | N76311 003 | Mar 27, 2009 | Mar NEWA |
| AB | | 200MG | N76311 004 | Mar 27, 2009 | Mar NEWA |
| AB | PLIVA HRVATSKA DOO | 25MG | N77905 001 | Mar 30, 2009 | Mar NEWA |
| AB | | 50MG | N77905 002 | Mar 30, 2009 | Mar NEWA |
| AB | | 100MG | N77905 003 | Mar 30, 2009 | Mar NEWA |
| AB | | 200MG | N77905 004 | Mar 30, 2009 | Mar NEWA |
| AB | RANBAXY | 25MG | N76327 001 | Mar 27, 2009 | Mar NEWA |
| AB | | 100MG | N76327 002 | Mar 27, 2009 | Mar NEWA |
| AB | | 200MG | N76327 003 | Mar 27, 2009 | Mar NEWA |
| AB | ROXANE | 25MG | N76306 001 | Mar 27, 2009 | Mar NEWA |
| AB | | 50MG | N76306 002 | Mar 27, 2009 | Mar NEWA |
| AB | | 100MG | N76306 003 | Mar 27, 2009 | Mar NEWA |
| AB | | 200MG | N76306 004 | Mar 27, 2009 | Mar NEWA |
| AB | SUN PHARM INDS LTD | 25MG | N90278 001 | Mar 27, 2009 | Mar NEWA |
| AB | | 50MG | N90278 002 | Mar 27, 2009 | Mar NEWA |
| AB | | 100MG | N90278 003 | Mar 27, 2009 | Mar NEWA |
| AB | | 200MG | N90278 004 | Mar 27, 2009 | Mar NEWA |
| AB | TEVA | 25MG | N76317 001 | Mar 27, 2009 | Mar NEWA |
| AB | | 50MG | N76317 002 | Mar 27, 2009 | Mar NEWA |

TABLET; ORALTOPIRAMATE

| | | | | | | |
|----|----------------------|-------|------------|--------------|-----|------|
| AB | TEVA | 100MG | N76317 003 | Mar 27, 2009 | Mar | NEWA |
| AB | | 200MG | N76317 004 | Mar 27, 2009 | Mar | NEWA |
| AB | TORRENT PHARMS | 25MG | N79153 001 | Mar 27, 2009 | Mar | NEWA |
| AB | | 50MG | N79153 002 | Mar 27, 2009 | Mar | NEWA |
| AB | | 100MG | N79153 003 | Mar 27, 2009 | Mar | NEWA |
| AB | | 200MG | N79153 004 | Mar 27, 2009 | Mar | NEWA |
| AB | UNICHEM | 25MG | N90162 001 | Mar 27, 2009 | Mar | NEWA |
| AB | | 50MG | N90162 002 | Mar 27, 2009 | Mar | NEWA |
| AB | | 100MG | N90162 003 | Mar 27, 2009 | Mar | NEWA |
| AB | ZYDUS PHARMS USA INC | 25MG | N78235 001 | Mar 27, 2009 | Mar | NEWA |
| AB | | 50MG | N78235 002 | Mar 27, 2009 | Mar | NEWA |
| AB | | 100MG | N78235 003 | Mar 27, 2009 | Mar | NEWA |
| AB | | 200MG | N78235 004 | Mar 27, 2009 | Mar | NEWA |

TORSEMIDETABLET; ORALTORSEMIDE

| | | | | | | |
|----|--------------|-------|------------|--------------|-----|------|
| AB | HETERO DRUGS | 5MG | N79234 001 | Jan 27, 2009 | Jan | NEWA |
| AB | | 10MG | N79234 002 | Jan 27, 2009 | Jan | NEWA |
| AB | | 20MG | N79234 003 | Jan 27, 2009 | Jan | NEWA |
| AB | | 100MG | N79234 004 | Jan 27, 2009 | Jan | NEWA |

TRAMADOL HYDROCHLORIDETABLET, EXTENDED RELEASE; ORALRYZOLT

| | | | | | | |
|----|-----------------|-------|------------|--------------|-----|------|
| BC | + PURDUE PHARMA | 100MG | N21745 001 | Dec 30, 2008 | Mar | CAHN |
| BC | | 200MG | N21745 002 | Dec 30, 2008 | Mar | CAHN |
| BC | | 300MG | N21745 003 | Dec 30, 2008 | Mar | CAHN |

TABLET, ORALLY DISINTEGRATING; ORALTRAMADOL HYDROCHLORIDE

@ ETHYPHARM NORTH 50MG

N21693 001 May 05, 2005 Mar CAHN

TRAZODONE HYDROCHLORIDETABLET; ORALTRAZODONE HYDROCHLORIDE

| | | | | | | |
|-----|-----------------|-------|------------|--------------|-----|------|
| AB | ALVOGEN | 50MG | N71636 001 | Apr 18, 1988 | Feb | CAHN |
| AB | | 100MG | N71514 001 | Apr 18, 1988 | Feb | CAHN |
| >D> | APOTEX INC | 300MG | N71196 003 | Apr 26, 1999 | May | CTEC |
| >A> | AB | 300MG | N71196 003 | Apr 26, 1999 | May | CTEC |
| >A> | MATRIX LABS LTD | 50MG | N90514 001 | Jun 02, 2009 | May | NEWA |
| >A> | AB | 100MG | N90514 002 | Jun 02, 2009 | May | NEWA |
| >A> | AB | 150MG | N90514 003 | Jun 02, 2009 | May | NEWA |
| >A> | AB | 300MG | N90514 004 | Jun 02, 2009 | May | NEWA |
| | @ SANDOZ | 50MG | N72484 001 | Apr 30, 1990 | Mar | DISC |
| | @ | 100MG | N72483 001 | Apr 30, 1990 | Mar | DISC |

TRIAMCINOLONE ACETONIDEINJECTABLE; INJECTIONKENALOG-10

| | | | | | | |
|-----|-------------------|---------|------------|--|-----|------|
| >D> | APOTHECON | 10MG/ML | N12041 001 | | May | CFTG |
| >A> | AB | 10MG/ML | N12041 001 | | May | CFTG |
| | <u>KENALOG-40</u> | | | | | |
| >D> | + APOTHECON | 40MG/ML | N14901 001 | | May | CFTG |
| >A> | AB + | 40MG/ML | N14901 001 | | May | CFTG |

INJECTABLE; INJECTION

| | | | | | | | | |
|-----|----|-------------------------|---------|--------|-----|--------------|-----|------|
| >A> | | TRIAMCINOLONE ACETONIDE | | | | | | |
| >A> | AB | SANDOZ | 10MG/ML | N90166 | 001 | May 27, 2009 | May | NEWA |
| >A> | AB | | 40MG/ML | N90164 | 001 | May 27, 2009 | May | NEWA |

TROSPIDIUM CHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL

| | | | | | | | | |
|---|--|-------------|------|--------|-----|--------------|-----|------|
| | | SANCTURA XR | | | | | | |
| + | | ALLERGAN | 60MG | N22103 | 001 | Aug 03, 2007 | Apr | CAHN |
| + | | ENDO PHARMS | 60MG | N22103 | 001 | Aug 03, 2007 | Mar | CAHN |

TABLET; ORAL

| | | | | | | | | |
|---|--|-------------|------|--------|-----|--------------|-----|------|
| | | SANCTURA | | | | | | |
| + | | ALLERGAN | 20MG | N21595 | 001 | May 28, 2004 | Apr | CAHN |
| + | | ENDO PHARMS | 20MG | N21595 | 001 | May 28, 2004 | Mar | CAHN |

TRYPAN BLUE

SOLUTION; OPHTHALMIC

| | | | | | | | | |
|---|--|--------------|-------|--------|-----|--------------|-----|------|
| | | MEMBRANEBLUE | | | | | | |
| + | | DORC | 0.15% | N22278 | 001 | Feb 20, 2009 | Feb | NEWA |

URSODIOL

TABLET; ORAL

| | | | | | | | | |
|-----|----|-------------|-------|--------|-----|--------------|-----|------|
| | | URSO 250 | | | | | | |
| >D> | | AXCAN | 250MG | N20675 | 001 | Dec 10, 1997 | May | CFTG |
| >A> | AB | | 250MG | N20675 | 001 | Dec 10, 1997 | May | CFTG |
| | | URSO FORTE | | | | | | |
| >D> | + | AXCAN | 500MG | N20675 | 002 | Jul 21, 2004 | May | CFTG |
| >A> | AB | + | 500MG | N20675 | 002 | Jul 21, 2004 | May | CFTG |
| >A> | | URSODIOL | | | | | | |
| >A> | AB | TEVA PHARMS | 250MG | N79184 | 001 | May 13, 2009 | May | NEWA |
| >A> | AB | | 500MG | N79184 | 002 | May 13, 2009 | May | NEWA |

VALRUBICIN

SOLUTION; INTRAVESICAL

| | | | | | | | | |
|---|--|---------------------------|---------|--------|-----|--------------|-----|------|
| | | VALSTAR PRESERVATIVE FREE | | | | | | |
| + | | ENDO PHARM | 40MG/ML | N20892 | 001 | Sep 25, 1998 | Apr | CAHN |
| + | | ENDO PHARMS | 40MG/ML | N20892 | 001 | Sep 25, 1998 | Mar | CAHN |

VANCOMYCIN HYDROCHLORIDE

INJECTABLE; INJECTION

| | | | | | | | | |
|-----|----|--------------------------|--------------------|--------|-----|--------------|-----|------|
| | | VANCOMYCIN HYDROCHLORIDE | | | | | | |
| AP | + | ABRAXIS PHARM | EQ 10GM BASE/VIAL | N62663 | 004 | Nov 28, 1997 | Apr | CTEC |
| >D> | | HOSPIRA | EQ 750MG BASE/VIAL | N62912 | 002 | Jan 07, 2009 | May | CTEC |
| >A> | AP | | EQ 750MG BASE/VIAL | N62912 | 002 | Jan 07, 2009 | May | CTEC |
| >A> | AP | | EQ 750MG BASE/VIAL | N62933 | 002 | May 27, 2009 | May | NEWA |
| AP | | HOSPIRA INC | EQ 10GM BASE/VIAL | N65455 | 001 | Apr 29, 2009 | Apr | NEWA |

VERAPAMIL HYDROCHLORIDE

INJECTABLE; INJECTION

| | | | | | | | | |
|---|--|-------------------------|----------|--------|-----|--------------|-----|------|
| | | VERAPAMIL HYDROCHLORIDE | | | | | | |
| @ | | BEDFORD | 2.5MG/ML | N72888 | 001 | Jul 28, 1995 | Apr | DISC |

TABLET; ORAL

| | | | | | | | | |
|---|--|-------------------------|-------|--------|-----|--------------|-----|------|
| | | VERAPAMIL HYDROCHLORIDE | | | | | | |
| @ | | SANDOZ | 40MG | N73168 | 001 | Jul 31, 1992 | Mar | DISC |
| @ | | | 80MG | N71423 | 001 | May 24, 1988 | Mar | DISC |
| @ | | | 120MG | N71424 | 001 | May 25, 1988 | Mar | DISC |

ZOLPIDEM TARTRATE

TABLET; SUBLINGUAL

EDLUAR

| | | | | | |
|----------|------|------------|--------------|-----|------|
| OREXO AB | 5MG | N21997 001 | Mar 13, 2009 | Mar | NEWA |
| + | 10MG | N21997 002 | Mar 13, 2009 | Mar | NEWA |

ZONISAMIDE

CAPSULE; ORAL

ZONISAMIDE

| | | | | | | | |
|-----|----|--------------|-------|------------|--------------|-----|------|
| >D> | AB | MUTUAL PHARM | 25MG | N77635 001 | Dec 22, 2005 | May | DISC |
| >A> | | @ | 25MG | N77635 001 | Dec 22, 2005 | May | DISC |
| >D> | AB | | 50MG | N77635 002 | Dec 22, 2005 | May | DISC |
| >A> | | @ | 50MG | N77635 002 | Dec 22, 2005 | May | DISC |
| >D> | AB | | 100MG | N77635 003 | Dec 22, 2005 | May | DISC |
| >A> | | @ | 100MG | N77635 003 | Dec 22, 2005 | May | DISC |

OTC DRUG PRODUCT LIST - 29TH EDITION

OTC DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 5 - May 2009

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ACETAMINOPHEN

TABLET, EXTENDED RELEASE; ORAL

ACETAMINOPHEN

OHM LABS 650MG N76200 001 Mar 19, 2002 Mar CAHN

CETIRIZINE HYDROCHLORIDE

SYRUP; ORAL

CHILDREN'S CETIRIZINE HYDROCHLORIDE ALLERGY

DR REDDYS LABS LTD 5MG/5ML N90474 002 Mar 30, 2009 Mar NEWA

CHILDREN'S CETIRIZINE HYDROCHLORIDE HIVES RELIEF

DR REDDYS LABS LTD 5MG/5ML N90474 001 Mar 30, 2009 Mar NEWA

TABLET; ORAL

CETIRIZINE HYDROCHLORIDE ALLERGY

ORCHID HLTHCARE 5MG N78862 001 Feb 19, 2009 Feb NEWA

10MG N78862 002 Feb 19, 2009 Feb NEWA

CETIRIZINE HYDROCHLORIDE HIVES

ORCHID HLTHCARE 5MG N78862 003 Feb 19, 2009 Feb NEWA

10MG N78862 004 Feb 19, 2009 Feb NEWA

CHLORPHENIRAMINE MALEATE

TABLET, EXTENDED RELEASE; ORAL

CHLORPHENIRAMINE MALEATE

AVANTHI INC 12MG N40829 001 May 13, 2009 Apr NEWA

DEXTROMETHORPHAN POLISTIREX

SUSPENSION, EXTENDED RELEASE; ORAL

DELSYM

+ RECKITT BENCKISER EQ 30MG HBR/5ML N18658 001 Oct 08, 1982 Feb CAHN

IBUPROFEN

CAPSULE; ORAL

IBUPROFEN

BANNER PHARMACAPS EQ 200MG FREE ACID AND POTASSIUM SALT N78682 001 Mar 24, 2009 Mar NEWA

MIDOL LIQUID GELS

+ BANNER PHARMACAPS 200MG N21472 001 Oct 18, 2002 Feb CTNA

TABLET; ORAL

IBUPROFEN

@ SANDOZ 200MG N70733 001 Sep 19, 1986 Mar DISC

MEDIPREN

@ MCNEIL 200MG N70475 001 Feb 06, 1986 Apr DISC

@ 200MG N71215 001 Jun 26, 1986 Apr DISC

INSULIN RECOMBINANT HUMAN; INSULIN SUSP ISOPHANE RECOMBINANT HUMAN

INJECTABLE; INJECTION

HUMULIN 50/50

@ LILLY 50 UNITS/ML;50 UNITS/ML N20100 001 Apr 29, 1992 Jan DISC

>A> LANSOPRAZOLE

>A> CAPSULE, DELAYED REL PELLETS; ORAL

>A> PREVACID 24 HR

>A> + NOVARTIS 15MG N22327 001 May 18, 2009 May NEWA

NICOTINE POLACRILEX

GUM, CHEWING; BUCCAL

NICOTINE POLACRILEX

IVAX PHARMS

EQ 2MG BASE

N76880 001 Feb 18, 2009 Feb NEWA

EQ 4MG BASE

N77850 001 Feb 18, 2009 Feb NEWA

TROCHE/LOZENGE; ORAL

>A>

NICORETTE

>A>

GLAXOSMITHKLINE CONS

EQ 2MG BASE

N22360 001 May 18, 2009 May NEWA

>A>

+

EQ 4MG BASE

N22360 002 May 18, 2009 May NEWA

POTASSIUM IODIDE

SOLUTION; ORAL

THYROSHIELD

+ FLEMING

65MG/ML

N77218 001 Jan 12, 2005 Apr CRLD

RANITIDINE HYDROCHLORIDE

TABLET; ORAL

RANITIDINE

@ SANDOZ

EQ 75MG BASE

N75519 001 Sep 26, 2002 Mar DISC

**DRUG PRODUCTS WITH APPROVAL UNDER SECTION 505 OF THE ACT
ADMINISTERED BY THE CENTER FOR BIOLOGICS EVALUATION AND RESEARCH LIST**

CUMULATIVE SUPPLEMENT NUMBER 05 MAY 2009

NO MAY 2009 APPROVALS

ORPHAN PRODUCT DESIGNATIONS AND APPROVALS LIST

The list of List of Orphan Designations and Approvals is available at:

<http://www.fda.gov/orphan/designat/list.htm>

**DRUG PRODUCTS WHICH MUST DEMONSTRATE *IN VIVO* BIOAVAILABILITY
ONLY IF PRODUCT FAILS TO ACHIEVE ADEQUATE DISSOLUTION**

NO MAY 2009 ADDITIONS

PATENT & EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 5 - May 2009

See List footnote for information regarding List content

| APPL/PROD NO | PATENT NO | PATENT EXPIRATION DATE | PATENT CODES | PATENT DELIST REQUESTED | EXCLUSIVITY CODE(S) | EXCLUSIVITY EXPIRATION DATE |
|---|-----------------|------------------------------|-----------------|-------------------------------|------------------------|-----------------------------------|
| <u>ADAPALENE; BENZOYL PEROXIDE - EPIDUO</u> | | | | | | |
| 022320 001 | 4717720 | May 31, 2010 | DS DP | | | |
| | RE34440 | May 31, 2010 | | | U-818 | |
| <u>ALBUTEROL SULFATE - VENTOLIN HFA</u> | | | | | | |
| 020983 001 | 6161724 | Jan 16, 2018 | DP | | | |
| | 6161724*PED | Jul 16, 2018 | | | | |
| | 6170717 | Dec 23, 2017 | DP | | | |
| | 6170717*PED | Jun 23, 2018 | | | | |
| | 6431168 | Jun 08, 2018 | DP | | | |
| | 6431168*PED | Dec 08, 2018 | | | | |
| | 6435372 | Jan 16, 2018 | DP | | | |
| | 6435372*PED | Jul 16, 2018 | | | | |
| | 6596260 | Aug 10, 2014 | DP | | | |
| | 6596260*PED | Feb 10, 2015 | | | | |
| | 6938796 | Jan 16, 2018 | DP | | | |
| | 6938796*PED | Jul 16, 2018 | | | | |
| | 6966467 | Dec 23, 2017 | DP | | | |
| | 6966467*PED | Jun 23, 2018 | | | | |
| | 6997349 | Jan 16, 2018 | DP | | | |
| | 6997349*PED | Jul 16, 2018 | | | | |
| | 7107986 | Jun 08, 2018 | DP | | | |
| | 7107986*PED | Dec 06, 2018 | | | | |
| | 7143908 | Jan 16, 2018 | DP | | | |
| | 7143908*PED | Jul 16, 2018 | | | | |
| | 7350676 | Aug 24, 2018 | DP | | | |
| | 7350676*PED | Feb 24, 2019 | | | | |
| | 7500444 | Jan 04, 2025 | DP | | | |
| | 7500444*PED | Jul 04, 2025 | | | | |
| <u>ALMOTRIPTAN MALATE - AXERT</u> | | | | | | |
| 021001 001 | >A> 5565447 | May 07, 2015 | DS DP | | U-969 | |
| | >A> 5565447*PED | Nov 07, 2015 | | | | |
| <u>ALMOTRIPTAN MALATE - AXERT</u> | | | | | | |
| 021001 002 | >A> 5565447 | May 07, 2015 | DS DP | | U-969 | |
| | >A> 5565447*PED | Nov 07, 2015 | | | | |
| <u>ALPRAZOLAM - ALPRAZOLAM</u> | | | | | | |
| 078088 001 | | | | | PC | Jul 13, 2009 |
| <u>ALPRAZOLAM - ALPRAZOLAM</u> | | | | | | |
| 078088 002 | | | | | PC | Jul 13, 2009 |
| <u>ALPRAZOLAM - ALPRAZOLAM</u> | | | | | | |
| 078088 003 | | | | | PC | Jul 13, 2009 |
| <u>ALPRAZOLAM - ALPRAZOLAM</u> | | | | | | |
| 078088 004 | | | | | PC | Jul 13, 2009 |
| <u>AMIODARONE HYDROCHLORIDE - NEXTERONE</u> | | | | | | |
| 022325 001 | 5134127 | Jan 23, 2010 | DP | | | |
| | 5376645 | Jan 23, 2010 | DP | | | |
| | 6869939 | May 04, 2022 | DP | | | |

PATENT & EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 5 - May 2009

See List footnote for information regarding List content

| APPL/PROD NO | PATENT NO | PATENT EXPIRATION DATE | PATENT CODES | PATENT DELIST REQUESTED | EXCLUSIVITY CODE(S) | EXCLUSIVITY EXPIRATION DATE |
|---|-------------|------------------------------|-----------------|-------------------------------|------------------------|-----------------------------------|
| <u>AMLODIPINE BESYLATE; ATORVASTATIN CALCIUM - CADUET</u> | | | | | | |
| 021540 001 | RE40667 | Dec 28, 2010 | DS DP U-162 | | | |
| | RE40667*PED | Jun 28, 2011 | | | | |
| <u>AMLODIPINE BESYLATE; ATORVASTATIN CALCIUM - CADUET</u> | | | | | | |
| 021540 002 | RE40667 | Dec 28, 2010 | DS DP U-162 | | | |
| | RE40667*PED | Jun 28, 2011 | | | | |
| <u>AMLODIPINE BESYLATE; ATORVASTATIN CALCIUM - CADUET</u> | | | | | | |
| 021540 003 | RE40667 | Dec 28, 2010 | DS DP U-162 | | | |
| | RE40667*PED | Jun 28, 2011 | | | | |
| <u>AMLODIPINE BESYLATE; ATORVASTATIN CALCIUM - CADUET</u> | | | | | | |
| 021540 004 | RE40667 | Dec 28, 2010 | DS DP U-162 | | | |
| | RE40667*PED | Jun 28, 2011 | | | | |
| <u>AMLODIPINE BESYLATE; ATORVASTATIN CALCIUM - CADUET</u> | | | | | | |
| 021540 005 | RE40667 | Dec 28, 2010 | DS DP U-162 | | | |
| | RE40667*PED | Jun 28, 2011 | | | | |
| <u>AMLODIPINE BESYLATE; ATORVASTATIN CALCIUM - CADUET</u> | | | | | | |
| 021540 006 | RE40667 | Dec 28, 2010 | DS DP U-162 | | | |
| | RE40667*PED | Jun 28, 2011 | | | | |
| <u>AMLODIPINE BESYLATE; ATORVASTATIN CALCIUM - CADUET</u> | | | | | | |
| 021540 007 | RE40667 | Dec 28, 2010 | DS DP U-162 | | | |
| | RE40667*PED | Jun 28, 2011 | | | | |
| <u>AMLODIPINE BESYLATE; ATORVASTATIN CALCIUM - CADUET</u> | | | | | | |
| 021540 008 | RE40667 | Dec 28, 2010 | DS DP U-162 | | | |
| | RE40667*PED | Jun 28, 2011 | | | | |
| <u>AMLODIPINE BESYLATE; ATORVASTATIN CALCIUM - CADUET</u> | | | | | | |
| 021540 009 | RE40667 | Dec 28, 2010 | DS DP U-162 | | | |
| | RE40667*PED | Jun 28, 2011 | | | | |
| <u>AMLODIPINE BESYLATE; ATORVASTATIN CALCIUM - CADUET</u> | | | | | | |
| 021540 010 | RE40667 | Dec 28, 2010 | DS DP U-162 | | | |
| | RE40667*PED | Jun 28, 2011 | | | | |
| <u>AMLODIPINE BESYLATE; ATORVASTATIN CALCIUM - CADUET</u> | | | | | | |
| 021540 011 | RE40667 | Dec 28, 2010 | DS DP U-162 | | | |
| | RE40667*PED | Jun 28, 2011 | | | | |
| <u>AMLODIPINE; HYDROCHLOROTHIAZIDE; VALSARTAN - EXFORGE HCT</u> | | | | | | |
| 022314 001 | 5399578 | Mar 21, 2012 | DS DP U-3 | | NC | Apr 30, 2012 |
| | 5399578*PED | Sep 21, 2012 | | | | |
| | 6294197 | Jun 18, 2017 | DP U-3 | | | |
| | 6294197*PED | Dec 18, 2017 | | | | |
| <u>AMLODIPINE; HYDROCHLOROTHIAZIDE; VALSARTAN - EXFORGE HCT</u> | | | | | | |
| 022314 002 | 5399578 | Mar 21, 2012 | DS DP U-3 | | NC | Apr 30, 2012 |
| | 5399578*PED | Sep 21, 2012 | | | | |
| | 6294197 | Jun 18, 2017 | DP U-3 | | | |
| | 6294197*PED | Dec 18, 2017 | | | | |

PATENT & EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 5 - May 2009

See List footnote for information regarding List content

| APPL/PROD NO | PATENT NO | PATENT EXPIRATION DATE | PATENT CODES | PATENT DELIST REQUESTED | EXCLUSIVITY CODE (S) | EXCLUSIVITY EXPIRATION DATE |
|---|-------------|------------------------------|-----------------|-------------------------------|-------------------------|-----------------------------------|
| <u>AMLODIPINE; HYDROCHLOROTHIAZIDE; VALSARTAN - EXFORGE HCT</u> | | | | | | |
| 022314 003 | 5399578 | Mar 21, 2012 | DS DP U-3 | | NC | Apr 30, 2012 |
| | 5399578*PED | Sep 21, 2012 | | | | |
| | 6294197 | Jun 18, 2017 | DP U-3 | | | |
| | 6294197*PED | Dec 18, 2017 | | | | |
| <u>AMLODIPINE; HYDROCHLOROTHIAZIDE; VALSARTAN - EXFORGE HCT</u> | | | | | | |
| 022314 004 | 5399578 | Mar 21, 2012 | DS DP U-3 | | NC | Apr 30, 2012 |
| | 5399578*PED | Sep 21, 2012 | | | | |
| | 6294197 | Jun 18, 2017 | DP U-3 | | | |
| | 6294197*PED | Dec 18, 2017 | | | | |
| <u>AMLODIPINE; HYDROCHLOROTHIAZIDE; VALSARTAN - EXFORGE HCT</u> | | | | | | |
| 022314 005 | 5399578 | Mar 21, 2012 | DS DP U-3 | | NC | Apr 30, 2012 |
| | 5399578*PED | Sep 21, 2012 | | | | |
| | 6294197 | Jun 18, 2017 | DP U-3 | | | |
| | 6294197*PED | Dec 18, 2017 | | | | |
| <u>AMMONIA, N-13 - AMMONIA N 13</u> | | | | | | |
| 022119 001 | | | | | NCE W | Aug 23, 2012 Aug 23, 2012 |
| <u>AMOXICILLIN; CLARITHROMYCIN; LANSOPRAZOLE - PREVPAC</u> | | | | | | |
| 050757 001 | 4628098 | May 10, 2009 | DS | | | |
| | 4628098*PED | Nov 10, 2009 | | | | |
| | 5013743 | Feb 12, 2010 | | U-452 | | |
| | 5013743*PED | Aug 12, 2010 | | | | |
| | 5045321 | Sep 03, 2008 | DP | | | |
| | 5045321*PED | Mar 03, 2009 | | | | |
| | 5093132 | Sep 03, 2008 | DP | | | |
| | 5093132*PED | Mar 03, 2009 | | | | |
| | 5433959 | Sep 03, 2008 | DP | | | |
| | 5433959*PED | Mar 03, 2009 | | | | |
| <u>ANASTROZOLE - ARIMIDEX</u> | | | | | | |
| 020541 001 | RE36617 | Dec 27, 2009 | DS DP U-946 | | | |
| <u>ANIDULAFUNGIN - ERAXIS</u> | | | | | | |
| 021632 001 | >A> 5965525 | Feb 17, 2020 | DS DP U-540 | | | |
| <u>ANIDULAFUNGIN - ERAXIS</u> | | | | | | |
| 021632 002 | >A> 5965525 | Feb 17, 2020 | DS DP U-540 | | | |
| <u>ARMODAFINIL - NUVIGIL</u> | | | | | | |
| 021875 002 | | | | | NP | Jun 15, 2010 |
| <u>ARMODAFINIL - NUVIGIL</u> | | | | | | |
| 021875 005 | | | | | NP | Jun 15, 2010 |
| <u>ARSENIC TRIOXIDE - TRISENOX</u> | | | | | | |
| 021248 001 | >A> 6982096 | Nov 10, 2018 | U-651 | | | |
| <u>ARTEMETHER; LUMEFANTRINE - COARTEM</u> | | | | | | |
| 022268 001 | | | | | NCE | Apr 07, 2014 |
| <u>ATORVASTATIN CALCIUM - LIPITOR</u> | | | | | | |
| 020702 001 | RE40667 | Dec 28, 2010 | DS DP U-162 | | | |
| | RE40667*PED | Jun 28, 2011 | | | | |

PATENT & EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 5 - May 2009

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| APPL/PROD NO | PATENT NO | PATENT EXPIRATION DATE | PATENT CODES | PATENT DELIST REQUESTED | EXCLUSIVITY CODE(S) | EXCLUSIVITY EXPIRATION DATE |
|---|-------------|------------------------------|-----------------|-------------------------------|------------------------|-----------------------------------|
| <u>ATORVASTATIN CALCIUM - LIPITOR</u> | | | | | | |
| 020702 002 | RE40667 | Dec 28, 2010 | DS DP U-162 | | | |
| | RE40667*PED | Jun 28, 2011 | | | | |
| <u>ATORVASTATIN CALCIUM - LIPITOR</u> | | | | | | |
| 020702 003 | RE40667 | Dec 28, 2010 | DS DP U-162 | | | |
| | RE40667*PED | Jun 28, 2011 | | | | |
| <u>ATORVASTATIN CALCIUM - LIPITOR</u> | | | | | | |
| 020702 004 | RE40667 | Dec 28, 2010 | DS DP U-162 | | | |
| | RE40667*PED | Jun 28, 2011 | | | | |
| <u>AZITHROMYCIN - AZASITE</u> | | | | | | |
| 050810 001 | 5192535 | Mar 09, 2010 | DP U-709 | | | |
| | 6239113 | Mar 31, 2019 | U-709 | | | |
| | 6569443 | Mar 31, 2019 | DP U-709 | | | |
| | 6861411 | Nov 25, 2018 | U-709 | | | |
| | 7056893 | Mar 31, 2019 | DP U-709 | | | |
| <u>BENDAMUSTINE HYDROCHLORIDE - TREANDA</u> | | | | | | |
| 022249 002 | | | | | >A> I-580 | Oct 31, 2011 |
| | | | | | >A> NCE | Mar 20, 2013 |
| | | | | | >A> ODE | Mar 20, 2015 |
| <u>BENZOYL PEROXIDE; CLINDAMYCIN PHOSPHATE - ACANYA</u> | | | | | | |
| 050819 001 | 5733886 | Mar 31, 2015 | DP U-124 | | | |
| | 6117843 | Feb 18, 2012 | DP | | | |
| <u>BENZOYL PEROXIDE; CLINDAMYCIN PHOSPHATE - DUAC</u> | | | | | | |
| 050741 001 | 5466446 | Feb 16, 2014 | DS DP | | | |
| <u>BENZYL ALCOHOL - ULESFIA</u> | | | | | | |
| 022129 001 | >A> 5858383 | Aug 11, 2017 | U-970 | | NCE | Apr 09, 2014 |
| | >A> 6139849 | Aug 11, 2017 | U-970 | | | |
| | >A> 6793931 | Jul 11, 2022 | DP U-970 | | | |
| | >A> 7294342 | Jul 11, 2022 | U-970 | | | |
| <u>BESIFLOXACIN HYDROCHLORIDE - BESIVANCE</u> | | | | | | |
| 022308 001 | | | | | >A> NCE | May 28, 2014 |
| <u>BETAMETHASONE VALERATE - LUXIQ</u> | | | | | | |
| 020934 001 | 7078058 | May 24, 2017 | DP | | | |
| <u>BIMATOPROST - LATISSE</u> | | | | | | |
| 022369 001 | | | | | NP | Dec 24, 2011 |
| <u>BISMUTH SUBCITRATE POTASSIUM; METRONIDAZOLE; TETRACYCLINE - PYLERA</u> | | | | | | |
| 050786 001 | 5196205 | Mar 23, 2010 | U-933 | | | |
| | 5476669 | Mar 23, 2010 | U-933 | | | |
| | 6350468 | Dec 14, 2018 | U-956 | | | |
| | 6350468 | Dec 14, 2018 | U-932 | | | |
| <u>BROMOCRIPTINE MESYLATE - CYCLOSET</u> | | | | | | |
| 020866 001 | | | | | >A> NP | May 05, 2012 |
| <u>BUDESONIDE - PULMICORT RESPULES</u> | | | | | | |
| 020929 001 | 7524834 | Nov 11, 2018 | DP U-966 | | | |
| | 7524834*PED | May 11, 2019 | | | | |

PATENT & EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 5 - May 2009

See List footnote for information regarding List content

| APPL/PROD NO | PATENT NO | PATENT EXPIRATION DATE | PATENT CODES | PATENT DELIST REQUESTED | EXCLUSIVITY CODE(S) | EXCLUSIVITY EXPIRATION DATE |
|--|-------------|------------------------------|-----------------|-------------------------------|------------------------|-----------------------------------|
| <u>BUDESONIDE - PULMICORT RESPULES</u> | | | | | | |
| 020929 002 | 7524834 | Nov 11, 2018 | DP U-966 | | | |
| | 7524834*PED | May 11, 2019 | | | | |
| <u>BUDESONIDE - PULMICORT RESPULES</u> | | | | | | |
| 020929 003 | 7524834 | Nov 11, 2018 | DP U-966 | | | |
| | 7524834*PED | May 11, 2019 | | | | |
| <u>BUDESONIDE; FORMOTEROL FUMARATE DIHYDRATE - SYMBICORT</u> | | | | | | |
| 021929 001 | | | | | I-582 | Feb 27, 2012 |
| <u>BUDESONIDE; FORMOTEROL FUMARATE DIHYDRATE - SYMBICORT</u> | | | | | | |
| 021929 002 | | | | | I-582 | Feb 27, 2012 |
| <u>CALCITRIOL - VECTICAL</u> | | | | | | |
| 022087 001 | | | | | NDF | Jan 23, 2012 |
| <u>CALCIUM CARBONATE; FAMOTIDINE; MAGNESIUM HYDROXIDE - PEPCID COMPLETE</u> | | | | | | |
| 020958 001 | 5075114 | May 23, 2010 | DP | | | |
| | 5075114*PED | Nov 23, 2010 | | | | |
| | 6814978 | Aug 26, 2021 | DP | | | |
| | 6814978*PED | Feb 26, 2022 | | | | |
| <u>CALCIUM CARBONATE; RISEDRONATE SODIUM - ACTONEL WITH CALCIUM (COPACKAGED)</u> | | | | | | |
| 021823 001 | 5583122 | Dec 10, 2013 | DS DP U-353 | | | |
| | 5583122*PED | Jun 10, 2014 | | | | |
| | 5994329 | Jul 17, 2018 | U-353 | | | |
| | 5994329*PED | Jan 17, 2019 | | | | |
| | 6015801 | Jul 17, 2018 | U-353 | | | |
| | 6015801*PED | Jan 17, 2019 | | | | |
| | 6096342 | Nov 21, 2011 | DP | | | |
| | 6096342*PED | May 21, 2012 | | | | |
| | 6165513 | Jun 10, 2018 | DP | | | |
| | 6165513*PED | Dec 10, 2018 | | | | |
| | 6432932 | Jul 17, 2018 | U-595 | | | |
| | 6432932*PED | Jan 17, 2019 | | | | |
| | 6465443 | Aug 14, 2018 | DP | | | |
| | 6465443*PED | Feb 14, 2019 | | | | |
| <u>CICLESONIDE - ALVESCO</u> | | | | | | |
| 021658 002 | | | | | NDF NCE | Jan 10, 2011 Oct 20, 2011 |
| <u>CICLESONIDE - ALVESCO</u> | | | | | | |
| 021658 003 | | | | | NDF NCE | Jan 10, 2011 Oct 20, 2011 |
| <u>CIPROFLOXACIN HYDROCHLORIDE - CETRAXAL</u> | | | | | | |
| 021918 001 | | | | | >A> NDF | May 01, 2012 |
| <u>CIPROFLOXACIN HYDROCHLORIDE; HYDROCORTISONE - CIPRO HC</u> | | | | | | |
| 020805 001 | >A> 5843930 | Jun 06, 2015 | U-646 | | | |
| <u>CLARITHROMYCIN - BIAXIN XL</u> | | | | | | |
| 050775 001 | 6551616 | Jul 15, 2017 | U-924 | | | |
| <u>CLOBETASOL PROPIONATE - OLUX</u> | | | | | | |
| 021142 001 | 6126920 | Mar 01, 2016 | U-484 | | | |

PATENT & EXCLUSIVITY DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 5 - May 2009

See List footnote for information regarding List content

| APPL/PROD NO | PATENT NO | PATENT EXPIRATION DATE | PATENT CODES | PATENT DELIST REQUESTED | EXCLUSIVITY CODE(S) | EXCLUSIVITY EXPIRATION DATE |
|--|-------------|------------------------------|-----------------|-------------------------------|------------------------|-----------------------------------|
| <u>CLOPIDOGREL BISULFATE - PLAVIX</u> | | | | | | |
| 020839 002 | 4847265 | Nov 17, 2011 | DS DP | | | |
| | 6429210 | Jun 10, 2019 | DS DP | | | |
| | 6504030 | Jun 10, 2019 | DS | | | |
| <u>COLESEVELAM HYDROCHLORIDE - WELCHOL</u> | | | | | | |
| 021141 001 | 5607669 | Jun 10, 2014 | | U-323 | | |
| | 5607669*PED | Dec 10, 2014 | | | | |
| | 5679717 | Apr 29, 2014 | | U-323 | | |
| | 5679717*PED | Oct 29, 2014 | | | | |
| | 5693675 | Dec 02, 2014 | | | | |
| | 5693675*PED | Jun 02, 2015 | | | | |
| | 5917007 | Apr 29, 2014 | | U-323 | | |
| | 5917007*PED | Oct 29, 2014 | | | | |
| | 5919832 | Jun 10, 2014 | | | | |
| | 5919832*PED | Dec 10, 2014 | | | | |
| | 6066678 | Jun 10, 2014 | | U-323 | | |
| | 6066678*PED | Dec 10, 2014 | | | | |
| | 6433026 | Jun 10, 2014 | | | | |
| | 6433026*PED | Dec 10, 2014 | | | | |
| <u>COLESEVELAM HYDROCHLORIDE - WELCHOL</u> | | | | | | |
| 021176 001 | 5607669 | Jun 10, 2014 | | U-323 | I-553 PED | Jan 18, 2011 Jul 18, 2011 |
| | 5607669*PED | Dec 10, 2014 | | | | |
| | 5679717 | Apr 29, 2014 | | U-323 | | |
| | 5679717*PED | Oct 29, 2014 | | | | |
| | 5693675 | Dec 02, 2014 | DS | | | |
| | 5693675*PED | Jun 02, 2015 | | | | |
| | 5917007 | Apr 29, 2014 | DS | U-323 | | |
| | 5917007*PED | Oct 29, 2014 | | | | |
| | 5919832 | Apr 29, 2014 | DS | | | |
| | 5919832*PED | Oct 29, 2014 | | | | |
| | 6066678 | Apr 29, 2014 | DS | U-323 | | |
| | 6066678*PED | Oct 29, 2014 | | | | |
| | 6433026 | Apr 29, 2014 | DS | | | |
| | 6433026*PED | Oct 29, 2014 | | | | |
| | 6784254 | Apr 29, 2014 | DS DP | | | |
| | 6784254*PED | Oct 29, 2014 | | | | |
| | 7101960 | Apr 29, 2014 | DS DP | U-757 | | |
| | 7101960*PED | Oct 29, 2014 | | | | |
| | 7229613 | Apr 17, 2022 | | U-851 | | |
| | 7229613*PED | Oct 17, 2022 | | | | |
| <u>CYCLOSPORINE - SANDIMMUNE</u> | | | | | | |
| 050625 001 | 7511014 | Feb 16, 2010 | DP | | | |
| <u>CYCLOSPORINE - SANDIMMUNE</u> | | | | | | |
| 050625 002 | 7511014 | Feb 16, 2010 | DP | | | |
| <u>CYCLOSPORINE - SANDIMMUNE</u> | | | | | | |
| 050625 003 | 7511014 | Feb 16, 2010 | DP | | | |
| <u>DASATINIB - SPRYCEL</u> | | | | | | |
| 021986 001 | 7491725 | Oct 13, 2025 | DS DP | | >A> D-120 | May 21, 2012 |

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|--|-------------|------------------------------|-----------------|-------------------------------|------------------------|-----------------------------------|
| <u>DASATINIB - SPRYCEL</u> | | | | | | |
| 021986 002 | 7491725 | Oct 13, 2025 | DS DP | | >A> D-120 | May 21, 2012 |
| <u>DASATINIB - SPRYCEL</u> | | | | | | |
| 021986 003 | 7491725 | Oct 13, 2025 | DS DP | | >A> D-120 | May 21, 2012 |
| <u>DASATINIB - SPRYCEL</u> | | | | | | |
| 021986 004 | 7491725 | Oct 13, 2025 | DS DP | | >A> D-120 | May 21, 2012 |
| <u>DEGARELIX ACETATE - DEGARELIX ACETATE</u> | | | | | | |
| 022201 001 | 5925730 | Apr 11, 2017 | DS DP U-943 | | | |
| <u>DEGARELIX ACETATE - DEGARELIX ACETATE</u> | | | | | | |
| 022201 002 | 5925730 | Apr 11, 2017 | DS DP U-943 | | | |
| <u>DEXAMETHASONE; TOBRAMYCIN - TOBRADEX ST</u> | | | | | | |
| 050818 001 | 5149694 | Sep 22, 2009 | | U-953 | | |
| <u>DEXLANSOPRAZOLE - KAPIDEX</u> | | | | | | |
| 022287 001 | 5045321 | Sep 03, 2008 | DP | | NP | Jan 30, 2012 |
| | 5045321*PED | Mar 03, 2009 | | | PED | Jul 30, 2012 |
| | 5093132 | Sep 03, 2008 | DP U-949 | | | |
| | 5093132 | Sep 03, 2008 | DP U-950 | | | |
| | 5093132 | Sep 03, 2008 | DP U-951 | | | |
| | 5093132*PED | Mar 03, 2009 | | | | |
| | 5433959 | Sep 03, 2008 | DP U-949 | | | |
| | 5433959 | Sep 03, 2008 | DP U-950 | | | |
| | 5433959 | Sep 03, 2008 | DP U-951 | | | |
| | 5433959*PED | Mar 03, 2009 | | | | |
| | 6462058 | Jun 15, 2020 | DS DP U-951 | | | |
| | 6462058 | Jun 15, 2020 | DS DP U-950 | | | |
| | 6462058 | Jun 15, 2020 | DS DP U-949 | | | |
| | 6462058*PED | Dec 15, 2020 | | | | |
| | 6664276 | Jun 15, 2020 | DS DP U-949 | | | |
| | 6664276 | Jun 15, 2020 | DS DP U-950 | | | |
| | 6664276 | Jun 15, 2020 | DS DP U-951 | | | |
| | 6664276*PED | Dec 15, 2020 | | | | |
| | 6939971 | Jun 15, 2020 | U-949 | | | |
| | 6939971 | Jun 15, 2020 | U-950 | | | |
| | 6939971 | Jun 15, 2020 | U-951 | | | |
| | 6939971*PED | Dec 15, 2020 | | | | |
| | 7285668 | Jun 15, 2020 | DS | | | |
| | 7285668*PED | Dec 15, 2020 | | | | |

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|--|-------------|------------------------------|-----------------|-------------------------------|-------------------------|-----------------------------------|
| <u>DEXLANSOPRAZOLE - KAPIDEX</u> | | | | | | |
| 022287 002 | 5045321 | Sep 03, 2008 | DP | | NP | Jan 30, 2012 |
| | 5045321*PED | Mar 03, 2009 | | | PED | Jul 30, 2012 |
| | 5093132 | Sep 03, 2008 | DP U-949 | | | |
| | 5093132 | Sep 03, 2008 | DP U-950 | | | |
| | 5093132 | Sep 03, 2008 | DP U-951 | | | |
| | 5093132*PED | Mar 03, 2009 | | | | |
| | 5433959 | Sep 03, 2008 | DP U-949 | | | |
| | 5433959 | Sep 03, 2008 | DP U-950 | | | |
| | 5433959 | Sep 03, 2008 | DP U-951 | | | |
| | 5433959*PED | Mar 03, 2009 | | | | |
| | 6462058 | Jun 15, 2020 | DS DP U-951 | | | |
| | 6462058 | Jun 15, 2020 | DS DP U-950 | | | |
| | 6462058 | Jun 15, 2020 | DS DP U-949 | | | |
| | 6462058*PED | Dec 15, 2020 | | | | |
| | 6664276 | Jun 15, 2020 | DS DP U-949 | | | |
| | 6664276 | Jun 15, 2020 | DS DP U-950 | | | |
| | 6664276 | Jun 15, 2020 | DS DP U-951 | | | |
| | 6664276*PED | Dec 15, 2020 | | | | |
| | 6939971 | Jun 15, 2020 | U-949 | | | |
| | 6939971 | Jun 15, 2020 | U-950 | | | |
| | 6939971 | Jun 15, 2020 | U-951 | | | |
| | 6939971*PED | Dec 15, 2020 | | | | |
| | 7285668 | Jun 15, 2020 | DS | | | |
| | 7285668*PED | Dec 15, 2020 | | | | |
| <u>DILTIAZEM HYDROCHLORIDE - CARDIZEM CD</u> | | | | | | |
| 020062 005 | 5286497 | May 20, 2011 | DP | | | |
| | 5439689 | Aug 08, 2012 | DP U-107 | | | |
| | 5470584 | May 20, 2011 | DP | | | |
| <u>DINOPROSTONE - CERVIDIL</u> | | | | | | |
| 020411 001 | 5269321 | Jul 14, 2012 | DP U-110 | | | |
| <u>DIVALPROEX SODIUM - DIVALPROEX SODIUM</u> | | | | | | |
| 077567 002 | | | | | PC | Aug 01, 2009 |
| <u>DOXERCALCIFEROL - HECTOROL</u> | | | | | | |
| 021027 001 | 5707980 | Aug 17, 2010 | U-321 | Y | | |
| <u>ELTROMBOPAG OLAMINE - PROMACTA</u> | | | | | | |
| 022291 001 | 7473686 | Jul 24, 2021 | DS DP U-930 | | | |
| <u>ELTROMBOPAG OLAMINE - PROMACTA</u> | | | | | | |
| 022291 002 | 7473686 | Jul 24, 2021 | DS DP U-930 | | | |
| <u>ESCITALOPRAM OXALATE - LEXAPRO</u> | | | | | | |
| 021323 001 | | | | | NPP | Mar 19, 2012 |
| <u>ESCITALOPRAM OXALATE - LEXAPRO</u> | | | | | | |
| 021323 002 | | | | | NPP | Mar 19, 2012 |
| <u>ESCITALOPRAM OXALATE - LEXAPRO</u> | | | | | | |
| 021323 003 | | | | | NPP | Mar 19, 2012 |
| <u>ESCITALOPRAM OXALATE - LEXAPRO</u> | | | | | | |
| 021365 001 | | | | | NPP | Mar 19, 2012 |

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|--|-------------|------------------------------|-----------------|-------------------------------|-------------------------|-----------------------------------|
| <u>ESOMEPRAZOLE MAGNESIUM - NEXIUM</u> | | | | | | |
| 021153 001 | | | | | NPP PED | Apr 28, 2009 Oct 28, 2009 |
| <u>ESOMEPRAZOLE MAGNESIUM - NEXIUM</u> | | | | | | |
| 021153 002 | | | | | NPP PED | Apr 28, 2009 Oct 28, 2009 |
| <u>ESOMEPRAZOLE MAGNESIUM - NEXIUM</u> | | | | | | |
| 021957 001 | | | | | NPP PED | Apr 28, 2009 Oct 28, 2009 |
| <u>ESOMEPRAZOLE MAGNESIUM - NEXIUM</u> | | | | | | |
| 021957 002 | | | | | NPP PED | Apr 28, 2009 Oct 28, 2009 |
| <u>ESOMEPRAZOLE MAGNESIUM - NEXIUM</u> | | | | | | |
| 022101 001 | | | | | NPP PED | Feb 27, 2011 Aug 27, 2011 |
| <u>ESTRADIOL - ELESTRIN</u> | | | | | | |
| 021813 001 | 7470433 | Aug 03, 2021 | DP | | | |
| <u>EVEROLIMUS - AFINITOR</u> | | | | | | |
| 022334 001 | 5665772 | Sep 09, 2014 | DS DP | | NCE | Mar 30, 2014 |
| | 6004973 | Jul 12, 2016 | DP | | | |
| | 7297703 | Dec 06, 2019 | DP | | | |
| <u>EVEROLIMUS - AFINITOR</u> | | | | | | |
| 022334 002 | 5665772 | Sep 09, 2014 | DS DP | | NCE | Mar 30, 2014 |
| | 6004973 | Jul 12, 2016 | DP | | | |
| | 7297703 | Dec 06, 2019 | DP | | | |
| <u>EXENATIDE SYNTHETIC - BYETTA</u> | | | | | | |
| 021773 001 | >A> 7521423 | Oct 15, 2017 | DP | | | |
| <u>EXENATIDE SYNTHETIC - BYETTA</u> | | | | | | |
| 021773 002 | >A> 7521423 | Oct 15, 2017 | DP | | | |
| <u>FEBUXOSTAT - ULORIC</u> | | | | | | |
| 021856 001 | 5614520 | Mar 25, 2014 | DS DP U-954 | | NCE | Feb 13, 2014 |
| | 6225474 | Jun 18, 2019 | DS | | | |
| | 7361676 | Mar 08, 2024 | DP | | | |
| <u>FEBUXOSTAT - ULORIC</u> | | | | | | |
| 021856 002 | 5614520 | Mar 25, 2014 | DS DP U-954 | | NCE | Feb 13, 2014 |
| | 6225474 | Jun 18, 2019 | DS | | | |
| | 7361676 | Mar 08, 2024 | DP | | | |
| <u>FLUDARABINE PHOSPHATE - FLUDARABINE PHOSPHATE</u> | | | | | | |
| 022273 001 | 7148207 | Dec 20, 2022 | DP U-944 | | NDF | Dec 18, 2011 |
| <u>FLUOXETINE HYDROCHLORIDE - PROZAC</u> | | | | | | |
| 018936 001 | 6960577 | Nov 01, 2017 | U-963 | | I-589 | Mar 19, 2012 |
| <u>FLUOXETINE HYDROCHLORIDE - PROZAC</u> | | | | | | |
| 018936 003 | 6960577 | Nov 01, 2017 | U-963 | | I-589 | Mar 19, 2012 |
| <u>FLUOXETINE HYDROCHLORIDE - PROZAC</u> | | | | | | |
| 018936 006 | 6960577 | Nov 01, 2017 | U-963 | | I-589 | Mar 19, 2012 |

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|---|-------------|------------------------------|-----------------|-------------------------------|-------------------------|-----------------------------------|
| <u>FLUOXETINE HYDROCHLORIDE; OLANZAPINE - SYMBYAX</u> | | | | | | |
| 021520 001 | 6960577 | Nov 01, 2017 | U-962 | | I-593 | Mar 19, 2012 |
| <u>FLUOXETINE HYDROCHLORIDE; OLANZAPINE - SYMBYAX</u> | | | | | | |
| 021520 002 | 6960577 | Nov 01, 2017 | U-962 | | I-593 | Mar 19, 2012 |
| <u>FLUOXETINE HYDROCHLORIDE; OLANZAPINE - SYMBYAX</u> | | | | | | |
| 021520 003 | 6960577 | Nov 01, 2017 | U-962 | | I-593 | Mar 19, 2012 |
| <u>FLUOXETINE HYDROCHLORIDE; OLANZAPINE - SYMBYAX</u> | | | | | | |
| 021520 004 | 6960577 | Nov 01, 2017 | U-962 | | I-593 | Mar 19, 2012 |
| <u>FLUOXETINE HYDROCHLORIDE; OLANZAPINE - SYMBYAX</u> | | | | | | |
| 021520 005 | 6960577 | Nov 01, 2017 | U-962 | | I-593 | Mar 19, 2012 |
| <u>FLUTICASONE PROPIONATE - FLOVENT DISKUS 100</u> | | | | | | |
| 020833 002 | 5590645 | Mar 01, 2011 | DP | | | |
| | 5590645*PED | Sep 01, 2011 | | | | |
| | 5860419 | Mar 01, 2011 | DP | | | |
| | 5860419*PED | Sep 01, 2011 | | | | |
| | 5873360 | Feb 23, 2016 | DP | | | |
| | 5873360*PED | Aug 23, 2016 | | | | |
| | 6032666 | Mar 01, 2011 | DP | | | |
| | 6032666*PED | Sep 01, 2011 | | | | |
| | 6378519 | Mar 01, 2011 | DP | | | |
| | 6378519*PED | Sep 01, 2011 | | | | |
| | 6536427 | Mar 01, 2011 | DP | | | |
| | 6536427*PED | Sep 01, 2011 | | | | |
| | 6792945 | Mar 01, 2011 | DP | | | |
| | 6792945*PED | Sep 01, 2011 | | | | |
| | 7225808 | Mar 01, 2011 | DP | | | |
| | 7225808*PED | Sep 01, 2011 | | | | |
| | 7389775 | Mar 01, 2011 | DP | | | |
| | 7389775*PED | Sep 01, 2011 | | | | |
| <u>FLUTICASONE PROPIONATE - FLOVENT DISKUS 250</u> | | | | | | |
| 020833 003 | 5590645 | Mar 01, 2011 | DP | | | |
| | 5590645*PED | Sep 01, 2011 | | | | |
| | 5860419 | Mar 01, 2011 | DP | | | |
| | 5860419*PED | Sep 01, 2011 | | | | |
| | 5873360 | Feb 23, 2016 | DP | | | |
| | 5873360*PED | Aug 23, 2016 | | | | |
| | 6032666 | Mar 01, 2011 | DP | | | |
| | 6032666*PED | Sep 01, 2011 | | | | |
| | 6378519 | Mar 01, 2011 | DP | | | |
| | 6378519*PED | Sep 01, 2011 | | | | |
| | 6536427 | Mar 01, 2011 | DP | | | |
| | 6536427*PED | Sep 01, 2011 | | | | |
| | 6792945 | Mar 01, 2011 | DP | | | |
| | 6792945*PED | Sep 01, 2011 | | | | |
| | 7225808 | Mar 01, 2011 | DP | | | |
| | 7225808*PED | Sep 01, 2011 | | | | |
| | 7389775 | Mar 01, 2011 | DP | | | |
| | 7389775*PED | Sep 01, 2011 | | | | |

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|---|-------------|------------------------------|-----------------|-------------------------------|------------------------|-----------------------------------|
| <u>FLUTICASONE PROPIONATE - FLOVENT DISKUS 50</u> | | | | | | |
| 020833 001 | 5590645 | Mar 01, 2011 | DP | | | |
| | 5590645*PED | Sep 01, 2011 | | | | |
| | 5860419 | Mar 01, 2011 | DP | | | |
| | 5860419*PED | Sep 01, 2011 | | | | |
| | 5873360 | Feb 23, 2016 | DP | | | |
| | 5873360*PED | Aug 23, 2016 | | | | |
| | 6032666 | Mar 01, 2011 | DP | | | |
| | 6032666*PED | Sep 01, 2011 | | | | |
| | 6378519 | Mar 01, 2011 | DP | | | |
| | 6378519*PED | Sep 01, 2011 | | | | |
| | 6536427*PED | Sep 01, 2011 | | | | |
| | 6792945 | Mar 01, 2011 | DP | | | |
| | 6792945*PED | Sep 01, 2011 | | | | |
| | 7225808 | Mar 01, 2011 | DP | | | |
| | 7225808*PED | Sep 01, 2011 | | | | |
| | 7389775 | Mar 01, 2011 | DP | | | |
| | 7389775*PED | Sep 01, 2011 | | | | |

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| <u>FLUTICASONE PROPIONATE - FLOVENT HFA</u> | | | | | | |
| 021433 001 | 5658549 | Aug 19, 2014 | DP U-710 | | | |
| | 5658549*PED | Feb 19, 2015 | | | | |
| | 5674472 | Oct 07, 2014 | DP | | | |
| | 5674472*PED | Apr 07, 2015 | | | | |
| | 6161724 | Jan 16, 2018 | DP | | | |
| | 6161724*PED | Jul 16, 2018 | | | | |
| | 6170717 | Dec 23, 2017 | DP | | | |
| | 6170717*PED | Jun 23, 2018 | | | | |
| | 6251368 | Dec 04, 2012 | DP | | | |
| | 6251368*PED | Jun 04, 2013 | | | | |
| | 6253762 | Apr 14, 2015 | DP U-582 | | | |
| | 6253762*PED | Oct 14, 2015 | | | | |
| | 6315173 | Jun 23, 2017 | DP | | | |
| | 6315173*PED | Jun 23, 2018 | | | | |
| | 6431168 | Jun 08, 2018 | DP | | | |
| | 6431168*PED | Dec 08, 2018 | | | | |
| | 6435372 | Jan 16, 2018 | DP | | | |
| | 6435372*PED | Jul 16, 2018 | | | | |
| | 6510969 | Dec 23, 2017 | DP | | | |
| | 6510969*PED | Jun 23, 2018 | | | | |
| | 6546928 | Apr 14, 2015 | DP U-583 | | | |
| | 6546928*PED | Oct 14, 2015 | | | | |
| | 6596260 | Aug 10, 2014 | DP | | | |
| | 6596260*PED | Feb 10, 2015 | | | | |
| | 6743413 | Jun 01, 2021 | U-581 | | | |
| | 6743413*PED | Dec 01, 2021 | | | | |
| | 6938796 | Jan 16, 2018 | DP | | | |
| | 6938796*PED | Jul 16, 2018 | | | | |
| | 6966467 | Dec 23, 2017 | DP | | | |
| | 6966467*PED | Jun 23, 2018 | | | | |
| | 6997349 | Jan 16, 2018 | DP | | | |
| | 6997349*PED | Jul 16, 2018 | | | | |
| | 7107986 | Jun 08, 2018 | DP | | | |
| | 7107986*PED | Dec 08, 2019 | | | | |
| | 7143908 | Jan 16, 2018 | DP | | | |
| | 7143908*PED | Jul 16, 2018 | | | | |
| | 7350676 | Aug 24, 2018 | DP | | | |
| | 7350676*PED | Feb 24, 2019 | | | | |
| | 7500444 | Jan 04, 2025 | DP | | | |
| | 7500444*PED | Jul 04, 2025 | | | | |

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|---|-------------|------------------------------|-----------------|-------------------------------|------------------------|-----------------------------------|
| <u>FLUTICASONE PROPIONATE - FLOVENT HFA</u> | | | | | | |
| 021433 002 | 5658549 | Aug 19, 2014 | DP U-710 | | | |
| | 5658549*PED | Feb 19, 2015 | | | | |
| | 5674472 | Oct 07, 2014 | DP | | | |
| | 5674472*PED | Apr 07, 2015 | | | | |
| | 6161724 | Jan 16, 2018 | DP | | | |
| | 6161724*PED | Jul 16, 2018 | | | | |
| | 6170717 | Dec 23, 2017 | DP | | | |
| | 6170717*PED | Jun 23, 2018 | | | | |
| | 6251368 | Dec 04, 2012 | DP | | | |
| | 6251368*PED | Jun 04, 2013 | | | | |
| | 6253762 | Apr 14, 2015 | DP U-582 | | | |
| | 6253762*PED | Oct 14, 2015 | | | | |
| | 6315173 | Dec 23, 2017 | DP | | | |
| | 6315173*PED | Jun 23, 2018 | | | | |
| | 6431168 | Jun 08, 2018 | DP | | | |
| | 6431168*PED | Dec 08, 2018 | | | | |
| | 6435372 | Jan 16, 2018 | DP | | | |
| | 6435372*PED | Jul 16, 2018 | | | | |
| | 6510969 | Dec 23, 2017 | DP | | | |
| | 6510969*PED | Jun 23, 2018 | | | | |
| | 6546928 | Apr 14, 2015 | DP U-583 | | | |
| | 6546928*PED | Oct 14, 2015 | | | | |
| | 6596260 | Aug 10, 2014 | DP | | | |
| | 6596260*PED | Feb 10, 2015 | | | | |
| | 6743413 | Jun 01, 2021 | U-581 | | | |
| | 6743413*PED | Dec 01, 2021 | | | | |
| | 6938796 | Jan 16, 2018 | DP | | | |
| | 6938796*PED | Jul 16, 2018 | | | | |
| | 6966467 | Dec 23, 2017 | DP | | | |
| | 6966467*PED | Jun 23, 2018 | | | | |
| | 6997349 | Jan 16, 2018 | DP | | | |
| | 6997349*PED | Jul 16, 2018 | | | | |
| | 7107986 | Jun 08, 2018 | DP | | | |
| | 7107986*PED | Dec 08, 2019 | | | | |
| | 7143908 | Jan 16, 2018 | DP | | | |
| | 7143908*PED | Jul 16, 2018 | | | | |
| | 7350676 | Aug 24, 2018 | DP | | | |
| | 7350676*PED | Feb 24, 2019 | | | | |
| | 7500444 | Jan 04, 2025 | DP | | | |
| | 7500444*PED | Jul 04, 2025 | | | | |

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|---|-------------|------------------------------|-----------------|-------------------------------|------------------------|-----------------------------------|
| <u>FLUTICASONE PROPIONATE - FLOVENT HFA</u> | | | | | | |
| 021433 003 | 5658549 | Aug 19, 2014 | DP | U-710 | | |
| | 5658549*PED | Feb 19, 2015 | | U-710 | | |
| | 5674472 | Oct 07, 2014 | DP | | | |
| | 5674472*PED | Apr 07, 2015 | | | | |
| | 6161724 | Jan 16, 2018 | DP | | | |
| | 6161724*PED | Jul 16, 2018 | | | | |
| | 6170717 | Dec 23, 2017 | DP | | | |
| | 6170717*PED | Jun 23, 2018 | | | | |
| | 6251368 | Dec 04, 2012 | DP | | | |
| | 6251368*PED | Jun 04, 2013 | | | | |
| | 6253762 | Apr 14, 2015 | DP | U-582 | | |
| | 6253762*PED | Oct 14, 2015 | | U-582 | | |
| | 6315173 | Dec 23, 2017 | DP | | | |
| | 6315173*PED | Jun 23, 2018 | DP | | | |
| | 6431168 | Jun 08, 2018 | DP | | | |
| | 6431168*PED | Dec 08, 2018 | | | | |
| | 6435372 | Jan 16, 2018 | DP | | | |
| | 6435372*PED | Jul 16, 2018 | | | | |
| | 6510969 | Dec 23, 2017 | DP | | | |
| | 6510969*PED | Jun 23, 2018 | DP | | | |
| | 6546928 | Apr 14, 2015 | DP | U-583 | | |
| | 6546928*PED | Oct 14, 2015 | | U-583 | | |
| | 6596260 | Aug 10, 2014 | DP | | | |
| | 6596260*PED | Feb 10, 2015 | | | | |
| | 6743413 | Jun 01, 2021 | | U-581 | | |
| | 6743413*PED | Dec 01, 2021 | | U-581 | | |
| | 6938796 | Jan 16, 2018 | DP | | | |
| | 6938796*PED | Jul 16, 2018 | | | | |
| | 6966467 | Dec 23, 2017 | DP | | | |
| | 6966467*PED | Jun 23, 2018 | | | | |
| | 6997349 | Jan 16, 2018 | DP | | | |
| | 6997349*PED | Jul 16, 2018 | | | | |
| | 7107986 | Jun 08, 2018 | DP | | | |
| | 7107986*PED | Dec 08, 2019 | | | | |
| | 7143908 | Jan 16, 2018 | DP | | | |
| | 7143908*PED | Jul 16, 2018 | | | | |
| | 7350676 | Aug 24, 2018 | DP | | | |
| | 7350676*PED | Feb 24, 2019 | | | | |
| | 7500444 | Jan 04, 2025 | DP | | | |
| | 7500444*PED | Jul 04, 2025 | | | | |

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|--|-------------|------------------------------|-----------------|-------------------------------|------------------------|-----------------------------------|
| <u>FLUTICASONE PROPIONATE; SALMETEROL XINAFOATE - ADVAIR DISKUS 100/50</u> | | | | | | |
| 021077 001 | 5590645 | Mar 01, 2011 | DP | | M-84 | Mar 31, 2012 |
| | 5590645*PED | Sep 01, 2011 | | | | |
| | 5860419 | Mar 01, 2011 | DP | | | |
| | 5860419*PED | Sep 01, 2011 | | | | |
| | 5873360 | Feb 23, 2016 | DP | | | |
| | 5873360*PED | Aug 23, 2016 | | | | |
| | 6032666 | Mar 01, 2011 | DP | | | |
| | 6032666*PED | Sep 01, 2011 | | | | |
| | 6378519 | Mar 01, 2011 | DP | | | |
| | 6378519*PED | Sep 01, 2011 | | | | |
| | 6792945 | Mar 01, 2011 | DP | | | |
| | 6792945*PED | Sep 01, 2011 | | | | |
| | 7225808 | Mar 01, 2011 | DP | | | |
| | 7225808*PED | Sep 01, 2011 | | | | |
| | 7389775 | Mar 01, 2011 | DP | | | |
| | 7389775*PED | Sep 01, 2011 | | | | |
| <u>FLUTICASONE PROPIONATE; SALMETEROL XINAFOATE - ADVAIR DISKUS 250/50</u> | | | | | | |
| 021077 002 | 5590645 | Mar 01, 2011 | DP | | M-84 | Mar 31, 2012 |
| | 5590645*PED | Sep 01, 2011 | | | | |
| | 5860419 | Mar 01, 2011 | DP | | | |
| | 5860419*PED | Sep 01, 2011 | | | | |
| | 5873360 | Feb 23, 2016 | DP | | | |
| | 5873360*PED | Aug 23, 2016 | | | | |
| | 6032666 | Mar 01, 2011 | DP | | | |
| | 6032666*PED | Sep 01, 2011 | | | | |
| | 6378519 | Mar 01, 2011 | DP | | | |
| | 6378519*PED | Sep 01, 2011 | | | | |
| | 6792945 | Mar 01, 2011 | DP | | | |
| | 6792945*PED | Sep 01, 2011 | | | | |
| | 7225808 | Mar 01, 2011 | DP | | | |
| | 7225808*PED | Sep 01, 2011 | | | | |
| | 7389775 | Mar 01, 2011 | DP | | | |
| | 7389775*PED | Sep 01, 2011 | | | | |

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| APPL/PROD NO | PATENT NO | PATENT EXPIRATION DATE | PATENT CODES | PATENT DELIST REQUESTED | EXCLUSIVITY CODE(S) | EXCLUSIVITY EXPIRATION DATE |
|--|-------------|------------------------------|-----------------|-------------------------------|------------------------|-----------------------------------|
| <u>FLUTICASONE PROPIONATE; SALMETEROL XINAFOATE - ADVAIR DISKUS 500/50</u> | | | | | | |
| 021077 003 | 5590645 | Mar 01, 2011 | DP | | M-84 | Mar 31, 2012 |
| | 5590645*PED | Sep 01, 2011 | | | | |
| | 5860419 | Mar 01, 2011 | DP | | | |
| | 5860419*PED | Sep 01, 2011 | | | | |
| | 5873360 | Feb 23, 2016 | DP | | | |
| | 5873360*PED | Aug 23, 2016 | | | | |
| | 6032666 | Mar 01, 2011 | DP | | | |
| | 6032666*PED | Sep 01, 2011 | | | | |
| | 6378519 | Mar 01, 2011 | DP | | | |
| | 6378519*PED | Sep 01, 2011 | | | | |
| | 6792945 | Mar 01, 2011 | DP | | | |
| | 6792945*PED | Sep 01, 2011 | | | | |
| | 7225808 | Mar 01, 2011 | DP | | | |
| | 7225808*PED | Sep 01, 2011 | | | | |
| | 7389775 | Mar 01, 2011 | DP | | | |
| | 7389775*PED | Sep 01, 2011 | | | | |

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|--|-------------|------------------------------|-----------------|-------------------------------|------------------------|-----------------------------------|
| <u>FLUTICASONE PROPIONATE; SALMETEROL XINAFOATE - ADVAIR HFA</u> | | | | | | |
| 021254 001 | 5658549 | Aug 19, 2014 | DP | | | U-738 |
| | 5658549*PED | Feb 19, 2015 | | | | U-738 |
| | 5674472 | Oct 07, 2014 | DP | | | |
| | 5674472*PED | Apr 07, 2015 | | | | |
| | 6161724 | Jan 16, 2018 | DP | | | |
| | 6161724*PED | Jul 16, 2018 | | | | |
| | 6170717 | Dec 23, 2017 | DP | | | |
| | 6170717*PED | Jun 23, 2018 | | | | |
| | 6251368 | Dec 04, 2012 | DP | | | |
| | 6251368*PED | Jun 04, 2013 | | | | |
| | 6253762 | Apr 14, 2015 | DP | | | U-738 |
| | 6253762*PED | Oct 14, 2015 | | | | U-738 |
| | 6315173 | Dec 23, 2017 | DP | | | |
| | 6315173*PED | Jun 23, 2018 | | | | |
| | 6341168 | Jun 08, 2018 | DP | | | |
| | 6341168*PED | Dec 08, 2018 | | | | |
| | 6435372 | Jan 16, 2018 | DP | | | |
| | 6435372*PED | Jul 16, 2018 | | | | |
| | 6510969 | Dec 23, 2017 | | | | |
| | 6510969*PED | Jun 23, 2018 | | | | |
| | 6546928 | Apr 14, 2015 | DP | | | |
| | 6546928*PED | Oct 14, 2015 | | | | |
| | 6596260 | Aug 10, 2014 | DP | | | |
| | 6596260*PED | Feb 10, 2015 | | | | |
| | 6743413 | Jun 01, 2021 | | | | U-841 |
| | 6743413*PED | Dec 01, 2021 | | | | U-841 |
| | 6938796 | Jan 16, 2018 | DP | | | |
| | 6938796*PED | Jul 16, 2018 | | | | |
| | 6966467 | Dec 23, 2017 | DP | | | |
| | 6966467*PED | Jun 23, 2018 | | | | |
| | 6997349 | Jan 16, 2018 | DP | | | |
| | 6997349*PED | Jul 16, 2018 | | | | |
| | 7107986 | Jun 08, 2018 | DP | | | |
| | 7107986*PED | Dec 08, 2018 | | | | |
| | 7143908 | Jan 16, 2018 | DP | | | |
| | 7143908*PED | Jul 16, 2018 | | | | |
| | 7350676 | Aug 24, 2018 | DP | | | |
| | 7350676*PED | Feb 24, 2019 | | | | |
| | 7500444 | Jan 04, 2025 | DP | | | |
| | 7500444*PED | Jul 04, 2025 | | | | |

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|--|-------------|------------------------------|-----------------|-------------------------------|------------------------|-----------------------------------|
| <u>FLUTICASONE PROPIONATE; SALMETEROL XINAFOATE - ADVAIR HFA</u> | | | | | | |
| 021254 002 | 5658549 | Aug 19, 2014 | DP U-738 | | | |
| | 5658549*PED | Feb 19, 2015 | DP U-738 | | | |
| | 5674472 | Oct 07, 2014 | DP | | | |
| | 5674472*PED | Apr 07, 2015 | DP | | | |
| | 6161724 | Jan 16, 2018 | DP | | | |
| | 6161724*PED | Jul 16, 2018 | | | | |
| | 6170717 | Dec 23, 2017 | DP | | | |
| | 6170717*PED | Jun 23, 2018 | | | | |
| | 6251368 | Dec 04, 2012 | DP | | | |
| | 6251368*PED | Jun 04, 2013 | DP | | | |
| | 6253762 | Apr 14, 2015 | DP U-738 | | | |
| | 6253762*PED | Oct 14, 2015 | DP U-738 | | | |
| | 6315173 | Dec 23, 2017 | DP | | | |
| | 6315173*PED | Jun 23, 2018 | DP | | | |
| | 6341168 | Jun 08, 2018 | DP | | | |
| | 6341168*PED | Dec 08, 2018 | | | | |
| | 6435372 | Jan 16, 2018 | DP | | | |
| | 6435372*PED | Jul 16, 2018 | | | | |
| | 6510969 | Dec 23, 2017 | DP | | | |
| | 6510969*PED | Jun 23, 2018 | DP | | | |
| | 6546928 | Apr 14, 2015 | DP | | | |
| | 6546928*PED | Oct 14, 2015 | DP | | | |
| | 6596260 | Aug 10, 2014 | DP | | | |
| | 6596260*PED | Feb 10, 2015 | | | | |
| | 6743413 | Jun 01, 2021 | | U-841 | | |
| | 6743413*PED | Dec 01, 2021 | | U-841 | | |
| | 6938796 | Jan 16, 2018 | DP | | | |
| | 6938796*PED | Jul 16, 2018 | | | | |
| | 6966467 | Dec 23, 2017 | DP | | | |
| | 6966467*PED | Jun 23, 2018 | | | | |
| | 6997349 | Jan 16, 2018 | DP | | | |
| | 6997349*PED | Jul 16, 2018 | | | | |
| | 7107986 | Jun 08, 2018 | DP | | | |
| | 7107986*PED | Dec 08, 2018 | | | | |
| | 7143908 | Jan 16, 2018 | DP | | | |
| | 7143908*PED | Jul 16, 2018 | | | | |
| | 7350676 | Aug 24, 2018 | DP | | | |
| | 7350676*PED | Feb 24, 2019 | | | | |
| | 7500444 | Jan 04, 2025 | DP | | | |
| | 7500444*PED | Jul 04, 2025 | | | | |

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|--|-------------|------------------------------|-----------------|-------------------------------|------------------------|-----------------------------------|
| <u>FLUTICASONE PROPIONATE; SALMETEROL XINAFOATE - ADVAIR HFA</u> | | | | | | |
| 021254 003 | 5658549 | Aug 19, 2014 | DP U-738 | | | |
| | 5658549*PED | Feb 19, 2015 | DP U-738 | | | |
| | 5674472 | Oct 07, 2014 | DP | | | |
| | 5674472*PED | Apr 07, 2015 | DP | | | |
| | 6161724 | Jan 16, 2018 | DP | | | |
| | 6161724*PED | Jul 16, 2018 | | | | |
| | 6170717 | Dec 23, 2017 | DP | | | |
| | 6170717*PED | Jun 23, 2018 | | | | |
| | 6251368 | Dec 04, 2012 | DP | | | |
| | 6251368*PED | Jun 04, 2013 | DP | | | |
| | 6253762 | Apr 14, 2015 | DP U-738 | | | |
| | 6253762*PED | Oct 14, 2015 | DP U-738 | | | |
| | 6315173 | Dec 23, 2017 | DP | | | |
| | 6315173*PED | Jun 23, 2018 | DP | | | |
| | 6341168 | Jun 08, 2018 | DP | | | |
| | 6341168*PED | Dec 08, 2018 | | | | |
| | 6435372 | Jan 16, 2018 | DP | | | |
| | 6435372*PED | Jul 16, 2018 | | | | |
| | 6510969 | Dec 23, 2017 | DP | | | |
| | 6510969*PED | Jun 23, 2018 | DP | | | |
| | 6546928 | Apr 14, 2015 | DP | | | |
| | 6546928*PED | Oct 14, 2015 | DP | | | |
| | 6596260 | Aug 10, 2014 | DP | | | |
| | 6596260*PED | Feb 10, 2015 | | | | |
| | 6743413 | Jun 01, 2021 | | U-841 | | |
| | 6743413*PED | Dec 01, 2021 | | U-841 | | |
| | 6938796 | Jan 16, 2018 | DP | | | |
| | 6938796*PED | Jul 16, 2018 | | | | |
| | 6966467 | Dec 23, 2017 | DP | | | |
| | 6966467*PED | Jun 23, 2018 | | | | |
| | 6997349 | Jan 16, 2018 | DP | | | |
| | 6997349*PED | Jul 16, 2018 | | | | |
| | 7107986 | Jun 08, 2018 | DP | | | |
| | 7107986*PED | Dec 08, 2018 | | | | |
| | 7143908 | Jan 16, 2018 | DP | | | |
| | 7143908*PED | Jul 16, 2018 | | | | |
| | 7350676 | Aug 24, 2018 | DP | | | |
| | 7350676*PED | Feb 24, 2019 | | | | |
| | 7500444 | Jan 04, 2025 | DP | | | |
| | 7500444*PED | Jul 04, 2025 | | | | |
| <u>FLUVOXAMINE MALEATE - LUVOX</u> | | | | | | |
| 021519 001 | | | | | M-83 | Apr 14, 2011 |
| <u>FLUVOXAMINE MALEATE - LUVOX</u> | | | | | | |
| 021519 002 | | | | | M-83 | Apr 14, 2011 |
| <u>FLUVOXAMINE MALEATE - LUVOX</u> | | | | | | |
| 021519 003 | | | | | M-83 | Apr 14, 2011 |
| <u>FOSPROPOFOL DISODIUM - LUSEDRA</u> | | | | | | |
| 022244 001 | 6204257 | Jun 07, 2018 | DS DP U-945 | | NCE | Dec 12, 2013 |

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|--|-----------------|------------------------------|-----------------|-------------------------------|------------------------|-----------------------------------|
| <u>GADODIAMIDE - OMNISCAN</u> | | | | | | |
| 022066 002 | 5362475 | Nov 08, 2011 | DS | | | |
| <u>GATIFLOXACIN - ZYMAR</u> | | | | | | |
| 021493 001 | >A> 4980470 | Dec 15, 2009 | DS DP | | | |
| | >A> 4980470*PED | Jun 15, 2010 | | | | |
| | >A> 5880283 | Dec 05, 2015 | | | | |
| | >A> 5880283*PED | Jun 05, 2016 | | | | |
| | >A> 6333045 | Aug 20, 2019 | DP | | | |
| | >A> 6333045*PED | Feb 20, 2020 | | | | |
| <u>GLATIRAMER ACETATE - COPAXONE</u> | | | | | | |
| 020622 001 | | | | | I-594 | Feb 27, 2012 |
| <u>GLATIRAMER ACETATE - COPAXONE</u> | | | | | | |
| 020622 002 | | | | | I-594 | Feb 27, 2012 |
| <u>GOSERELIN ACETATE - ZOLADEX</u> | | | | | | |
| 019726 001 | 7500964 | Feb 26, 2021 | DP | | | |
| <u>GOSERELIN ACETATE - ZOLADEX</u> | | | | | | |
| 020578 001 | 7500964 | Feb 26, 2021 | DP | | | |
| <u>HYDROCHLOROTHIAZIDE; TELMISARTAN - MICARDIS HCT</u> | | | | | | |
| 021162 003 | 5591762 | Jan 07, 2014 | DS DP U-3 | | | |
| <u>ILOPERIDONE - FANAPT</u> | | | | | | |
| 022192 001 | >A> RE39198 | Nov 15, 2011 | DS DP U-971 | | >A> NCE | May 06, 2014 |
| <u>ILOPERIDONE - FANAPT</u> | | | | | | |
| 022192 002 | >A> RE39198 | Nov 15, 2011 | DS DP U-971 | | >A> NCE | May 06, 2014 |
| <u>ILOPERIDONE - FANAPT</u> | | | | | | |
| 022192 003 | >A> RE39198 | Nov 15, 2011 | DS DP U-971 | | >A> NCE | May 06, 2014 |
| <u>ILOPERIDONE - FANAPT</u> | | | | | | |
| 022192 004 | >A> RE39198 | Nov 15, 2011 | DS DP U-971 | | >A> NCE | May 06, 2014 |
| <u>ILOPERIDONE - FANAPT</u> | | | | | | |
| 022192 005 | >A> RE39198 | Nov 15, 2011 | DS DP U-971 | | >A> NCE | May 06, 2014 |
| <u>ILOPERIDONE - FANAPT</u> | | | | | | |
| 022192 006 | >A> RE39198 | Nov 15, 2011 | DS DP U-971 | | >A> NCE | May 06, 2014 |
| <u>ILOPERIDONE - FANAPT</u> | | | | | | |
| 022192 007 | >A> RE39198 | Nov 15, 2011 | DS DP U-971 | | >A> NCE | May 06, 2014 |
| <u>IMATINIB MESYLATE - GLEEVEC</u> | | | | | | |
| 021588 001 | | | | | I-583 | Dec 19, 2011 |
| <u>IMATINIB MESYLATE - GLEEVEC</u> | | | | | | |
| 021588 002 | | | | | I-583 | Dec 19, 2011 |
| <u>INSULIN DETEMIR RECOMBINANT - LEVEMIR</u> | | | | | | |
| 021536 001 | 5750497 | May 16, 2019 | DS DP U-668 | | | |

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|--|-------------|------------------------------|-----------------|-------------------------------|------------------------|-----------------------------------|
| <u>INSULIN GLARGINE RECOMBINANT - LANTUS</u> | | | | | | |
| 021081 001 | 5656722 | Aug 12, 2014 | DS DP U-948 | | | |
| | 5656722*PED | Feb 12, 2015 | | | | |
| | 7476652 | Jul 23, 2023 | DP | | | |
| | 7476652*PED | Jan 23, 2024 | | | | |
| <u>INSULIN GLULISINE RECOMBINANT - APIDRA</u> | | | | | | |
| 021629 002 | | | | | NCE | Apr 16, 2009 |
| <u>INSULIN GLULISINE RECOMBINANT - APIDRA SOLOSTAR</u> | | | | | | |
| 021629 003 | | | | | NPP NCE | Oct 24, 2011 Apr 16, 2009 |
| <u>IODIXANOL - VISIPAQUE 270</u> | | | | | | |
| 020351 001 | 5366722 | Nov 22, 2011 | DP | | | |
| | RE36418 | Jul 12, 2011 | DP | | | |
| <u>IODIXANOL - VISIPAQUE 270</u> | | | | | | |
| 020808 001 | 5366722 | Nov 22, 2011 | DP | | | |
| | RE36418 | Jul 12, 2011 | DP | | | |
| <u>IODIXANOL - VISIPAQUE 320</u> | | | | | | |
| 020351 002 | RE36418 | Jul 12, 2011 | DP | | | |
| <u>IODIXANOL - VISIPAQUE 320</u> | | | | | | |
| 020808 002 | RE36418 | Jul 12, 2011 | DP | | | |
| <u>IXABEPILONE - IXEMPRA KIT</u> | | | | | | |
| 022065 001 | 6605599 | May 26, 2018 | DS DP U-961 | | | |
| | 6670384 | Jan 23, 2022 | DP U-960 | | | |
| | 6670384 | Jan 23, 2022 | DP U-959 | | | |
| | 7022330 | Jan 23, 2022 | DP U-958 | | | |
| | 7125899 | May 26, 2018 | DS DP U-957 | | | |
| | 7312237 | Aug 21, 2024 | U-965 | | | |
| <u>IXABEPILONE - IXEMPRA KIT</u> | | | | | | |
| 022065 002 | 6605599 | May 26, 2018 | DS DP U-961 | | | |
| | 6670384 | Jan 23, 2022 | DP U-960 | | | |
| | 6670384 | Jan 23, 2022 | DP U-959 | | | |
| | 7022330 | Jan 23, 2022 | DP U-958 | | | |
| | 7125899 | May 26, 2018 | DS DP U-957 | | | |
| | 7312237 | Aug 21, 2024 | U-965 | | | |
| <u>LANSOPRAZOLE - PREVACID</u> | | | | | | |
| 020406 001 | | | | | M-85 PED | Oct 28, 2011 Apr 28, 2012 |
| <u>LANSOPRAZOLE - PREVACID</u> | | | | | | |
| 020406 002 | | | | | M-85 PED | Oct 28, 2011 Apr 28, 2012 |
| <u>LANSOPRAZOLE - PREVACID</u> | | | | | | |
| 021281 001 | | | | | M-85 PED | Oct 28, 2011 Apr 28, 2012 |
| <u>LANSOPRAZOLE - PREVACID</u> | | | | | | |
| 021281 002 | | | | | M-85 PED | Oct 28, 2011 Apr 28, 2012 |

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|--|-------------|------------------------------|-----------------|-------------------------------|-------------------------|-----------------------------------|
| <u>LANSOPRAZOLE - PREVACID</u> | | | | | | |
| 021428 001 | 7431942 | May 17, 2019 | DP | | M-85 | Oct 28, 2011 |
| | 7431942*PED | Nov 17, 2019 | | | PED | Apr 28, 2012 |
| <u>LANSOPRAZOLE - PREVACID</u> | | | | | | |
| 021428 002 | 7431942 | May 17, 2019 | DP | | M-85 | Oct 28, 2011 |
| | 7431942*PED | Nov 17, 2019 | | | PED | Apr 28, 2012 |
| <u>LANSOPRAZOLE - PREVACID 24 HR</u> | | | | | | |
| 022327 001 | | | | | >A> NP | May 18, 2012 |
| <u>LANSOPRAZOLE - PREVACID IV</u> | | | | | | |
| 021566 001 | 4628098 | May 10, 2009 | DS | | | |
| | 4628098*PED | Nov 10, 2009 | | | | |
| | 7396841 | Aug 17, 2021 | DP U-947 | | | |
| | 7396841*PED | Feb 17, 2022 | | | | |
| <u>LANSOPRAZOLE; NAPROXEN - PREVACID NAPRAPAC 500 (COPACKAGED)</u> | | | | | | |
| 021507 004 | 4628098 | May 10, 2009 | DS | | | |
| | 4628098*PED | Nov 10, 2009 | | | | |
| | 5045321 | Sep 03, 2008 | DP | | | |
| | 5045321*PED | Mar 03, 2009 | | | | |
| | 5093132 | Sep 03, 2008 | DP | | | |
| | 5093132*PED | Mar 03, 2009 | | | | |
| | 5433959 | Sep 03, 2008 | DP | | | |
| | 5433959*PED | Mar 03, 2009 | | | | |
| <u>LANTHANUM CARBONATE - FOSRENOL</u> | | | | | | |
| 021468 001 | 5968976 | Oct 26, 2018 | DP U-613 | | | |
| <u>LANTHANUM CARBONATE - FOSRENOL</u> | | | | | | |
| 021468 002 | 5968976 | Oct 26, 2018 | DP U-613 | | | |
| <u>LANTHANUM CARBONATE - FOSRENOL</u> | | | | | | |
| 021468 003 | 5968976 | Oct 26, 2018 | DP U-613 | | | |
| <u>LANTHANUM CARBONATE - FOSRENOL</u> | | | | | | |
| 021468 004 | 5968976 | Oct 26, 2018 | DP U-613 | | | |
| <u>LEVETIRACETAM - KEPPRA XR</u> | | | | | | |
| 022285 002 | | | | | NDF | Sep 12, 2011 |
| <u>LIDOCAINE HYDROCHLORIDE - ZINGO</u> | | | | | | |
| 022114 001 | | | | | NPP | Jan 08, 2012 |
| <u>MEMANTINE HYDROCHLORIDE - NAMENDA</u> | | | | | | |
| 021487 001 | 5061703 | Apr 11, 2015 | U-539 | | | |
| <u>MEMANTINE HYDROCHLORIDE - NAMENDA</u> | | | | | | |
| 021487 002 | 5061703 | Apr 11, 2015 | U-539 | | | |
| <u>MEMANTINE HYDROCHLORIDE - NAMENDA</u> | | | | | | |
| 021627 001 | 5061703 | Apr 11, 2015 | U-539 | | | |
| <u>MICONAZOLE NITRATE - MONISTAT 1 COMBINATION PACK</u> | | | | | | |
| 021308 001 | >A> 5514698 | Mar 21, 2014 | | | Y | |
| | >A> 6153635 | Nov 28, 2020 | | | Y | |

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|--|-------------|------------------------------|-----------------|-------------------------------|------------------------|-----------------------------------|
| <u>MILNACIPRAN HYDROCHLORIDE - SAVELLA</u> | | | | | | |
| 022256 001 | 6602911 | Nov 05, 2021 | U-882 | | NCE | Jan 14, 2014 |
| | 6992110 | Nov 05, 2021 | U-882 | | | |
| <u>MILNACIPRAN HYDROCHLORIDE - SAVELLA</u> | | | | | | |
| 022256 002 | 6602911 | Nov 05, 2021 | U-882 | | NCE | Jan 14, 2014 |
| | 6992110 | Nov 05, 2021 | U-882 | | | |
| <u>MILNACIPRAN HYDROCHLORIDE - SAVELLA</u> | | | | | | |
| 022256 003 | 6602911 | Nov 05, 2021 | U-882 | | NCE | Jan 14, 2014 |
| | 6992110 | Nov 05, 2021 | U-882 | | | |
| <u>MILNACIPRAN HYDROCHLORIDE - SAVELLA</u> | | | | | | |
| 022256 004 | 6602911 | Nov 05, 2021 | U-882 | | NCE | Jan 14, 2014 |
| | 6992110 | Nov 05, 2021 | U-882 | | | |
| <u>MOMETASONE FUROATE - ASMANEX TWISTHALER</u> | | | | | | |
| 021067 002 | 5394868 | Jun 25, 2012 | DP | | NPP | Feb 01, 2011 |
| | 5394868*PED | Dec 25, 2012 | | | | |
| | 5687710 | Nov 18, 2014 | DP | | | |
| | 5687710*PED | May 18, 2015 | | | | |
| | 5829434 | Nov 03, 2015 | DP | | | |
| | 5829434*PED | May 03, 2016 | | | | |
| | 5889015 | Jan 27, 2014 | | U-645 | | |
| | 5889015*PED | Jul 27, 2014 | | | | |
| | 6057307 | Jan 27, 2014 | DP | U-645 | | |
| | 6057307*PED | Jul 27, 2014 | | | | |
| | 6240918 | Feb 20, 2017 | DP | | | |
| | 6240918*PED | Aug 20, 2017 | | | | |
| | 6365581 | Jan 27, 2014 | | U-645 | | |
| | 6365581*PED | Jul 27, 2014 | | | | |
| | 6503537 | Mar 17, 2018 | DP | | | |
| | 6503537*PED | Sep 17, 2018 | | | | |
| | 6677322 | Jan 27, 2014 | | U-645 | | |
| | 6677322*PED | Jul 27, 2014 | | | | |
| | 6949532 | Jan 27, 2014 | | U-645 | | |
| | 6949532*PED | Jul 27, 2014 | | | | |
| <u>MORPHINE SULFATE - AVINZA</u> | | | | | | |
| 021260 005 | 6066339 | Nov 25, 2017 | DP | | | |
| <u>MORPHINE SULFATE - AVINZA</u> | | | | | | |
| 021260 006 | 6066339 | Nov 25, 2017 | DP | | | |
| <u>NITROGLYCERIN - NITROMIST</u> | | | | | | |
| 021780 001 | 5869082 | Apr 16, 2016 | DP | | | |
| <u>OLANZAPINE - ZYPREXA</u> | | | | | | |
| 020592 001 | 6960577 | Nov 01, 2017 | U-963 | | I-591 | Mar 19, 2012 |
| <u>OLANZAPINE - ZYPREXA</u> | | | | | | |
| 020592 002 | 6960577 | Nov 01, 2017 | U-963 | | I-591 | Mar 19, 2012 |
| <u>OLANZAPINE - ZYPREXA</u> | | | | | | |
| 020592 003 | 6960577 | Nov 01, 2017 | U-963 | | I-591 | Mar 19, 2012 |

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|---|-------------|------------------------------|-----------------|-------------------------------|------------------------|-----------------------------------|
| <u>OLANZAPINE - ZYPREXA</u> | | | | | | |
| 020592 004 | 6960577 | Nov 01, 2017 | U-963 | | I-591 | Mar 19, 2012 |
| <u>OLANZAPINE - ZYPREXA</u> | | | | | | |
| 020592 005 | 6960577 | Nov 01, 2017 | U-963 | | I-591 | Mar 19, 2012 |
| <u>OLANZAPINE - ZYPREXA</u> | | | | | | |
| 020592 006 | 6960577 | Nov 01, 2017 | U-963 | | I-591 | Mar 19, 2012 |
| <u>OLANZAPINE - ZYPREXA ZYDIS</u> | | | | | | |
| 021086 001 | 6960577 | Nov 01, 2017 | U-964 | | I-591 | Mar 19, 2012 |
| <u>OLANZAPINE - ZYPREXA ZYDIS</u> | | | | | | |
| 021086 002 | 6960577 | Nov 01, 2017 | U-964 | | I-591 | Mar 19, 2012 |
| <u>OLANZAPINE - ZYPREXA ZYDIS</u> | | | | | | |
| 021086 003 | 6960577 | Nov 01, 2017 | U-964 | | I-591 | Mar 19, 2012 |
| <u>OLANZAPINE - ZYPREXA ZYDIS</u> | | | | | | |
| 021086 004 | 6960577 | Nov 01, 2017 | U-964 | | I-591 | Mar 19, 2012 |
| <u>OMEGA-3-ACID ETHYL ESTERS - LOVAZA</u> | | | | | | |
| 021654 001 | 5656667 | Apr 10, 2017 | DS DP U-822 | | | |
| <u>OXYBUTYNIN CHLORIDE - GELNIQUE</u> | | | | | | |
| 022204 001 | 7029694 | Apr 26, 2020 | DP U-318 | | NDF | Jan 27, 2012 |
| | 7179483 | Apr 26, 2020 | U-318 | | | |
| <u>PALIPERIDONE - INVEGA</u> | | | | | | |
| 021999 006 | 5158952 | Oct 27, 2009 | DP U-90 | | | |
| <u>PANTOPRAZOLE SODIUM - PROTONIX</u> | | | | | | |
| 020987 001 | 4758579 | Jul 19, 2010 | | | | |
| | 4758579*PED | Jan 19, 2011 | | | | |
| | 5997903 | Dec 07, 2016 | | | | |
| | 5997903*PED | Jun 07, 2017 | | | | |
| <u>PANTOPRAZOLE SODIUM - PROTONIX</u> | | | | | | |
| 020987 002 | 4758579 | Jul 19, 2010 | | | | |
| | 4758579*PED | Jan 19, 2011 | | | | |
| | 5997903 | Dec 07, 2016 | | | | |
| | 5997903*PED | Jun 07, 2017 | | | | |
| <u>PANTOPRAZOLE SODIUM - PROTONIX</u> | | | | | | |
| 022020 001 | 4758579 | Jul 19, 2010 | DS DP U-859 | | | |
| | 4758579*PED | Jan 19, 2011 | | | | |
| <u>PANTOPRAZOLE SODIUM - PROTONIX IV</u> | | | | | | |
| 020988 001 | 4758579 | Jul 19, 2010 | | | | |
| | 4758579*PED | Jan 19, 2011 | | | | |
| | 6780881 | Nov 17, 2021 | DP | | | |
| | 6780881*PED | May 17, 2022 | | | | |
| | 7351723 | Nov 17, 2021 | DP | | | |
| | 7351723*PED | May 17, 2022 | | | | |

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|---|-------------|------------------------|--------------|-------------------------|----------------------|-----------------------------|
| <u>PHENTOLAMINE MESYLATE - ORAVERSE</u> | | | | | | |
| 022159 001 | 6764678 | May 11, 2021 | U-967 | | | |
| | 6872390 | May 11, 2021 | DP | | | |
| | 7229630 | Jun 20, 2023 | DP | | | |
| <u>PRAMLINTIDE ACETATE - SYMLIN</u> | | | | | | |
| 021332 002 | 5814600 | Sep 29, 2015 | U-639 | | | |
| | 5814600 | Sep 29, 2015 | U-638 | | | |
| | 5814600 | Sep 29, 2015 | U-637 | | | |
| | 5998367 | Mar 08, 2011 | DS DP | | | |
| | 6114304 | Sep 05, 2017 | U-640 | | | |
| | 6114304 | Sep 05, 2017 | U-637 | | | |
| | 6608029 | Sep 07, 2013 | U-641 | | | |
| | 6608029 | Sep 07, 2013 | U-640 | | | |
| | 6608029 | Sep 07, 2013 | U-637 | | | |
| | 6610824 | Mar 03, 2011 | DS | | | |
| | 7407934 | Mar 08, 2011 | U-640 | | | |
| | 7407934 | Mar 08, 2011 | U-637 | | | |
| <u>PRAMLINTIDE ACETATE - SYMLIN</u> | | | | | | |
| 021332 003 | 5814600 | Sep 29, 2015 | U-639 | | | |
| | 5814600 | Sep 29, 2015 | U-638 | | | |
| | 5814600 | Sep 29, 2015 | U-637 | | | |
| | 5998367 | Mar 08, 2011 | DS DP | | | |
| | 6114304 | Sep 05, 2017 | U-640 | | | |
| | 6114304 | Sep 05, 2017 | U-637 | | | |
| | 6608029 | Sep 07, 2013 | U-641 | | | |
| | 6608029 | Sep 07, 2013 | U-640 | | | |
| | 6608029 | Sep 07, 2013 | U-637 | | | |
| | 6610824 | Mar 03, 2011 | DS | | | |
| | 7407934 | Mar 08, 2011 | U-640 | | | |
| | 7407934 | Mar 08, 2011 | U-637 | | | |
| <u>QUETIAPINE FUMARATE - SEROQUEL</u> | | | | | | |
| 020639 001 | 4879288 | Sep 26, 2011 | DS DP U-550 | | I-560 | May 13, 2011 |
| | 4879288*PED | Mar 26, 2012 | | | I-503 | Oct 20, 2009 |
| | | | | | PED | Nov 13, 2011 |
| | | | | | PED | Apr 20, 2010 |
| <u>QUETIAPINE FUMARATE - SEROQUEL</u> | | | | | | |
| 020639 002 | 4879288 | Sep 26, 2011 | DS DP U-550 | | I-560 | May 13, 2011 |
| | 4879288*PED | Mar 26, 2012 | | | I-503 | Oct 20, 2009 |
| | | | | | PED | Nov 13, 2011 |
| | | | | | PED | Apr 20, 2010 |
| <u>QUETIAPINE FUMARATE - SEROQUEL</u> | | | | | | |
| 020639 003 | 4879288 | Sep 26, 2011 | DS DP U-550 | | I-560 | May 13, 2011 |
| | 4879288*PED | Mar 26, 2012 | | | I-503 | Oct 20, 2009 |
| | | | | | PED | Nov 13, 2011 |
| | | | | | PED | Apr 20, 2010 |
| <u>QUETIAPINE FUMARATE - SEROQUEL</u> | | | | | | |
| 020639 004 | 4879288 | Sep 26, 2011 | DS DP U-550 | | I-560 | May 13, 2011 |
| | 4879288*PED | Mar 26, 2012 | | | I-503 | Oct 20, 2009 |
| | | | | | PED | Nov 13, 2011 |
| | | | | | PED | Apr 20, 2010 |

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|--|-------------|------------------------------|-----------------|-------------------------------|------------------------|--|
| <u>QUETIAPINE FUMARATE - SEROQUEL</u> | | | | | | |
| 020639 005 | 4879288 | Sep 26, 2011 | DS DP U-550 | | I-560 | May 13, 2011 |
| | 4879288*PED | Mar 26, 2012 | | | I-503 PED PED | Oct 20, 2009 Nov 13, 2011 Apr 20, 2010 |
| <u>QUETIAPINE FUMARATE - SEROQUEL</u> | | | | | | |
| 020639 006 | 4879288 | Sep 26, 2011 | DS DP U-550 | | I-560 | May 13, 2011 |
| | 4879288*PED | Mar 26, 2012 | | | I-503 PED PED | Oct 20, 2009 Nov 13, 2011 Apr 20, 2010 |
| <u>QUETIAPINE FUMARATE - SEROQUEL</u> | | | | | | |
| 020639 007 | 4879288 | Sep 26, 2011 | DS DP U-550 | | I-560 | May 13, 2011 |
| | 4879288*PED | Mar 26, 2012 | | | I-503 PED PED | Oct 20, 2009 Nov 13, 2011 Apr 20, 2010 |
| <u>QUETIAPINE FUMARATE - SEROQUEL XR</u> | | | | | | |
| 022047 001 | 4879288 | Sep 26, 2011 | DS DP U-814 | | D-117 | Oct 08, 2011 |
| | 4879288 | Sep 26, 2011 | DS DP U-601 | | I-576 | Oct 08, 2011 |
| | 4879288*PED | Mar 26, 2012 | | | I-575 I-574 | Oct 08, 2011 Oct 08, 2011 |
| | 5948437 | May 28, 2017 | DP U-814 | | NDF | May 17, 2010 |
| | 5948437 | May 28, 2017 | DP U-601 | | PED | Apr 08, 2012 |
| | 5948437*PED | Nov 28, 2017 | | | PED | Nov 17, 2010 |
| <u>QUETIAPINE FUMARATE - SEROQUEL XR</u> | | | | | | |
| 022047 002 | 4879288 | Sep 26, 2011 | DS DP U-814 | | D-117 | Oct 08, 2011 |
| | 4879288 | Sep 26, 2011 | DS DP U-601 | | I-576 | Oct 08, 2011 |
| | 4879288*PED | Mar 26, 2012 | | | I-575 I-574 | Oct 08, 2011 Oct 08, 2011 |
| | 5948437 | May 28, 2017 | DP U-814 | | NDF | May 17, 2010 |
| | 5948437 | May 28, 2017 | DP U-601 | | PED | Apr 08, 2012 |
| | 5948437*PED | Nov 28, 2017 | | | PED | Nov 17, 2010 |
| <u>QUETIAPINE FUMARATE - SEROQUEL XR</u> | | | | | | |
| 022047 003 | 4879288 | Sep 26, 2011 | DS DP U-814 | | D-117 | Oct 08, 2011 |
| | 4879288 | Sep 26, 2011 | DS DP U-601 | | I-576 | Oct 08, 2011 |
| | 4879288*PED | Mar 26, 2012 | | | I-575 I-574 | Oct 08, 2011 Oct 08, 2011 |
| | 5948437 | May 28, 2017 | DP U-814 | | NDF | May 17, 2010 |
| | 5948437 | May 28, 2017 | DP U-601 | | PED | Apr 08, 2012 |
| | 5948437*PED | Nov 28, 2017 | | | PED | Nov 17, 2010 |
| <u>QUETIAPINE FUMARATE - SEROQUEL XR</u> | | | | | | |
| 022047 004 | 4879288 | Sep 26, 2011 | DS DP U-814 | | D-117 | Oct 08, 2011 |
| | 4879288 | Sep 26, 2011 | DS DP U-601 | | I-576 | Oct 08, 2011 |
| | 4879288*PED | Mar 26, 2012 | | | I-575 I-574 | Oct 08, 2011 Oct 08, 2011 |
| | 5948437 | May 28, 2017 | DP U-814 | | NDF | May 17, 2010 |
| | 5948437 | May 28, 2017 | DP U-601 | | PED | Apr 08, 2012 |
| | 5948437*PED | Nov 28, 2017 | | | PED | Nov 17, 2010 |
| <u>QUETIAPINE FUMARATE - SEROQUEL XR</u> | | | | | | |
| 022047 005 | 4879288 | Sep 26, 2011 | DS DP U-814 | | D-117 | Oct 08, 2011 |
| | 4879288 | Sep 26, 2011 | DS DP U-601 | | I-576 | Oct 08, 2011 |
| | 4879288*PED | Mar 26, 2012 | | | I-575 I-574 | Oct 08, 2011 Oct 08, 2011 |
| | 5948437 | May 28, 2017 | DP U-814 | | NDF | May 17, 2010 |
| | 5948437 | May 28, 2017 | DP U-601 | | PED | Apr 08, 2012 |
| | 5948437*PED | Nov 28, 2017 | | | PED | Nov 17, 2010 |

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|--|-------------|------------------------------|-----------------|-------------------------------|------------------------|-----------------------------------|
| <u>RASAGILINE MESYLATE - AZILECT</u> | | | | | | |
| 021641 001 | >A> 5453446 | Feb 07, 2017 | U-219 | | | |
| <u>RASAGILINE MESYLATE - AZILECT</u> | | | | | | |
| 021641 002 | >A> 5453446 | Feb 07, 2017 | U-219 | | | |
| <u>REMIFENTANIL HYDROCHLORIDE - ULTIVA</u> | | | | | | |
| 020630 001 | 5019583 | Jul 12, 2010 | DS DP U-952 | | | |
| | 5019583*PED | Jan 12, 2011 | | | | |
| <u>REMIFENTANIL HYDROCHLORIDE - ULTIVA</u> | | | | | | |
| 020630 002 | 5019583 | Jul 12, 2010 | DS DP U-952 | | | |
| | 5019583*PED | Jan 12, 2011 | | | | |
| <u>REMIFENTANIL HYDROCHLORIDE - ULTIVA</u> | | | | | | |
| 020630 003 | 5019583 | Jul 12, 2010 | DS DP U-952 | | | |
| | 5019583*PED | Jan 12, 2011 | | | | |
| <u>REPAGLINIDE - PRANDIN</u> | | | | | | |
| 020741 001 | 6677358 | Jun 12, 2018 | DS DP U-968 | | | |
| <u>REPAGLINIDE - PRANDIN</u> | | | | | | |
| 020741 002 | 6677358 | Jun 12, 2018 | DS DP U-968 | | | |
| <u>REPAGLINIDE - PRANDIN</u> | | | | | | |
| 020741 003 | 6677358 | Jun 12, 2018 | DS DP U-968 | | | |
| <u>RISEDRONATE SODIUM - ACTONEL</u> | | | | | | |
| 020835 001 | 5583122 | Dec 10, 2013 | U-222 | | | |
| | 5583122*PED | Jun 10, 2014 | | | | |
| | 6096342 | Nov 22, 2011 | | | | |
| | 6096342*PED | May 22, 2012 | | | | |
| | 6165513 | Jun 10, 2018 | | | | |
| | 6165513*PED | Dec 10, 2018 | | | | |
| <u>RISEDRONATE SODIUM - ACTONEL</u> | | | | | | |
| 020835 002 | 5583122 | Dec 10, 2013 | U-222 | | | |
| | 5583122*PED | Jun 10, 2014 | | | | |
| | 6096342 | Nov 22, 2011 | | | | |
| | 6096342*PED | May 22, 2012 | | | | |
| | 6165513 | Jun 10, 2018 | | | | |
| | 6165513*PED | Dec 10, 2018 | | | | |

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|---|-------------|------------------------------|-----------------|-------------------------------|------------------------|-----------------------------------|
| <u>RISEDRONATE SODIUM - ACTONEL</u> | | | | | | |
| 020835 003 | 5583122 | Dec 10, 2013 | DS DP U-756 | | I-309 | Aug 11, 2009 |
| | 5583122 | Dec 10, 2013 | DS DP U-222 | | PED | Feb 11, 2010 |
| | 5583122*PED | Jun 10, 2014 | | | | |
| | 5994329 | Jul 17, 2018 | | U-353 | | |
| | 5994329*PED | Jan 17, 2019 | | | | |
| | 6015801 | Jul 17, 2018 | | U-353 | | |
| | 6015801*PED | Jan 17, 2019 | | | | |
| | 6096342 | Nov 22, 2011 | | DP | | |
| | 6096342*PED | May 22, 2012 | | | | |
| | 6165513 | Jun 10, 2018 | | DP | | |
| | 6165513*PED | Dec 10, 2018 | | | | |
| | 6432932 | Jul 17, 2018 | | U-595 | | |
| | 6432932*PED | Jan 17, 2019 | | | | |
| | 6465443 | Aug 14, 2018 | | DP | | |
| | 6465443*PED | Feb 14, 2019 | | | | |
| <u>RISEDRONATE SODIUM - ACTONEL</u> | | | | | | |
| 020835 004 | 5583122 | Dec 10, 2013 | DS DP U-353 | | D-105 | Apr 16, 2010 |
| | 5583122*PED | Jun 10, 2014 | | | PED | Oct 16, 2010 |
| | 6096342 | Nov 22, 2011 | | DP U-353 | | |
| | 6096342*PED | May 22, 2012 | | | | |
| | 6165513 | Jun 10, 2018 | | DP | | |
| | 6165513*PED | Dec 10, 2018 | | | | |
| <u>RISEDRONATE SODIUM - ACTONEL</u> | | | | | | |
| 020835 005 | 5583122 | Dec 10, 2013 | DS DP U-353 | | NS | Apr 22, 2011 |
| | 5583122*PED | Jun 10, 2014 | | | PED | Oct 22, 2011 |
| | 6165513 | Jun 10, 2018 | | DP | | |
| | 6165513*PED | Dec 10, 2018 | | | | |
| | 7192938 | May 06, 2023 | | U-353 | | |
| | 7192938*PED | Nov 06, 2023 | | | | |
| <u>RISPERIDONE - RISPERDAL CONSTA</u> | | | | | | |
| 021346 001 | | | | | >A> I-597 | May 15, 2012 |
| | | | | | >A> I-596 | May 15, 2012 |
| <u>RISPERIDONE - RISPERDAL CONSTA</u> | | | | | | |
| 021346 002 | | | | | >A> I-597 | May 15, 2012 |
| | | | | | >A> I-596 | May 15, 2012 |
| <u>RISPERIDONE - RISPERDAL CONSTA</u> | | | | | | |
| 021346 003 | | | | | >A> I-597 | May 15, 2012 |
| | | | | | >A> I-596 | May 15, 2012 |
| <u>RISPERIDONE - RISPERDAL CONSTA</u> | | | | | | |
| 021346 004 | | | | | >A> I-597 | May 15, 2012 |
| | | | | | >A> I-596 | May 15, 2012 |
| <u>RISPERIDONE - RISPERIDONE</u> | | | | | | |
| 076440 001 | | | | | PC | Jul 29, 2009 |
| <u>ROPINIROLE HYDROCHLORIDE - REQUIP XL</u> | | | | | | |
| 022008 006 | 5422123 | Jun 06, 2012 | | DP | NDF | Jun 13, 2011 |

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|---|-------------|------------------------------|-----------------|-------------------------------|------------------------|-----------------------------------|
| <u>SALMETEROL XINAFOATE - SEREVENT</u> | | | | | | |
| 020692 001 | 5590645 | Mar 01, 2011 | DP | | | |
| | 5590645*PED | Sep 01, 2011 | | | | |
| | 5860419 | Mar 01, 2011 | DP | | | |
| | 5860419*PED | Sep 01, 2011 | | | | |
| | 5873360 | Feb 23, 2016 | DP | | | |
| | 5873360*PED | Aug 23, 2016 | | | | |
| | 6032666 | Mar 01, 2011 | DP | | | |
| | 6032666*PED | Sep 01, 2011 | | | | |
| | 6378519 | Mar 01, 2011 | DP | | | |
| | 6378519*PED | Sep 01, 2011 | | | | |
| | 6536427 | Mar 01, 2011 | DP | | | |
| | 6536427*PED | Sep 01, 2011 | | | | |
| | 6792945 | Mar 01, 2011 | DP | | | |
| | 6792945*PED | Sep 01, 2011 | | | | |
| | 7225808 | Mar 01, 2011 | DP | | | |
| | 7225808*PED | Sep 01, 2011 | | | | |
| | 7389775 | Mar 01, 2011 | DP | | | |
| | 7389775*PED | Sep 01, 2011 | | | | |
| <u>SILDENAFIL CITRATE - REVATIO</u> | | | | | | |
| 021845 001 | | | | | >A> I-598 | May 07, 2009 |
| <u>SILODOSIN - RAPAFLO</u> | | | | | | |
| 022206 001 | 5780485 | Nov 13, 2012 | U-902 | | | |
| <u>SILODOSIN - RAPAFLO</u> | | | | | | |
| 022206 002 | 5780485 | Nov 13, 2012 | U-902 | | | |
| <u>SINECATECHINS - VEREGEN</u> | | | | | | |
| 021902 001 | 5795911 | Oct 31, 2020 | U-172 | | | |
| <u>SOMATROPIN RECOMBINANT - HUMATROPE</u> | | | | | | |
| 019640 001 | | | | | I-585 | Mar 12, 2012 |
| <u>SOMATROPIN RECOMBINANT - HUMATROPE</u> | | | | | | |
| 019640 004 | 5612315 | Mar 18, 2014 | DP | | I-585 | Mar 12, 2012 |
| <u>SOMATROPIN RECOMBINANT - HUMATROPE</u> | | | | | | |
| 019640 005 | 5612315 | Mar 18, 2014 | DP | | I-585 | Mar 12, 2012 |
| <u>SOMATROPIN RECOMBINANT - HUMATROPE</u> | | | | | | |
| 019640 006 | 5612315 | Mar 18, 2014 | DP | | I-585 | Mar 12, 2012 |
| <u>SOMATROPIN RECOMBINANT - HUMATROPE</u> | | | | | | |
| 019640 007 | 5612315 | Mar 18, 2014 | DP | | I-585 | Mar 12, 2012 |
| <u>SOMATROPIN RECOMBINANT - NORDITROPIN NORDIFLEX</u> | | | | | | |
| 021148 004 | 5849700 | Dec 15, 2015 | U-340 | | | |
| | 5849704 | Dec 15, 2015 | DP U-340 | | | |
| <u>SOMATROPIN RECOMBINANT - NORDITROPIN NORDIFLEX</u> | | | | | | |
| 021148 005 | 5849700 | Dec 15, 2015 | U-340 | | | |
| | 5849704 | Dec 15, 2015 | DP U-340 | | | |

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| <u>SOMATROPIN RECOMBINANT - NORDITROPIN NORDIFLEX</u> | | | | | | |
| 021148 006 | 5849700 | Dec 15, 2015 | U-340 | | | |
| | 5849704 | Dec 15, 2015 | DP U-340 | | | |
| <u>SOMATROPIN RECOMBINANT - NORDITROPIN NORDIFLEX</u> | | | | | | |
| 021148 007 | 5849700 | Dec 15, 2015 | U-340 | | I-572 | Oct 31, 2011 |
| | 5849704 | Dec 15, 2015 | DP U-340 | | I-551 | Sep 20, 2010 |
| | | | | | I-536 | May 31, 2010 |
| | | | | | ODE | May 31, 2014 |
| <u>SUMATRIPTAN SUCCINATE - SUMATRIPTAN SUCCINATE</u> | | | | | | |
| 076572 001 | | | | | PC | Aug 08, 2009 |
| <u>SUMATRIPTAN SUCCINATE - SUMATRIPTAN SUCCINATE</u> | | | | | | |
| 076840 001 | | | | | PC | Aug 08, 2009 |
| <u>SUMATRIPTAN SUCCINATE - SUMATRIPTAN SUCCINATE</u> | | | | | | |
| 076840 002 | | | | | PC | Aug 08, 2009 |
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| 076840 003 | | | | | PC | Aug 08, 2009 |
| <u>SUNITINIB MALATE - SUTENT</u> | | | | | | |
| 021938 004 | 6573293 | Feb 15, 2021 | DS DP U-703 | | NCE | Jan 26, 2011 |
| | 7125905 | Feb 15, 2021 | DS DP | | | |
| | 7211600 | Dec 22, 2020 | U-883 | | | |
| <u>TADALAFIL - ADCIRCA</u> | | | | | | |
| 022332 001 | | | | | >A> NP | May 22, 2012 |
| <u>TELBIVUDINE - TYZEKA</u> | | | | | | |
| 022154 001 | | | | | NCE | Oct 25, 2011 |
| <u>TEMOZOLOMIDE - TEMODAR</u> | | | | | | |
| 022277 001 | 5260291 | Aug 11, 2013 | DS DP U-619 | | | |
| | 5260291*PED | Feb 11, 2014 | | | | |
| | 6987108 | Sep 08, 2023 | DP | | | |
| <u>TIGECYCLINE - TYGACIL</u> | | | | | | |
| 021821 001 | | | | | I-588 | Mar 20, 2012 |
| | | | | | I-587 | Mar 20, 2012 |
| | | | | | I-586 | Mar 20, 2012 |
| <u>TOLVAPTAN - SAMSCA</u> | | | | | | |
| 022275 001 | | | | | >A> NCE | May 19, 2014 |
| <u>TOLVAPTAN - SAMSCA</u> | | | | | | |
| 022275 002 | | | | | >A> NCE | May 19, 2014 |
| <u>TOLVAPTAN - SAMSCA</u> | | | | | | |
| 022275 003 | | | | | >A> NCE | May 19, 2014 |
| <u>TOPIRAMATE - TOPAMAX</u> | | | | | | |
| 020505 001 | 7498311 | Oct 13, 2015 | U-955 | | | |
| | 7498311*PED | Apr 13, 2016 | | | | |
| <u>TOPIRAMATE - TOPAMAX</u> | | | | | | |
| 020505 002 | 7498311 | Oct 13, 2015 | U-955 | | | |
| | 7498311*PED | Apr 13, 2016 | | | | |
| <u>TOPIRAMATE - TOPAMAX</u> | | | | | | |
| 020505 003 | 7498311 | Oct 13, 2015 | U-955 | | | |
| | 7498311*PED | Apr 13, 2016 | | | | |

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| <u>TOPIRAMATE - TOPAMAX</u> | | | | | | |
| 020505 004 | 7498311 | Oct 13, 2015 | U-955 | | | |
| | 7498311*PED | Apr 13, 2016 | | | | |
| <u>TOPIRAMATE - TOPAMAX</u> | | | | | | |
| 020505 005 | 7498311 | Oct 13, 2015 | U-955 | | | |
| | 7498311*PED | Apr 13, 2016 | | | | |
| <u>TOPIRAMATE - TOPAMAX</u> | | | | | | |
| 020505 006 | 7498311 | Oct 13, 2015 | U-955 | | | |
| | 7498311*PED | Apr 13, 2016 | | | | |
| <u>TOPIRAMATE - TOPAMAX</u> | | | | | | |
| 020844 001 | 7498311 | Oct 13, 2015 | U-955 | | | |
| | 7498311*PED | Apr 13, 2016 | | | | |
| <u>TOPIRAMATE - TOPAMAX</u> | | | | | | |
| 020844 002 | 7498311 | Oct 13, 2015 | U-955 | | | |
| | 7498311*PED | Apr 13, 2016 | | | | |
| <u>TOPIRAMATE - TOPAMAX SPRINKLE</u> | | | | | | |
| 020844 003 | 7498311 | Oct 13, 2015 | U-955 | | | |
| | 7498311*PED | Apr 13, 2016 | | | | |
| <u>TOPIRAMATE - TOPIRAMATE</u> | | | | | | |
| 076448 001 | | | | | PC | Oct 12, 2009 |
| <u>TOPIRAMATE - TOPIRAMATE</u> | | | | | | |
| 076448 002 | | | | | PC | Oct 12, 2009 |
| <u>TOPIRAMATE - TOPIRAMATE</u> | | | | | | |
| 077868 001 | | | | | PC | Oct 12, 2009 |
| <u>TOPIRAMATE - TOPIRAMATE</u> | | | | | | |
| 077868 002 | | | | | PC | Oct 12, 2009 |
| <u>TRAMADOL HYDROCHLORIDE - RYZOLT</u> | | | | | | |
| 021745 001 | | | | | NP | Dec 30, 2011 |
| <u>TRAMADOL HYDROCHLORIDE - RYZOLT</u> | | | | | | |
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| <u>TRAMADOL HYDROCHLORIDE - RYZOLT</u> | | | | | | |
| 021745 003 | | | | | NP | Dec 30, 2011 |
| <u>TRYPAN BLUE - MEMBRANEBLUE</u> | | | | | | |
| 022278 001 | | | | | NCE ODE | Dec 16, 2009 Dec 16, 2011 |
| <u>ZOLEDRONIC ACID - RECLAST</u> | | | | | | |
| 021817 001 | | | | | >A> I-595 I-584 I-581 | May 29, 2012 Mar 15, 2012 Dec 19, 2011 |
| <u>ZOLPIDEM TARTRATE - EDLUAR</u> | | | | | | |
| 021997 001 | 6761910 | Sep 24, 2018 | DP U-674 | | | |
| <u>ZOLPIDEM TARTRATE - EDLUAR</u> | | | | | | |
| 021997 002 | 6761910 | Sep 24, 2018 | DP U-674 | | | |

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Footnote:

1. Patents are published upon receipt by the Orange Book Staff and may not reflect the official receipt date as described in 21 CFR 314.53(d)(5).
2. Patents listed prior to August 18, 2003 are flagged with method of use claims only as applicable and submitted by the sponsor. They may not be flagged with respect to other claims which may apply.

PATENT AND EXCLUSIVITY TERMS

Due to space limitations in the patent and exclusivity columns, abbreviations and references have been developed. Refer to the APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, 29th Edition for a full listing of patent and exclusivity terms (Abbreviations, Dosing Schedule, Indications, and Patent Use Codes).

The current complete list of patent terms is available at <http://www.accessdata.fda.gov/scripts/cder/ob/docs/pattermsall.cfm>