

APPROVED DRUG PRODUCTS

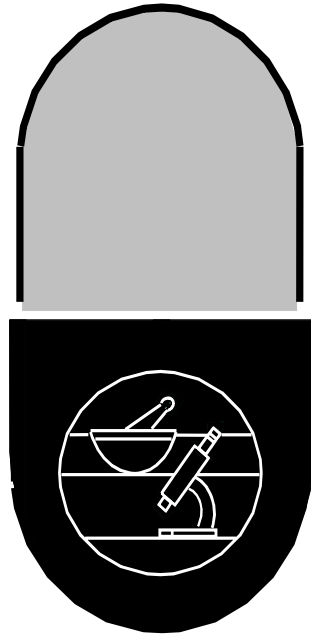
With Therapeutic Equivalence Evaluations



The "Orange Book"

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**CUMULATIVE
SUPPLEMENT 5
MAY 2005**



**APPROVED
DRUG PRODUCTS**

**WITH
THERAPEUTIC EQUIVALENCE EVALUATIONS**

25th EDITION

Department of Health and Human Services

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

2005

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

**APPROVED DRUG PRODUCTS
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25th EDITION

Cumulative Supplement 5

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**APPROVED DRUG PRODUCTS
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25th EDITION

**CUMULATIVE SUPPLEMENT 5
May 2005**

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, 25th 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are for exportation, are for military use, have been discontinued from marketing or that have had their approvals withdrawn for other than safety or efficacy reasons.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 25th Edition List will then be added to the "Discontinued Drug Product List" appearing in the 26th 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 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.

FORMER APPLICANT NAME
(FORMER ABBREVIATED NAME)

NEW APPLICANT NAME
(NEW ABBREVIATED NAME)

CELLTECH PHARMACEUTICALS INC
(CELLTECH PHARMS
FUJISAWA HEALTHCARE

UCB PHARMA INC
(UCB)
ASTELLAS PHARMA US INC

| | |
|--------------------------------------|------------------------|
| (FUJISAWA HLTHCARE) | (ASTELLAS) |
| SHIRE LABORATORIES INC | SHIRE DEVELOPMENT INC |
| (SHIRE LABS) | (SHIRE) |
| SHIRE PHARMACEUTICAL DEVELOPMENT INC | SHIRE DEVELOPMENT INC |
| (SHIRE PHARM) | (SHIRE) |
| YAMANOUCHI PHARMA AMERICA INC | ASTELLAS PHARMA US INC |
| (YAMANOUCHI) | (ASTELLAS) |

1.3 LEVOTHYROXINE SODIUM

The Description of Special Situations, Levothyroxine Sodium, published in the 25th Annual Edition of the Orange Book, has been modified in the Cumulative Supplement to include information on Genpharm ANDA 76752 approved in 2005. The full discussion as published in the 25th Annual Edition is repeated in the Cumulative Supplement and includes recent approval information on levothyroxine sodium.

Because there are multiple reference listed drugs of levothyroxine sodium tablets and some reference listed drugs' sponsors have conducted studies to establish their drugs' therapeutic equivalence to other reference listed drugs, FDA has determined that its usual practice of assigning two or three character TE codes may be potentially confusing and inadequate for these drug products. Accordingly, FDA provides the following explanation and chart of therapeutic equivalence evaluations for levothyroxine sodium drug products.

Levothyroxine Sodium (Mylan ANDA 76187) tablets have been determined to be therapeutically equivalent to corresponding strengths of Unithroid (Jerome Stevens NDA 021210) tablets.

Levo-T (Alara NDA 021342), Levothyroxine Sodium (Mylan ANDA 76187), Unithroid (Jerome Stevens NDA 021210) and Levothyroxine Sodium (Genpharm ANDA 76752) tablets have been determined to be therapeutically equivalent to corresponding strengths of Synthroid (Abbott NDA 021402) tablets.

Levo-T (Alara NDA 021342), Unithroid (Jerome Stevens NDA 021210) and Levothyroxine Sodium (Mylan ANDA 076187) tablets have been determined to be therapeutically equivalent to corresponding strengths of Levoxyl (King/Jones Pharma NDA 021301) tablets.

Novothyrox (Genpharm NDA 021292) requires further investigation and review to establish therapeutic equivalence to corresponding strengths of any other levothyroxine sodium drug products and is rated BX.

Thyro-Tabs (Lloyd NDA 021116) requires further investigation and review to establish therapeutic equivalence to corresponding strengths of any other levothyroxine sodium drug products and is rated BX.

Levolet (Vintage NDA 021137) requires further investigation and review to establish therapeutic equivalence to corresponding strengths of any other levothyroxine sodium drug products and is rated BX.

The chart outlines TE codes for all 0.025mg products with other products being similar. Therapeutic equivalence has been established between products that have the same AB+number TE code. More than one TE code may apply to some products. One common TE code indicates therapeutic equivalence between products.

| Trade Name | Applicant | Potency | TE Code | Appl No | Product No |
|----------------------|----------------|---------|---------|---------|------------|
| UNITHROID | STEVENS J | 0.025MG | AB1 | 21210 | 001 |
| LEVOTHYROXINE SODIUM | MYLAN | 0.025MG | AB1 | 76187 | 001 |
| LEVOXYL | JONES PHARMA | 0.025MG | AB1 | 21301 | 001 |
| | | | | | |
| SYNTHROID | ABBOTT | 0.025MG | AB2 | 21402 | 001 |
| LEVOTHYROXINE SODIUM | MYLAN | 0.025MG | AB2 | 76187 | 001 |
| LEVO-T | ALARA PHARM | 0.025MG | AB2 | 21342 | 001 |
| UNITHROID | STEVENS J | 0.025MG | AB2 | 21210 | 001 |
| LEVOTHYROXINE SODIUM | GENPHARM | 0.025MG | AB2 | 76752 | 001 |
| | | | | | |
| LEVOXYL | JONES PHARMA | 0.025MG | AB3 | 21301 | 001 |
| LEVO-T | ALARA PHARM | 0.025MG | AB3 | 21342 | 001 |
| UNITHROID | STEVENS J | 0.025MG | AB3 | 21210 | 001 |
| LEVOTHYROXINE SODIUM | MYLAN | 0.025MG | AB3 | 76187 | 001 |
| | | | | | |
| NOVOTHYROX | GENPHARM | 0.025MG | BX | 21292 | 001 |
| | | | | | |
| THYRO-TABS | LLOYD | 0.025MG | BX | 21116 | 001 |
| | | | | | |
| LEVOLET | VINTAGE PHARMS | 0.025MG | BX | 21137 | 001 |

1.4 AVAILABILITY OF THE EDITION

Commencing with the 25th edition, the Annual Edition and monthly Cumulative Supplements will not be available in a published paper version.

Since 1997, the Electronic Orange Book (EOB) <http://www.fda.gov/cder/ob/default.htm>, has been available on the internet and has become the updated-every-month Orange Book.

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

The Electronic Orange Book Query (EOB) is at <http://www.fda.gov/cder/ob/default.htm>. 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.

Currently, In addition to monthly updates, in the public interest, the EOB is updated on a daily basis with new generic product approval information and new patent information. Current month updates are accomplished by the third week of the following month.

The Internet version of the Orange Book annual edition is at <http://www.fda.gov/cder/ob/docs/preface/ectablec.htm> The Internet version of the monthly supplement is at <http://www.fda.gov/cder/orange/supplement/cspreface.htm>.

There are historical lists of Orange Book cumulative supplement product monthly changes at <http://www.fda.gov/cder/rxotcdpl/pdplarchive.htm>

There are ASCII text files of the Orange Book drug product, patent, and exclusivity data at <http://www.fda.gov/cder/orange/obreadme.htm> . The drug product text files are zipped into eobzip.exe. The files are updated concurrently with the monthly cumulative supplements. Appendix A and Appendix B text files of the annual Orange Book Edition 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 2004) 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 2004</u> | <u>MAR 2005</u> | <u>JUN 2005</u> | <u>SEP 2005</u> |
|---------------------------|-----------------|-----------------|-----------------|-----------------|
| DRUG PRODUCTS LISTED | 11082 | 11184 | | |
| SINGLE SOURCE | 2427 (21.9%) | 2437 (21.8%) | | |
| MULTISOURCE | 8547 (77.1%) | 8637 (77.2%) | | |
| THERAPEUTICALLY | | | | |
| EQUIVALENT | 8327 (75.1%) | 8428 (75.4%) | | |
| NOT THERAPEUTICALLY | | | | |
| EQUIVALENT | 220 (2.0%) | 209 (1.9%) | | |
| EXCEPTIONS ¹ | 108 (1.0%) | 110 (1.0%) | | |
| NEW MOLECULAR ENTITIES | | | | |
| APPROVED | 9 | 2 | | |
| NUMBER OF APPLICANTS | 625 | 631 | | |

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. |

WDAG Withdrawn. The applicant holder has notified the FDA in writing that the product is no longer being marketed resulting in the product approval being withdrawn by mutual agreement. The product will be listed in the Discontinued Section.

WDRP Withdrawn. The application approval has been withdrawn for failure to provide Annual Reports. The product will be moved to the Discontinued Section in the next edition

PRESCRIPTION DRUG PRODUCT LIST - 25TH EDITION

RX DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 5 - May 2005

1-1

ACETAMINOPHEN; BUTALBITAL; CAFFEINE

TABLET; ORAL

BUTALBITAL, ACETAMINOPHEN AND CAFFEINE

| | | | | | | | | |
|-----|----|-------------|--------------------------------|--------|-----|--------------|-----|------|
| >D> | AB | ABLE | 325MG;50MG;40MG | N40390 | 001 | Jul 23, 2001 | May | DISC |
| >A> | | @ | 325MG;50MG;40MG | N40390 | 001 | Jul 23, 2001 | May | DISC |
| >D> | AB | | 500MG;50MG;40MG | N40394 | 001 | Jul 23, 2001 | May | DISC |
| >A> | | @ | 500MG;50MG;40MG | N40394 | 001 | Jul 23, 2001 | May | DISC |
| | | | BUTALBITAL, APAP, AND CAFFEINE | | | | | |
| | AB | WATSON LABS | 325MG;50MG;40MG | N89536 | 001 | Feb 16, 1988 | Feb | CAHN |

ACETAMINOPHEN; BUTALBITAL; CAFFEINE; CODEINE PHOSPHATE

CAPSULE; ORAL

BUTALBITAL; ACETAMINOPHEN; CAFFEINE AND CODEINE PHOSPHATE

| | | | | | | | | |
|-----|----|------|----------------------|--------|-----|--------------|-----|------|
| >D> | AB | ABLE | 325MG;50MG;40MG;30MG | N76528 | 001 | Aug 21, 2003 | May | DISC |
| >A> | | @ | 325MG;50MG;40MG;30MG | N76528 | 001 | Aug 21, 2003 | May | DISC |

ACETAMINOPHEN; CODEINE PHOSPHATE

TABLET; ORAL

ACETAMINOPHEN AND CODEINE PHOSPHATE

| | | | | | | | | |
|-----|----|------|------------|--------|-----|--------------|-----|------|
| >D> | AA | ABLE | 300MG;30MG | N40452 | 001 | Aug 01, 2002 | May | DISC |
| >A> | | @ | 300MG;30MG | N40452 | 001 | Aug 01, 2002 | May | DISC |
| >D> | AA | | 300MG;60MG | N40459 | 001 | Aug 01, 2002 | May | DISC |
| >A> | | @ | 300MG;60MG | N40459 | 001 | Aug 01, 2002 | May | DISC |

ACETAMINOPHEN; HYDROCODONE BITARTRATE

TABLET; ORAL

HYDROCODONE BITARTRATE AND ACETAMINOPHEN

| | | | | | | | | |
|-----|----|------|-------------|--------|-----|--------------|-----|------|
| >D> | AA | ABLE | 325MG;5MG | N40478 | 001 | Nov 08, 2002 | May | DISC |
| >A> | | @ | 325MG;5MG | N40478 | 001 | Nov 08, 2002 | May | DISC |
| >D> | AA | | 325MG;7.5MG | N40464 | 001 | Oct 23, 2002 | May | DISC |
| >A> | | @ | 325MG;7.5MG | N40464 | 001 | Oct 23, 2002 | May | DISC |
| >D> | AA | | 325MG;10MG | N40464 | 002 | Oct 23, 2002 | May | DISC |
| >A> | | @ | 325MG;10MG | N40464 | 002 | Oct 23, 2002 | May | DISC |
| >D> | AA | | 500MG;5MG | N40477 | 001 | Nov 06, 2002 | May | DISC |
| >A> | | @ | 500MG;5MG | N40477 | 001 | Nov 06, 2002 | May | DISC |
| >D> | AA | | 500MG;7.5MG | N40490 | 001 | May 21, 2003 | May | DISC |
| >A> | | @ | 500MG;7.5MG | N40490 | 001 | May 21, 2003 | May | DISC |
| >D> | AA | | 500MG;10MG | N40473 | 001 | Nov 06, 2002 | May | DISC |
| >A> | | @ | 500MG;10MG | N40473 | 001 | Nov 06, 2002 | May | DISC |
| >D> | AA | | 650MG;7.5MG | N40474 | 001 | Jan 02, 2003 | May | DISC |
| >A> | | @ | 650MG;7.5MG | N40474 | 001 | Jan 02, 2003 | May | DISC |
| >D> | AA | | 650MG;10MG | N40476 | 001 | Oct 23, 2002 | May | DISC |
| >A> | | @ | 650MG;10MG | N40476 | 001 | Oct 23, 2002 | May | DISC |
| >D> | AA | | 750MG;7.5MG | N40469 | 001 | Oct 25, 2002 | May | DISC |
| >A> | | @ | 750MG;7.5MG | N40469 | 001 | Oct 25, 2002 | May | DISC |

ACETAMINOPHEN; PROPOXYPHENE NAPSYLATE

TABLET; ORAL

PROPOXYPHENE NAPSYLATE AND ACETAMINOPHEN

| | | | | | | | | |
|-----|----|------|-------------|--------|-----|--------------|-----|------|
| >D> | AB | ABLE | 650MG;100MG | N75838 | 001 | Jul 11, 2001 | May | DISC |
| >A> | | @ | 650MG;100MG | N75838 | 001 | Jul 11, 2001 | May | DISC |

ACETAMINOPHEN; TRAMADOL HYDROCHLORIDE

TABLET; ORAL

ACETAMINOPHEN AND TRAMADOL HCL

| | | | | | | | |
|----|---|--------------------|--------------|------------|--------------|-----|------|
| AB | | KALI LABS | 325MG;37.5MG | N76475 001 | Apr 21, 2005 | Mar | NEWA |
| | | ULTRACET | | | | | |
| AB | + | ORTHO MCNEIL PHARM | 325MG;37.5MG | N21123 001 | Aug 15, 2001 | Mar | CFTG |

ACETIC ACID, GLACIAL

SOLUTION/DROPS; OTIC

ACETIC ACID

| | | | | | | | |
|----|---|-----------------------|----|------------|--------------|-----|------|
| AT | + | MORTON GROVE | 2% | N40166 001 | Jul 26, 1996 | Jan | CRLD |
| AT | | VINTAGE | 2% | N40607 001 | Feb 24, 2005 | Feb | NEWA |
| | | VOSOL | | | | | |
| | | @ MEDPOINTE PHARM HLC | 2% | N12179 001 | | Jan | DISC |

ACETYLCYSTEINE

SOLUTION; INHALATION, ORAL

| | | | | | | | |
|-----|----|------------|-----|------------|--------------|-----|------|
| >D> | | MUCOSIL-10 | | | | | |
| >D> | AN | DEY | 10% | N70575 001 | Oct 14, 1986 | May | DISC |
| >A> | | @ | 10% | N70575 001 | Oct 14, 1986 | May | DISC |
| >D> | | MUCOSIL-20 | | | | | |
| >D> | AN | DEY | 20% | N70576 001 | Oct 14, 1986 | May | DISC |
| >A> | | @ | 20% | N70576 001 | Oct 14, 1986 | May | DISC |

ACRIVASTINE; PSEUDOEPHEDRINE HYDROCHLORIDE

CAPSULE; ORAL

SEMPREX-D

| | | | | | | | |
|--|---|-----|----------|------------|--------------|-----|------|
| | + | UCB | 8MG;60MG | N19806 001 | Mar 25, 1994 | Mar | CAHN |
|--|---|-----|----------|------------|--------------|-----|------|

ACYCLOVIR

CAPSULE; ORAL

ACYCLOVIR

| | | | | | | | |
|----|--|-------------|-------|------------|--------------|-----|------|
| AB | | TEVA PHARMS | 200MG | N74914 001 | Nov 26, 1997 | Mar | CAHN |
|----|--|-------------|-------|------------|--------------|-----|------|

SUSPENSION; ORAL

ACYCLOVIR

| | | | | | | | |
|-----|----|----------------|-----------|------------|--------------|-----|------|
| >A> | AB | HI TECH PHARMA | 200MG/5ML | N77026 001 | Jun 07, 2005 | May | NEWA |
|-----|----|----------------|-----------|------------|--------------|-----|------|

TABLET; ORAL

ACYCLOVIR

| | | | | | | | |
|----|--|-------------|-------|------------|--------------|-----|------|
| AB | | TEVA PHARMS | 400MG | N75021 001 | Mar 18, 1998 | Mar | CAHN |
| AB | | | 800MG | N75021 002 | Mar 18, 1998 | Mar | CAHN |

ACYCLOVIR SODIUM

INJECTABLE; INJECTION

ACYCLOVIR

| | | | | | | | |
|--|---|--------|-----------------|------------|--------------|-----|------|
| | @ | ABBOTT | EQ 50MG BASE/ML | N75114 001 | Jul 26, 1999 | Feb | DISC |
|--|---|--------|-----------------|------------|--------------|-----|------|

ADENOSINE

INJECTABLE; INJECTION

ADENOSINE

| | | | | | | | |
|----|--|----------|--------|------------|--------------|-----|------|
| AP | | AM PHARM | 3MG/ML | N77133 001 | Apr 27, 2005 | Apr | NEWA |
|----|--|----------|--------|------------|--------------|-----|------|

ALBUTEROL SULFATE

SOLUTION; INHALATION

ALBUTEROL SULFATE

| | | | | | | | |
|----|---|-----|----------------|------------|--------------|-----|------|
| AN | + | DEY | EQ 0.083% BASE | N72652 001 | Feb 21, 1992 | Jan | CRLD |
|----|---|-----|----------------|------------|--------------|-----|------|

TABLET; ORAL

ALBUTEROL SULFATE

| | | | | | | | |
|----|---|-------|-------------|------------|--------------|-----|------|
| AB | + | MYLAN | EQ 2MG BASE | N72894 002 | Jan 17, 1991 | Apr | CMS1 |
|----|---|-------|-------------|------------|--------------|-----|------|

ALENDRONATE SODIUM

SOLUTION; ORAL

FOSAMAX

| | | | | | | | |
|--|---|-------|-------------------|------------|--------------|-----|------|
| | + | MERCK | EQ 70MG BASE/75ML | N21575 001 | Sep 17, 2003 | Apr | CPOT |
|--|---|-------|-------------------|------------|--------------|-----|------|

ALENDRONATE SODIUM; CHOLECALCIFEROL

TABLET; ORAL

FOSAMAX PLUS D

| | | | | | | | |
|--|---|-------|-----------------------|------------|--------------|-----|------|
| | + | MERCK | EQ 70MG BASE;2,800 IU | N21762 001 | Apr 07, 2005 | Apr | NEWA |
|--|---|-------|-----------------------|------------|--------------|-----|------|

ALPRAZOLAM

TABLET, ORALLY DISINTEGRATING; ORAL

NIRAVAM

SCHWARZ PHARMA

0.25MG

| | | | | | | | |
|--|--|--|--|------------|--------------|-----|------|
| | | | | N21726 001 | Jan 19, 2005 | Jan | NEWA |
|--|--|--|--|------------|--------------|-----|------|

0.5MG

| | | | | | | | |
|--|--|--|--|------------|--------------|-----|------|
| | | | | N21726 002 | Jan 19, 2005 | Jan | NEWA |
|--|--|--|--|------------|--------------|-----|------|

1MG

| | | | | | | | |
|--|--|--|--|------------|--------------|-----|------|
| | | | | N21726 003 | Jan 19, 2005 | Jan | NEWA |
|--|--|--|--|------------|--------------|-----|------|

+

2MG

| | | | | | | | |
|--|--|--|--|------------|--------------|-----|------|
| | | | | N21726 004 | Jan 19, 2005 | Jan | NEWA |
|--|--|--|--|------------|--------------|-----|------|

ALPROSTADIL

INJECTABLE; INJECTION

EDEX

| | | | | | | | |
|----|---|----------------|-------------|------------|--------------|-----|------|
| AP | + | SCHWARZ PHARMA | 0.01MG/VIAL | N20649 005 | Jul 30, 1998 | Apr | CTEC |
|----|---|----------------|-------------|------------|--------------|-----|------|

| | | | | | | | |
|----|---|--|-------------|------------|--------------|-----|------|
| AP | + | | 0.02MG/VIAL | N20649 006 | Jul 30, 1998 | Apr | CTEC |
|----|---|--|-------------|------------|--------------|-----|------|

| | | | | | | | |
|----|---|--|-------------|------------|--------------|-----|------|
| AP | + | | 0.04MG/VIAL | N20649 007 | Jul 30, 1998 | Apr | CTEC |
|----|---|--|-------------|------------|--------------|-----|------|

AMANTADINE HYDROCHLORIDE

SYRUP; ORAL

AMANTADINE HCL

| | | | | | | | |
|----|--|-------------|----------|------------|--------------|-----|------|
| AA | | TEVA PHARMS | 50MG/5ML | N73115 001 | Aug 23, 1991 | Mar | CAHN |
|----|--|-------------|----------|------------|--------------|-----|------|

AMINO ACIDS

INJECTABLE; INJECTION

| | | | | | | | |
|-----|--|---|--|--|--|--|--|
| >D> | | AMINESS 5.2% ESSENTIAL AMINO ACIDS W/ HISTADINE | | | | | |
|-----|--|---|--|--|--|--|--|

| | | | | | | | |
|-----|--|---------|--------------------|------------|--------------|-----|------|
| >D> | | HOSPIRA | 5.2% (5.2GM/100ML) | N18901 001 | Apr 06, 1984 | May | DISC |
|-----|--|---------|--------------------|------------|--------------|-----|------|

| | | | | | | | |
|-----|--|---|--------------------|------------|--------------|-----|------|
| >A> | | @ | 5.2% (5.2GM/100ML) | N18901 001 | Apr 06, 1984 | May | DISC |
|-----|--|---|--------------------|------------|--------------|-----|------|

AMINOSYN 7%

HOSPIRA

7% (7GM/100ML)

| | | | | | | | |
|--|--|--|--|------------|--|-----|------|
| | | | | N17673 002 | | Mar | CMFD |
|--|--|--|--|------------|--|-----|------|

AMINOSYN 8.5%

HOSPIRA

8.5% (8.5GM/100ML)

| | | | | | | | |
|--|--|--|--|------------|--|-----|------|
| | | | | N17673 004 | | Mar | CMFD |
|--|--|--|--|------------|--|-----|------|

AMIODARONE

INJECTABLE; INTRAVENOUS

AMIODARONE HCL

| | | | | | | | |
|----|--|--------|---------|------------|--------------|-----|------|
| AP | | APOTEX | 50MG/ML | N77161 001 | Apr 20, 2005 | Mar | NEWA |
|----|--|--------|---------|------------|--------------|-----|------|

AMIODARONE HYDROCHLORIDE

INJECTABLE; INJECTION

AMIODARONE HCL

| | | | | | | | |
|----|---|-------------------|---------|------------|--------------|-----|------|
| AP | + | AM PHARM PARTNERS | 50MG/ML | N75761 001 | Oct 15, 2002 | Mar | CRLD |
|----|---|-------------------|---------|------------|--------------|-----|------|

| | | | | | | | |
|----|---|--------|---------|------------|--------------|-----|------|
| AP | + | APOTEX | 50MG/ML | N76394 001 | Apr 25, 2003 | Mar | CRLD |
|----|---|--------|---------|------------|--------------|-----|------|

| | | | | | | | |
|----|---|---------|---------|------------|--------------|-----|------|
| AP | + | BEDFORD | 50MG/ML | N76018 001 | Oct 15, 2002 | Mar | CRLD |
|----|---|---------|---------|------------|--------------|-----|------|

| | | | | | | | |
|----|---|--------------|---------|------------|--------------|-----|------|
| AP | + | BEDFORD LABS | 50MG/ML | N76299 001 | Oct 24, 2002 | Mar | CRLD |
|----|---|--------------|---------|------------|--------------|-----|------|

INJECTABLE; INJECTION

AMIODARONE HCL

| | | | | | | | | |
|----|---|-------------------|---------|--------|-----|--------------|-----|------|
| AP | + | BEN VENUE | 50MG/ML | N76088 | 001 | Oct 15, 2002 | Mar | CRLD |
| AP | + | BIONICHE (CANADA) | 50MG/ML | N76217 | 001 | Oct 15, 2002 | Mar | CRLD |
| AP | + | MAYNE PHARMA USA | 50MG/ML | N76108 | 001 | Oct 15, 2002 | Mar | CRLD |
| AP | + | SICOR PHARMS | 50MG/ML | N76163 | 001 | Sep 05, 2003 | Mar | CRLD |

TABLET; ORAL

AMIODARONE HCL

| | | | | | | | | |
|----|--|----------------|-------|--------|-----|--------------|-----|------|
| AB | | AUROSAL PHARMS | 200MG | N77069 | 001 | Apr 08, 2005 | Mar | NEWA |
| AB | | | 400MG | N77069 | 002 | Apr 08, 2005 | Mar | NEWA |
| AB | | TARO | 100MG | N75424 | 002 | Dec 18, 2002 | Mar | CTEC |
| AB | | TEVA PHARMS | 200MG | N74739 | 001 | Nov 30, 1998 | Mar | CAHN |
| AB | | UPSHER SMITH | 100MG | N75135 | 002 | Apr 12, 2005 | Mar | NEWA |

AMOXICILLIN

FOR SUSPENSION; ORAL

TRIMOX

| | | | | | | | | |
|----|--|-----------|-----------|--------|-----|--|-----|------|
| AB | | APOTHECON | 50MG/ML | N61886 | 001 | | Apr | CMFD |
| AB | | | 125MG/5ML | N61886 | 002 | | Apr | CMFD |
| AB | | | 250MG/5ML | N61886 | 003 | | Apr | CMFD |

AMOXICILLIN; CLAVULANATE POTASSIUM

FOR SUSPENSION; ORAL

AMOXICILLIN AND CLAVULANATE POTASSIUM

| | | | | | | | | |
|----|--|--------------|------------------------------|--------|-----|--------------|-----|------|
| AB | | HIKMA PHARMS | 200MG/5ML;EQ 28.5MG BASE/5ML | N65191 | 002 | Jan 25, 2005 | Jan | NEWA |
| AB | | | 400MG/5ML;EQ 57MG BASE/5ML | N65191 | 001 | Jan 25, 2005 | Jan | NEWA |

TABLET, CHEWABLE; ORAL

AMOXICILLIN AND CLAVULANATE POTASSIUM

| | | | | | | | | |
|----|--|------|----------------------|--------|-----|--------------|-----|------|
| AB | | TEVA | 200MG;EQ 28.5MG BASE | N65205 | 001 | Feb 09, 2005 | Jan | NEWA |
| AB | | | 400MG;EQ 57MG BASE | N65205 | 002 | Feb 09, 2005 | Jan | NEWA |

AMPHOTERICIN B

INJECTABLE, LIPID COMPLEX; INJECTION

AMPHOTEC

| | | | | | | | | |
|-----|---|---------------------|------------|--------|-----|--------------|-----|------|
| >D> | + | INTERMUNE PHARMS | 50MG/VIAL | N50729 | 001 | Nov 22, 1996 | May | CAHN |
| >D> | + | | 100MG/VIAL | N50729 | 002 | Nov 22, 1996 | May | CAHN |
| >A> | + | THREE RIVERS PHARMS | 50MG/VIAL | N50729 | 001 | Nov 22, 1996 | May | CAHN |
| >A> | + | | 100MG/VIAL | N50729 | 002 | Nov 22, 1996 | May | CAHN |

AMPICILLIN SODIUM

INJECTABLE; INJECTION

AMPICILLIN SODIUM

| | | | | | | | | |
|----|--|----------------------|--------------------|--------|-----|--------------|-----|------|
| AP | | INSTITUTO BIOCHEMICO | EQ 125MG BASE/VIAL | N62797 | 001 | Jul 12, 1993 | Jan | CMFD |
| AP | | | EQ 2GM BASE/VIAL | N62797 | 002 | Jul 12, 1993 | Jan | CAHN |

AMPRENAVIR

CAPSULE; ORAL

AGENERASE

| | | | | | | | | |
|-----|---|-----------------|-------|--------|-----|--------------|-----|------|
| >D> | | GLAXOSMITHKLINE | 50MG | N21007 | 001 | Apr 15, 1999 | May | CRLD |
| >A> | + | | 50MG | N21007 | 001 | Apr 15, 1999 | May | CRLD |
| >D> | + | | 150MG | N21007 | 002 | Apr 15, 1999 | May | DISC |
| >A> | @ | | 150MG | N21007 | 002 | Apr 15, 1999 | May | DISC |

ANAGRELIDE HYDROCHLORIDE

CAPSULE; ORAL

AGRYLIN

| | | | | | | |
|----|-------|---------------|------------|--------------|-----|------|
| AB | SHIRE | EQ 0.5MG BASE | N20333 001 | Mar 14, 1997 | Mar | CFTG |
| AB | + | EQ 1MG BASE | N20333 002 | Mar 14, 1997 | Mar | CFTG |

ANAGRELIDE HCL

| | | | | | | |
|----|-------------|---------------|------------|--------------|-----|------|
| AB | BARR | EQ 0.5MG BASE | N76530 001 | Apr 18, 2005 | Mar | NEWA |
| AB | | EQ 1MG BASE | N76530 002 | Apr 18, 2005 | Mar | NEWA |
| AB | EON | EQ 0.5MG BASE | N76683 001 | Apr 18, 2005 | Mar | NEWA |
| AB | | EQ 1MG BASE | N76683 002 | Apr 18, 2005 | Mar | NEWA |
| AB | IMPAX LABS | EQ 0.5MG BASE | N76910 001 | Apr 18, 2005 | Mar | NEWA |
| AB | | EQ 1MG BASE | N76910 002 | Apr 18, 2005 | Mar | NEWA |
| AB | IVAX PHARMS | EQ 0.5MG BASE | N76468 001 | Apr 18, 2005 | Mar | NEWA |
| AB | | EQ 1MG BASE | N76468 002 | Apr 18, 2005 | Mar | NEWA |
| AB | MYLAN | EQ 0.5MG BASE | N76811 001 | Apr 18, 2005 | Mar | NEWA |
| AB | | EQ 1MG BASE | N76811 002 | Apr 18, 2005 | Mar | NEWA |
| AB | ROXANE | EQ 0.5MG BASE | N76489 001 | Apr 18, 2005 | Mar | NEWA |
| AB | | EQ 1MG BASE | N76489 002 | Apr 18, 2005 | Mar | NEWA |
| AB | WATSON LABS | EQ 0.5MG BASE | N76417 001 | Apr 18, 2005 | Mar | NEWA |
| AB | | EQ 1MG BASE | N76417 002 | Apr 18, 2005 | Mar | NEWA |

ASPIRIN; BUTALBITAL; CAFFEINE

TABLET; ORAL

| | | | | | | |
|-----|----------------------------------|-----------------|------------|--------------|-----|------|
| >D> | BUTALBITAL W/ ASPIRIN & CAFFEINE | | | | | |
| >D> | AB PHARMERAL | 325MG;50MG;40MG | N87048 002 | Dec 09, 1983 | May | DISC |
| >A> | @ | 325MG;50MG;40MG | N87048 002 | Dec 09, 1983 | May | DISC |
| | BUTALBITAL, ASPIRIN AND CAFFEINE | | | | | |
| >D> | AB WEST WARD | 325MG;50MG;40MG | N86162 002 | Feb 16, 1984 | May | CRLD |
| >A> | AB + | 325MG;50MG;40MG | N86162 002 | Feb 16, 1984 | May | CRLD |
| >D> | FIORINAL | | | | | |
| >D> | AB + WATSON PHARMS | 325MG;50MG;40MG | N17534 003 | Apr 16, 1986 | May | DISC |
| >A> | @ | 325MG;50MG;40MG | N17534 003 | Apr 16, 1986 | May | DISC |

ASPIRIN; HYDROCODONE BITARTRATE

TABLET; ORAL

AZDONE

| | | | | | | |
|-----|------------------|-----------|------------|--------------|-----|------|
| >D> | + CENT PHARMS | 500MG;5MG | N89420 001 | Jan 25, 1988 | May | CAHN |
| >A> | + SCHWARZ PHARMA | 500MG;5MG | N89420 001 | Jan 25, 1988 | May | CAHN |

ATENOLOL

TABLET; ORAL

ATENOLOL

| | | | | | | |
|-----|------------------|-------|------------|--------------|-----|------|
| >D> | AB ABLE | 25MG | N76907 001 | Jul 30, 2004 | May | DISC |
| >A> | @ | 25MG | N76907 001 | Jul 30, 2004 | May | DISC |
| >D> | AB | 50MG | N76907 002 | Jul 30, 2004 | May | DISC |
| >A> | @ | 50MG | N76907 002 | Jul 30, 2004 | May | DISC |
| >D> | AB | 100MG | N76907 003 | Jul 30, 2004 | May | DISC |
| >A> | @ | 100MG | N76907 003 | Jul 30, 2004 | May | DISC |
| AB | MYLAN | 25MG | N73457 002 | Apr 26, 1999 | Mar | CTEC |
| AB | TEVA PHARMS | 50MG | N74120 001 | Feb 24, 1995 | Mar | CAHN |
| AB | | 100MG | N74120 002 | Feb 24, 1995 | Mar | CAHN |
| AB | ZYDUS PHARMS USA | 25MG | N76900 001 | Jan 28, 2005 | Jan | NEWA |
| AB | | 50MG | N76900 002 | Jan 28, 2005 | Jan | NEWA |
| AB | | 100MG | N76900 003 | Jan 28, 2005 | Jan | NEWA |

ATOMOXETINE HYDROCHLORIDE

CAPSULE; ORAL

STRATTERA

LILLY

80MG

N21411 007 Feb 14, 2005 Feb NEWA

100MG

N21411 008 Feb 14, 2005 Feb NEWA

ATROPINE SULFATE; DIPHENOXYLATE HYDROCHLORIDE

TABLET; ORAL

DIPHENOXYLATE HCL AND ATROPINE SULFATE

>D> AA

ABLE

0.025MG;2.5MG

N40395 001 Nov 27, 2000 May DISC

>A>

@

0.025MG;2.5MG

N40395 001 Nov 27, 2000 May DISC

AZELAIC ACID

GEL; TOPICAL

FINACEA

>D>

+

BERLEX

15%

N21470 001 Dec 24, 2002 May CAHN

>A>

+

INTENDIS

15%

N21470 001 Dec 24, 2002 May CAHN

BECLOMETHASONE DIPROPIONATE

AEROSOL, METERED; INHALATION

VANCERIL

@ SCHERING

0.042MG/INH

N17573 001

Apr DISC

BENZYL PENICILLOYL-POLYLYSINE

INJECTABLE; INJECTION

PRE-PEN

@ HOLLISTER STIER LABS

60UMOLAR

N50114 001

Mar DISC

BETAMETHASONE DIPROPIONATE

LOTION; TOPICAL

BETAMETHASONE DIPROPIONATE

AB

TEVA PHARMS

EQ 0.05% BASE

N71882 001 Jun 06, 1988 Mar CAHN

OINTMENT; TOPICAL

ALPHATREX

@ SAVAGE LABS

EQ 0.05% BASE

N19143 001 Sep 04, 1984 Jan DISC

BETAMETHASONE DIPROPIONATE; CLOTRIMAZOLE

LOTION; TOPICAL

CLOTRIMAZOLE AND BETAMETHASONE DIPROPIONATE

>A> AB

ALTANA PHARMA

EQ 0.05% BASE;1%

N76516 001 Jun 16, 2005 May NEWA

BETAMETHASONE VALERATE

LOTION; TOPICAL

BETAMETHASONE VALERATE

AB

TEVA PHARMS

EQ 0.1% BASE

N71883 001 Apr 22, 1988 Mar CAHN

BETHANECHOL CHLORIDE

TABLET; ORAL

BETHANECHOL CHLORIDE

>D> AA

ABLE

5MG

N40492 001 Jul 27, 2004 May DISC

>A>

@

5MG

N40492 001 Jul 27, 2004 May DISC

>D> AA

@

10MG

N40483 001 Jul 27, 2004 May DISC

>A>

@

10MG

N40483 001 Jul 27, 2004 May DISC

>D> AA

@

25MG

N40485 001 Jul 27, 2004 May DISC

>A>

@

25MG

N40485 001 Jul 27, 2004 May DISC

TABLET; ORAL

BETHANECHOL CHLORIDE

| | | | | | | | |
|-----|----|------------------|------|------------|--------------|-----|------|
| >D> | AA | ABLE | 50MG | N40509 001 | Jul 27, 2004 | May | DISC |
| >A> | | @ | 50MG | N40509 001 | Jul 27, 2004 | May | DISC |
| >A> | AA | UPSHER SMITH | 5MG | N40633 001 | Jun 01, 2005 | May | NEWA |
| >A> | AA | | 10MG | N40634 001 | Jun 01, 2005 | May | NEWA |
| >A> | AA | | 25MG | N40635 001 | Jun 01, 2005 | May | NEWA |
| >A> | AA | | 50MG | N40636 001 | Jun 01, 2005 | May | NEWA |
| | | DUVOID | | | | | |
| | AA | WELLSPRING PHARM | 50MG | N85882 003 | | Apr | CMFD |

BISOPROLOL FUMARATE

TABLET; ORAL

BISOPROLOL FUMARATE

| | | | | | | | |
|----|--|-------------|------|------------|--------------|-----|------|
| AB | | TEVA PHARMS | 5MG | N75644 001 | Jun 26, 2001 | Mar | CAHN |
| AB | | | 10MG | N75644 002 | Jun 26, 2001 | Mar | CAHN |

BROMFENAC SODIUM

SOLUTION/DROPS; OPHTHALMIC

XIBROM

| | | | | | | | |
|---|--|-------------|-------|------------|--------------|-----|------|
| + | | ISTA PHARMS | 0.09% | N21664 001 | Mar 24, 2005 | Mar | NEWA |
|---|--|-------------|-------|------------|--------------|-----|------|

BROMOCRIPTINE MESYLATE

CAPSULE; ORAL

BROMOCRIPTINE MESYLATE

| | | | | | | | |
|----|---|----------|-------------|------------|--------------|-----|------|
| AB | | MYLAN | EQ 5MG BASE | N77226 001 | Apr 04, 2005 | Mar | NEWA |
| AB | + | NOVARTIS | EQ 5MG BASE | N17962 002 | Mar 01, 1982 | Mar | CTEC |

BROMPHENIRAMINE MALEATE; DEXTROMETHORPHAN HYDROBROMIDE; PSEUDOEPHEDRINE HYDROCHLORIDE

SYRUP; ORAL

BROMFED-DM

| | | | | | | | |
|-----|----|---------------------|---------------------------|------------|--------------|-----|------|
| >A> | AA | BRIGHTON PHARMS INC | 2MG/5ML;10MG/5ML;30MG/5ML | N89681 001 | Dec 22, 1988 | May | CAHN |
| >D> | AA | VERUM PHARMS | 2MG/5ML;10MG/5ML;30MG/5ML | N89681 001 | Dec 22, 1988 | May | CAHN |

BUPRENORPHINE HYDROCHLORIDE

INJECTABLE; INJECTION

BUPRENORPHINE HCL

| | | | | | | | |
|----|--|---------|------------------|------------|--------------|-----|------|
| AP | | BEDFORD | EQ 0.3MG BASE/ML | N76931 001 | Mar 02, 2005 | Feb | NEWA |
|----|--|---------|------------------|------------|--------------|-----|------|

BUPROPION HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL

BUPROPION HCL

| | | | | | | | |
|-----|-----|-----|-------|------------|--------------|-----|------|
| >A> | AB1 | EON | 200MG | N75932 003 | Jun 22, 2005 | May | NEWA |
|-----|-----|-----|-------|------------|--------------|-----|------|

BUTENAFINE HYDROCHLORIDE

CREAM; TOPICAL

MENTAX

| | | | | | | | |
|---|--|--------------|----|------------|--------------|-----|------|
| + | | MYLAN BERTEK | 1% | N20524 001 | Oct 18, 1996 | Apr | CAHN |
|---|--|--------------|----|------------|--------------|-----|------|

CAFFEINE; ERGOTAMINE TARTRATE

SUPPOSITORY; RECTAL

MIGERGOT

| | | | | | | | |
|----|--|--------------|-----------|------------|--------------|-----|------|
| BR | | G AND W LABS | 100MG;2MG | N86557 001 | Oct 04, 1983 | Feb | CMFD |
|----|--|--------------|-----------|------------|--------------|-----|------|

CAPTOPRIL

TABLET; ORAL

CAPTOPRIL

| | | | | | | |
|----|-------------|--------|------------|--------------|-----|------|
| AB | TEVA PHARMS | 12.5MG | N74462 001 | Feb 13, 1996 | Mar | CAHN |
| AB | | 25MG | N74462 002 | Feb 13, 1996 | Mar | CAHN |
| AB | | 50MG | N74462 003 | Feb 13, 1996 | Mar | CAHN |
| AB | | 100MG | N74462 004 | Feb 13, 1996 | Mar | CAHN |

CARBAMAZEPINE

SUSPENSION; ORAL

CARBAMAZEPINE

@ TARO

100MG/5ML

N75875 001 Dec 21, 2000 Mar DISC

CARBIDOPA; LEVODOPA

TABLET, FOR SUSPENSION; ORAL

CARBILEV

| | | | | | | |
|-----|---------|------------|------------|--------------|-----|------|
| >A> | | | | | | |
| >A> | RANBAXY | 10MG;100MG | N76643 001 | Jun 10, 2005 | May | NEWA |
| >A> | | 25MG;100MG | N76643 002 | Jun 10, 2005 | May | NEWA |
| >A> | + | 25MG;250MG | N76643 003 | Jun 10, 2005 | May | NEWA |

CARBOPLATIN

INJECTABLE; INJECTION

CARBOPLATIN

| | | | | | | |
|----|-----|------------|------------|--------------|-----|------|
| AP | EON | 50MG/VIAL | N76959 001 | Mar 18, 2005 | Mar | NEWA |
| AP | | 150MG/VIAL | N76959 002 | Mar 18, 2005 | Mar | NEWA |
| AP | | 450MG/VIAL | N76959 003 | Mar 18, 2005 | Mar | NEWA |

INJECTABLE; IV (INFUSION)

CARBOPLATIN

| | | | | | | | |
|-----|----|-----------------|------------------------|------------|--------------|-----|------|
| >A> | AP | SPECTRUM PHARMS | EQ 50MG/5ML(10MG/ML) | N77096 001 | Jun 14, 2005 | May | NEWA |
| >A> | AP | | EQ 150MG/15ML(10MG/ML) | N77096 002 | Jun 14, 2005 | May | NEWA |
| >A> | AP | | EQ 450MG/45ML(10MG/ML) | N77096 003 | Jun 14, 2005 | May | NEWA |

CARISOPRODOL

TABLET; ORAL

CARISOPRODOL

| | | | | | | | |
|-----|----|------|-------|------------|--------------|-----|------|
| >D> | AA | ABLE | 350MG | N40421 001 | Jun 21, 2001 | May | DISC |
| >A> | | @ | 350MG | N40421 001 | Jun 21, 2001 | May | DISC |
| >A> | AA | NEIL | 350MG | N40576 001 | Jun 07, 2005 | May | NEWA |

CEFACLOR

CAPSULE; ORAL

CECLOR

@ LILLY

EQ 250MG BASE

N50521 001

Mar DISC

@

EQ 500MG BASE

N50521 002

Mar DISC

CEFACLOR

| | | | | | | | |
|----|---|---------|---------------|------------|--------------|-----|------|
| AB | + | RANBAXY | EQ 500MG BASE | N64156 002 | Aug 28, 1997 | Mar | CRLD |
|----|---|---------|---------------|------------|--------------|-----|------|

FOR SUSPENSION; ORAL

CECLOR

| | | | | | | | |
|----|-----------|--|-------------------|------------|--------------|-----|------|
| AB | CEPH INTL | | EQ 375MG BASE/5ML | N62206 004 | Apr 20, 1988 | Mar | CRLD |
| | @ LILLY | | EQ 125MG BASE/5ML | N50522 001 | | Mar | DISC |
| | @ | | EQ 250MG BASE/5ML | N50522 002 | | Mar | DISC |

CEFACLOR

| | | | | | | | |
|----|-----------|--|-------------------|------------|--------------|-----|------|
| AB | CEPH INTL | | EQ 125MG BASE/5ML | N62206 001 | | Apr | CTNA |
| AB | | | EQ 187MG BASE/5ML | N62206 003 | Apr 20, 1988 | Apr | CTNA |
| AB | | | EQ 250MG BASE/5ML | N62206 002 | | Apr | CTNA |

FOR SUSPENSION; ORAL

CEFLACLOR

| | | | | | | |
|----|-----------|-------------------|------------|--------------|-----|------|
| AB | CEPH INTL | EQ 375MG BASE/5ML | N62206 004 | Apr 20, 1988 | Apr | CTNA |
| AB | + RANBAXY | EQ 375MG BASE/5ML | N64155 001 | Oct 02, 1997 | Mar | CRLD |

CEFADROXIL/CEFADROXIL HEMIHYDRATE

TABLET; ORAL

CEFADROXIL

| | | | | | | |
|----|-------------|-------------|------------|--------------|-----|------|
| AB | IVAX PHARMS | EQ 1GM BASE | N62774 001 | Apr 08, 1987 | Apr | CMFD |
|----|-------------|-------------|------------|--------------|-----|------|

CEFAZOLIN SODIUM

INJECTABLE; INJECTION

CEFAZOLIN SODIUM

| | | | | | | |
|----|---------------------|--------------------|------------|--------------|-----|------|
| AP | + AM PHARM PARTNERS | EQ 500MG BASE/VIAL | N64169 001 | Aug 14, 1998 | Mar | CRLD |
| AP | + | EQ 1GM BASE/VIAL | N64169 002 | Aug 14, 1998 | Mar | CRLD |
| AP | + | EQ 10GM BASE/VIAL | N64170 001 | Mar 18, 1998 | Mar | CRLD |
| AP | ORCHID HLTHCARE | EQ 500MG BASE/VIAL | N65226 001 | Apr 21, 2005 | Apr | NEWA |
| AP | | EQ 1GM BASE/VIAL | N65226 002 | Apr 21, 2005 | Apr | NEWA |

CEFTRIAZONE SODIUM

INJECTABLE; IM-IV

CEFTRIAZONE

| | | | | | | |
|----|--------|--------------------|------------|--------------|-----|------|
| AP | SANDOZ | EQ 250MG BASE/VIAL | N65169 001 | May 09, 2005 | Apr | NEWA |
| AP | | EQ 500MG BASE/VIAL | N65169 002 | May 09, 2005 | Apr | NEWA |
| AP | | EQ 1GM BASE/VIAL | N65169 003 | May 09, 2005 | Apr | NEWA |
| AP | | EQ 2GM BASE/VIAL | N65169 004 | May 09, 2005 | Apr | NEWA |

INJECTABLE; INJECTION

CEFTRIAZONE

| | | | | | | |
|----|--------|-------------------|------------|--------------|-----|------|
| AP | SANDOZ | EQ 1GM BASE/VIAL | N65204 001 | May 03, 2005 | Apr | NEWA |
| AP | | EQ 2GM BASE/VIAL | N65204 002 | May 03, 2005 | Apr | NEWA |
| AP | | EQ 10GM BASE/VIAL | N65168 001 | May 17, 2005 | Apr | NEWA |

CEFTRIAZONE AND DEXTROSE IN DUPLX CONTAINER

| | | | | | | |
|----|-----------|------------------|------------|--------------|-----|------|
| AP | + B BRAUN | EQ 1GM BASE/VIAL | N50796 001 | Apr 20, 2005 | Apr | NEWA |
| AP | + | EQ 2GM BASE/VIAL | N50796 002 | Apr 20, 2005 | Apr | NEWA |

ROCEPHIN

| | | | | | | |
|----|-------|--------------------|------------|--------------|-----|------|
| | @ HLR | EQ 250MG BASE/VIAL | N63239 001 | Aug 13, 1993 | Apr | DISC |
| | @ | EQ 500MG BASE/VIAL | N63239 002 | Aug 13, 1993 | Apr | DISC |
| | + | EQ 1GM BASE/VIAL | N62654 002 | Apr 30, 1987 | Mar | CRLD |
| AP | + | EQ 1GM BASE/VIAL | N62654 002 | Apr 30, 1987 | Apr | CFTG |
| | @ | EQ 1GM BASE/VIAL | N63239 003 | Aug 13, 1993 | Apr | DISC |
| AP | + | EQ 2GM BASE/VIAL | N62654 003 | Apr 30, 1987 | Apr | CFTG |
| AP | + | EQ 10GM BASE/VIAL | N50585 005 | Dec 21, 1984 | Apr | CFTG |

CEFUROXIME SODIUM

INJECTABLE; INJECTION

CEFUROXIME AND DEXTROSE IN DUPLX CONTAINER

| | | | | | | |
|----|-----------|--------------------|------------|--------------|-----|------|
| AP | + B BRAUN | EQ 750MG BASE/VIAL | N50780 001 | Feb 21, 2001 | Apr | CPOT |
| AP | + | EQ 1.5GM BASE/VIAL | N50780 002 | Feb 21, 2001 | Apr | CPOT |

CEPHALEXIN

CAPSULE; ORAL

CEPHALEXIN

| | | | | | | |
|----|-------------|---------------|------------|--------------|-----|------|
| | @ APOTHECON | EQ 250MG BASE | N63186 001 | Dec 30, 1994 | Mar | DISC |
| | @ | EQ 500MG BASE | N63186 002 | Dec 30, 1994 | Mar | DISC |
| AB | BELCHER | EQ 250MG BASE | N62713 001 | Jul 15, 1988 | Jan | CAHN |
| AB | | EQ 500MG BASE | N62713 002 | Jul 15, 1988 | Jan | CAHN |

CAPSULE; ORALCEPHALEXIN

| | | | | | | |
|----|---------------------|---------------|------------|--------------|-----|------|
| AB | SUN PHARM INDS (IN) | EQ 250MG BASE | N62791 001 | Jun 11, 1987 | Jan | CAHN |
| AB | | EQ 500MG BASE | N62791 002 | Jun 11, 1987 | Jan | CAHN |
| AB | YUNG SHIN PHARM | EQ 250MG BASE | N65152 001 | Feb 24, 2005 | Feb | NEWA |
| AB | | EQ 500MG BASE | N65152 002 | Feb 24, 2005 | Feb | NEWA |

CHLOROTHIAZIDESUSPENSION; ORALDIURIL

| | | | | | | |
|-----|---------|-----------|------------|--|-----|------|
| >D> | @ MERCK | 250MG/5ML | N11870 001 | | May | CMFD |
| >A> | + | 250MG/5ML | N11870 001 | | May | CMFD |

CHLORPHENIRAMINE POLISTIREX; CODEINE POLISTIREXSUSPENSION, EXTENDED RELEASE; ORALCODEPREX

| | | | | | | |
|---|-----|--|------------|--------------|-----|------|
| + | UCB | EQ 4MG MALEATE/5ML;EQ 20MG BASE/5ML | N21369 001 | Jun 21, 2004 | Mar | CAHN |
|---|-----|--|------------|--------------|-----|------|

CHLORPHENIRAMINE POLISTIREX; HYDROCODONE POLISTIREXSUSPENSION, EXTENDED RELEASE; ORALTUSSIONEX

| | | | | | | |
|---|-----|--|------------|--------------|-----|------|
| + | UCB | EQ 8MG MALEATE/5ML;EQ 10MG BITARTRATE/5ML | N19111 001 | Dec 31, 1987 | Mar | CAHN |
|---|-----|--|------------|--------------|-----|------|

CHLORPROMAZINE HYDROCHLORIDETABLET; ORALCHLORPROMAZINE HCL

| | | | | | | | |
|-----|----|---|--------|-------|------------|-----|------|
| >D> | BP | + | SANDOZ | 10MG | N80439 001 | May | CRLD |
| >A> | BP | | | 10MG | N80439 001 | May | CRLD |
| | BP | + | | 10MG | N80439 001 | Apr | CRLD |
| | BP | + | | 100MG | N80439 004 | Apr | CRLD |

THORAZINE

| | | | | | | |
|--|---|-----------------|-------|------------|-----|------|
| | @ | GLAXOSMITHKLINE | 10MG | N09149 002 | Apr | DISC |
| | @ | | 25MG | N09149 007 | Apr | DISC |
| | @ | | 50MG | N09149 013 | Apr | DISC |
| | @ | | 100MG | N09149 018 | Apr | DISC |
| | @ | | 200MG | N09149 020 | Apr | DISC |

CHOLESTYRAMINEPOWDER; ORALCHOLESTYRAMINE

| | | | | | | |
|----|-------------|-----------------------------|------------|--------------|-----|------|
| AB | TEVA PHARMS | EQ 4GM RESIN/SCOOPFUL | N74554 002 | Oct 02, 1996 | Mar | CAHN |
| AB | | EQ 4GM RESIN/PACKET | N74554 001 | Oct 02, 1996 | Mar | CAHN |
| | | <u>CHOLESTYRAMINE LIGHT</u> | | | | |
| AB | TEVA PHARMS | EQ 4GM RESIN/SCOOPFUL | N74555 002 | Sep 30, 1998 | Mar | CAHN |
| AB | | EQ 4GM RESIN/PACKET | N74555 001 | Sep 30, 1998 | Mar | CAHN |

CICLOPIROXCREAM; TOPICALCICLOPIROX

| | | | | | | |
|----|------|-------|------------|--------------|-----|------|
| AB | TARO | 0.77% | N76790 001 | Apr 12, 2005 | Mar | NEWA |
|----|------|-------|------------|--------------|-----|------|

CILOSTAZOLTABLET; ORALCILOSTAZOL

| | | | | | | |
|----|------------|------|------------|--------------|-----|------|
| AB | COREPHARMA | 50MG | N77150 001 | Mar 11, 2005 | Feb | NEWA |
|----|------------|------|------------|--------------|-----|------|

TABLET; ORAL

CILOSTAZOL

| | | | | | | |
|----|-------------|-------|------------|--------------|-----|------|
| AB | IVAX PHARMS | 100MG | N77020 002 | Mar 01, 2005 | Feb | NEWA |
| AB | ROXANE | 50MG | N77024 001 | May 17, 2005 | Apr | NEWA |
| AB | | 100MG | N77024 002 | May 17, 2005 | Apr | NEWA |

CIMETIDINE HYDROCHLORIDE

INJECTABLE; INJECTION

CIMETIDINE HCL

| | | | | | | | | |
|---|----|--|-------------------|-------------------|--------------|--------------|------|------|
| >D> | AP | LUITPOLD | EQ 300MG BASE/2ML | N74353 001 | Dec 20, 1994 | May | DISC | |
| >A> | | @ | EQ 300MG BASE/2ML | N74353 001 | Dec 20, 1994 | May | DISC | |
| CIMETIDINE HCL IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER | | | | | | | | |
| >D> | AP | HOSPIRA | EQ 6MG BASE/ML | N74269 001 | Dec 27, 1994 | May | CRLD | |
| >A> | | + | EQ 6MG BASE/ML | N74269 001 | Dec 27, 1994 | May | CRLD | |
| >D> | | TAGAMET | | | | | | |
| >D> | AP | + | GLAXOSMITHKLINE | EQ 300MG BASE/2ML | N17939 002 | May | DISC | |
| >A> | | @ | EQ 300MG BASE/2ML | N17939 002 | | May | DISC | |
| >D> | | TAGAMET HCL IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER | | | | | | |
| >D> | AP | + | GLAXOSMITHKLINE | EQ 6MG BASE/ML | N19434 001 | Oct 31, 1985 | May | DISC |
| >A> | | @ | EQ 6MG BASE/ML | N19434 001 | Oct 31, 1985 | May | DISC | |

SOLUTION; ORAL

CIMETIDINE HCL

| | | | | | | |
|----|-------------|-------------------|------------|--------------|-----|------|
| AA | TEVA PHARMS | EQ 300MG BASE/5ML | N74859 001 | Jul 09, 1998 | Mar | CAHN |
|----|-------------|-------------------|------------|--------------|-----|------|

CIPROFLOXACIN HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC

CIPROFLOXACIN

| | | | | | | | | |
|-----|--------------------------------|--------------|-------------|---------------|------------|--------------|-----|------|
| AT | HITECH PHARMA | EQ 0.3% BASE | N76673 001 | Jan 21, 2005 | Jan | NEWA | | |
| >A> | TABLET, EXTENDED RELEASE; ORAL | | | | | | | |
| >A> | | PROQUIN XR | | | | | | |
| >A> | | + | DEPOMED INC | EQ 500MG BASE | N21744 001 | May 19, 2005 | May | NEWA |

TABLET; ORAL

CIPROFLOXACIN

| | | | | | | | |
|-----|--------|---------------|---------------|--------------|--------------|------|------|
| AB | COBALT | EQ 100MG BASE | N76794 001 | Feb 10, 2005 | Jan | NEWA | |
| >A> | AB | PLIVA | EQ 100MG BASE | N76426 001 | Jun 15, 2005 | May | NEWA |
| >A> | AB | | EQ 250MG BASE | N76426 002 | Jun 15, 2005 | May | NEWA |
| >A> | AB | | EQ 500MG BASE | N76426 003 | Jun 15, 2005 | May | NEWA |
| >A> | AB | | EQ 750MG BASE | N76426 004 | Jun 15, 2005 | May | NEWA |
| AB | SANDOZ | EQ 100MG BASE | N75939 001 | Mar 03, 2005 | Feb | NEWA | |
| AB | TARO | EQ 100MG BASE | N76912 001 | Feb 18, 2005 | Jan | NEWA | |

CITALOPRAM HYDROBROMIDE

TABLET; ORAL

CITALOPRAM HYDROBROMIDE

| | | | | | | |
|----|--------------|--------------|------------|--------------|-----|------|
| AB | AKYMA PHARMS | EQ 10MG BASE | N77045 003 | Apr 29, 2005 | Apr | NEWA |
| AB | | EQ 20MG BASE | N77045 002 | Apr 29, 2005 | Apr | NEWA |
| AB | | EQ 40MG BASE | N77045 001 | Apr 29, 2005 | Apr | NEWA |
| AB | MYLAN | EQ 10MG BASE | N77039 001 | Feb 03, 2005 | Jan | NEWA |
| AB | | EQ 20MG BASE | N77039 002 | Feb 03, 2005 | Jan | NEWA |
| AB | | EQ 40MG BASE | N77039 003 | Feb 03, 2005 | Jan | NEWA |

CLARITHROMYCIN

TABLET, EXTENDED RELEASE; ORAL

CLARITHROMYCIN

| | | | | | | |
|----|---------|-------|------------|--------------|-----|------|
| | RANBAXY | 1GM | N65210 001 | Jan 26, 2005 | Jan | NEWA |
| AB | TEVA | 500MG | N65154 001 | May 18, 2005 | Apr | NEWA |

TABLET; ORAL

CLARITHROMYCIN

| | | | | | | |
|-----|-------------|-------|------------|--------------|-----|------|
| AB | GENPHARM | 250MG | N65195 001 | Mar 11, 2005 | Feb | NEWA |
| AB | | 500MG | N65195 002 | Mar 11, 2005 | Feb | NEWA |
| >A> | IVAX PHARMS | 250MG | N65137 001 | May 31, 2005 | May | NEWA |
| >A> | | 500MG | N65137 002 | May 31, 2005 | May | NEWA |
| >A> | TEVA | 250MG | N65155 001 | May 31, 2005 | May | NEWA |
| >A> | | 500MG | N65155 002 | May 31, 2005 | May | NEWA |

CLEMASTINE FUMARATE

SYRUP; ORAL

CLEMASTINE FUMARATE

| | | | | | | |
|----|-------------|-------------------|------------|--------------|-----|------|
| AA | TEVA PHARMS | EQ 0.5MG BASE/5ML | N73095 001 | Apr 21, 1992 | Mar | CAHN |
|----|-------------|-------------------|------------|--------------|-----|------|

CLINDAMYCIN HYDROCHLORIDE

CAPSULE; ORAL

CLINDAMYCIN HYDROCHLORIDE

| | | | | | | |
|----|------------------|---------------|------------|--------------|-----|------|
| AB | ZYDUS PHARMS USA | EQ 75MG BASE | N65217 001 | Jan 31, 2005 | Jan | NEWA |
| AB | | EQ 150MG BASE | N65217 002 | Jan 31, 2005 | Jan | NEWA |
| AB | | EQ 300MG BASE | N65217 003 | Jan 31, 2005 | Jan | NEWA |

CLINDAMYCIN PHOSPHATE

INJECTABLE; INJECTION

CLINDAMYCIN PHOSPHATE

| | | | | | | |
|-----|---|------------------|-----------------|---------------------|------------|-----------------------|
| AP | HOSPIRA | EQ 150MG BASE/ML | N62943 001 | Sep 29, 1988 | Mar | CMFD |
| >D> | CLINDAMYCIN PHOSPHATE IN DEXTROSE 5% IN PLASTIC CONTAINER | | | | | |
| >D> | AP | + | BAXTER HLTHCARE | EQ 6MG BASE/ML | N50648 001 | Dec 29, 1989 May DISC |
| >A> | | @ | | EQ 6MG BASE/ML | N50648 001 | Dec 29, 1989 May DISC |
| >D> | AP | + | | EQ 12MG BASE/ML | N50648 002 | Dec 29, 1989 May DISC |
| >A> | | @ | | EQ 12MG BASE/ML | N50648 002 | Dec 29, 1989 May DISC |
| >D> | AP | + | | EQ 900MG BASE/100ML | N50648 003 | Dec 29, 1989 May DISC |
| >A> | | @ | | EQ 900MG BASE/100ML | N50648 003 | Dec 29, 1989 May DISC |

CLOBETASOL PROPIONATE

CREAM; TOPICAL

CLOBETASOL PROPIONATE

| | | | | | | |
|-----|-------------|-------|------------|--------------|-----|------|
| AB1 | TEVA PHARMS | 0.05% | N74087 001 | Feb 16, 1994 | Mar | CAHN |
|-----|-------------|-------|------------|--------------|-----|------|

OINTMENT; TOPICAL

CLOBETASOL PROPIONATE

| | | | | | | |
|----|-------------|-------|------------|--------------|-----|------|
| AB | TEVA PHARMS | 0.05% | N74089 001 | Feb 16, 1994 | Mar | CAHN |
|----|-------------|-------|------------|--------------|-----|------|

CLONAZEPAM

TABLET; ORAL

CLONAZEPAM

| | | | | | | |
|----|-----------|-------|------------|--------------|-----|------|
| AB | KALI LABS | 0.5MG | N77147 001 | May 02, 2005 | Apr | NEWA |
| AB | | 1MG | N77147 002 | May 02, 2005 | Apr | NEWA |
| AB | | 2MG | N77147 003 | May 02, 2005 | Apr | NEWA |

CLORAZEPATE DIPOTASSIUM

TABLET; ORAL

CLORAZEPATE DIPOTASSIUM

| | | | | | | |
|-----|----|------|--------|------------|--------------|----------|
| >D> | AB | ABLE | 3.75MG | N71780 001 | Jun 26, 1987 | May DISC |
| >A> | | @ | 3.75MG | N71780 001 | Jun 26, 1987 | May DISC |
| >D> | AB | | 7.5MG | N71781 001 | Jun 26, 1987 | May DISC |
| >A> | | @ | 7.5MG | N71781 001 | Jun 26, 1987 | May DISC |
| >D> | AB | | 15MG | N71782 001 | Jun 26, 1987 | May DISC |

| | | | | | | | | | |
|-----|-------------------------------------|-----------------|---------|------------|--------------|-----|--|------|--|
| | TABLET; ORAL | | | | | | | | |
| | CLORAZEPATE DIPOTASSIUM | | | | | | | | |
| >A> | @ ABLE | 15MG | | N71782 001 | Jun 26, 1987 | May | | DISC | |
| | <u>CLOTRIMAZOLE</u> | | | | | | | | |
| | CREAM; TOPICAL | | | | | | | | |
| | CLOTRIMAZOLE | | | | | | | | |
| | + TARO | 1% | | N72640 001 | Aug 31, 1993 | Feb | | CRLD | |
| | LOTTRIMIN | | | | | | | | |
| | @ SCHERING PLOUGH | 1% | | N17619 001 | | Feb | | DISC | |
| | MYCELEX | | | | | | | | |
| | @ BAYER PHARMS | 1% | | N18183 001 | | Feb | | DISC | |
| | <u>CLOZAPINE</u> | | | | | | | | |
| | TABLET; ORAL | | | | | | | | |
| | CLOZAPINE | | | | | | | | |
| | IVAX PHARMS | 50MG | | N74949 004 | Apr 25, 2005 | Apr | | NEWA | |
| AB | TEVA | 25MG | | N75162 001 | Apr 26, 2005 | Apr | | NEWA | |
| AB | | 100MG | | N75162 002 | Apr 26, 2005 | Apr | | NEWA | |
| | <u>CROMOLYN SODIUM</u> | | | | | | | | |
| | SOLUTION, CONCENTRATE; ORAL | | | | | | | | |
| | GASTROCROM | | | | | | | | |
| | + UCB | 100MG/5ML | | N20479 001 | Feb 29, 1996 | Mar | | CAHN | |
| | SOLUTION; INHALATION | | | | | | | | |
| | CROMOLYN SODIUM | | | | | | | | |
| >A> | AN | BREATH LTD | 10MG/ML | N76469 001 | Jun 17, 2005 | May | | NEWA | |
| | <u>CYANOCOBALAMIN</u> | | | | | | | | |
| | SPRAY, METERED; NASAL | | | | | | | | |
| | NASCOBAL | | | | | | | | |
| | + NASTECH PHARM | 0.5MG/SPRAY | | N21642 001 | Jan 31, 2005 | Jan | | NEWA | |
| | + QUESTCOR PHARMS | 0.5MG/SPRAY | | N21642 001 | Jan 31, 2005 | Feb | | CAHN | |
| | <u>CYCLOSPORINE</u> | | | | | | | | |
| | CAPSULE; ORAL | | | | | | | | |
| | CYCLOSPORINE | | | | | | | | |
| AB1 | IVAX PHARMS | 25MG | | N65110 003 | Mar 29, 2005 | Mar | | NEWA | |
| AB1 | | 50MG | | N65110 001 | Mar 29, 2005 | Mar | | NEWA | |
| AB1 | | 100MG | | N65110 002 | Mar 29, 2005 | Mar | | NEWA | |
| | GENGRAF | | | | | | | | |
| AB1 | ABBOTT | 50MG | | N65003 002 | May 12, 2000 | Mar | | CTEC | |
| | SOLUTION; ORAL | | | | | | | | |
| | CYCLOSPORINE | | | | | | | | |
| AB1 | IVAX PHARMS | 100MG/ML | | N65078 001 | Mar 25, 2005 | Mar | | NEWA | |
| | <u>CYPROHEPTADINE HYDROCHLORIDE</u> | | | | | | | | |
| | TABLET; ORAL | | | | | | | | |
| | CYPROHEPTADINE HCL | | | | | | | | |
| | @ ABC HOLDING | 4MG | | N88212 001 | May 26, 1983 | Feb | | DISC | |
| | <u>DALTEPARIN SODIUM</u> | | | | | | | | |
| | INJECTABLE; INJECTION | | | | | | | | |
| | FRAGMIN | | | | | | | | |
| | + PHARMACIA AND UPJOHN | 7,500 IU/0.3ML | | N20287 005 | Apr 04, 2002 | Jan | | NEWA | |
| | @ | 7,500 IU/0.75ML | | N20287 008 | Apr 04, 2002 | Apr | | DISC | |

INJECTABLE; INJECTION

FRAGMIN

| | | | | | | |
|---|----------------------|-----------------------------|------------|--------------|-----|------|
| + | PHARMACIA AND UPJOHN | 95,000IU/9.5ML(10,000IU/ML) | N20287 007 | Apr 04, 2002 | Apr | NEWA |
| + | | 95,000IU/3.8ML(25,000IU/ML) | N20287 006 | Apr 04, 2002 | Apr | NEWA |

DANTROLENE SODIUM

CAPSULE; ORAL

DANTRIUM

| | | | | | | |
|----|--------------------|-------|------------|--|-----|------|
| AB | PROCTER AND GAMBLE | 25MG | N17443 001 | | Feb | CFTG |
| AB | | 50MG | N17443 003 | | Feb | CFTG |
| AB | + | 100MG | N17443 002 | | Feb | CFTG |

DANTROLENE SODIUM

| | | | | | | |
|----|------------|-------|------------|--------------|-----|------|
| AB | IMPAX LABS | 25MG | N76856 001 | Mar 01, 2005 | Feb | NEWA |
| AB | | 50MG | N76856 002 | Mar 01, 2005 | Feb | NEWA |
| AB | | 100MG | N76856 003 | Mar 01, 2005 | Feb | NEWA |

DESIRUDIN RECOMBINANT

INJECTABLE; SUBCUTANEOUS

IPRIVASK

| | | | | | | |
|---|--------|-----------|------------|--------------|-----|------|
| + | CANYON | 15MG/VIAL | N21271 001 | Apr 04, 2003 | Mar | CAIN |
|---|--------|-----------|------------|--------------|-----|------|

DESLORATADINE; PSEUDOEPHEDRINE SULFATE

TABLET, EXTENDED RELEASE; ORAL

CLARINEX D 24 HOUR

| | | | | | | |
|---|----------|-----------|------------|--------------|-----|------|
| + | SCHERING | 5MG;240MG | N21605 001 | Mar 03, 2005 | Mar | NEWA |
|---|----------|-----------|------------|--------------|-----|------|

DESMOPRESSIN ACETATE

SPRAY, METERED; NASAL

DESMOPRESSIN ACETATE (NEEDS NO REFRIGERATION)

| | | | | | | |
|----|--------|--------------|------------|--------------|-----|------|
| AB | APOTEX | 0.01MG/SPRAY | N76703 001 | Jan 27, 2005 | Jan | NEWA |
|----|--------|--------------|------------|--------------|-----|------|

DESONIDE

CREAM; TOPICAL

DESONIDE

| | | | | | | |
|----|-------------|-------|------------|--------------|-----|------|
| AB | TEVA PHARMS | 0.05% | N74027 001 | Sep 28, 1992 | Mar | CAHN |
|----|-------------|-------|------------|--------------|-----|------|

DEXAMETHASONE

TABLET; ORAL

DEXAMETHASONE

| | | | | | | |
|----|-----------|--------|------------|--------------|-----|------|
| | PAR PHARM | 0.25MG | N88149 001 | Apr 28, 1983 | Mar | CRLD |
| BP | ROXANE | 1.5MG | N84610 001 | | Mar | CRLD |

DEXAMETHASONE SODIUM PHOSPHATE

INJECTABLE; INJECTION

DEXAMETHASONE SODIUM PHOSPHATE

| | | | | | | |
|----|----------|----------------------|------------|--------------|-----|------|
| AP | AM PHARM | EQ 10MG PHOSPHATE/ML | N40572 001 | Apr 22, 2005 | Apr | NEWA |
|----|----------|----------------------|------------|--------------|-----|------|

DEXMETHYLPHENIDATE HYDROCHLORIDE

>A> CAPSULE, EXTENDED RELEASE; ORAL

>A> FOCALIN XR

| | | | | | | |
|-----|----------|-----|------------|--------------|-----|------|
| >A> | NOVARTIS | 5MG | N21802 001 | May 26, 2005 | May | NEWA |
|-----|----------|-----|------------|--------------|-----|------|

| | | | | | | |
|-----|--|------|------------|--------------|-----|------|
| >A> | | 10MG | N21802 002 | May 26, 2005 | May | NEWA |
|-----|--|------|------------|--------------|-----|------|

| | | | | | | |
|-----|---|------|------------|--------------|-----|------|
| >A> | + | 20MG | N21802 003 | May 26, 2005 | May | NEWA |
|-----|---|------|------------|--------------|-----|------|

DEXTROAMPHETAMINE SULFATE

CAPSULE, EXTENDED RELEASE; ORAL
 DEXTROAMPHETAMINE SULFATE

| | | | | | | | |
|-----|----|------|------|------------|--------------|-----|------|
| >D> | AB | ABLE | 5MG | N76814 001 | Aug 25, 2004 | May | DISC |
| >A> | | @ | 5MG | N76814 001 | Aug 25, 2004 | May | DISC |
| >D> | AB | | 10MG | N76814 002 | Aug 25, 2004 | May | DISC |
| >A> | | @ | 10MG | N76814 002 | Aug 25, 2004 | May | DISC |
| >D> | AB | | 15MG | N76814 003 | Aug 25, 2004 | May | DISC |
| >A> | | @ | 15MG | N76814 003 | Aug 25, 2004 | May | DISC |

DEXTROSE

INJECTABLE; INJECTION
 DEXTROSE 50% IN PLASTIC CONTAINER

| | | | | | | | |
|----|--|---------|----------|------------|--------------|-----|------|
| AP | | HOSPIRA | 500MG/ML | N19445 001 | Jun 03, 1986 | Mar | CMFD |
|----|--|---------|----------|------------|--------------|-----|------|

DIAZEPAM

GEL; RECTAL
 DIASTAT

VALEANT 2.5MG/0.5ML
 5MG/ML
 10MG/2ML
 15MG/3ML
 + 20MG/4ML

| | | | |
|------------|--------------|-----|------|
| N20648 001 | Jul 29, 1997 | Apr | CAHN |
| N20648 002 | Jul 29, 1997 | Apr | CAHN |
| N20648 003 | Jul 29, 1997 | Apr | CAHN |
| N20648 004 | Jul 29, 1997 | Apr | CAHN |
| N20648 005 | Jul 29, 1997 | Apr | CAHN |

DICLOFENAC SODIUM

TABLET, DELAYED RELEASE; ORAL
 DICLOFENAC SODIUM

| | | | |
|----|--|-------------|------|
| AB | | TEVA PHARMS | 25MG |
| AB | | | 50MG |
| AB | | | 75MG |

| | | | |
|------------|--------------|-----|------|
| N74459 001 | Jun 25, 1997 | Mar | CAHN |
| N74459 002 | Jun 25, 1997 | Mar | CAHN |
| N74459 003 | Jun 25, 1997 | Mar | CAHN |

VOLTAREN

| | | | | |
|-----|----|---|----------|------|
| >D> | AB | + | NOVARTIS | 25MG |
| >A> | | | @ | 25MG |
| >D> | AB | + | | 50MG |
| >A> | | | @ | 50MG |

| | | | |
|------------|--------------|-----|------|
| N19201 001 | Jul 28, 1988 | May | DISC |
| N19201 001 | Jul 28, 1988 | May | DISC |
| N19201 002 | Jul 28, 1988 | May | DISC |
| N19201 002 | Jul 28, 1988 | May | DISC |

DICLOFENAC SODIUM; MISOPROSTOL

TABLET, DELAYED RELEASE; ORAL
 ARTHROTEC

| | | | |
|-----|---|---------------|------------|
| >D> | + | GD SEARLE LLC | 50MG;0.2MG |
| >A> | | | 50MG;0.2MG |

| | | | |
|------------|--------------|-----|------|
| N20607 001 | Dec 24, 1997 | May | CRLD |
| N20607 001 | Dec 24, 1997 | May | CRLD |

DICYCLOMINE HYDROCHLORIDE

SYRUP; ORAL
 BENTYL

| | | | |
|----|---|-------------------|----------|
| AA | + | AXCAN SCANDIPHARM | 10MG/5ML |
| AA | | DICYCLOMINE HCL | |
| AA | | MIKART | 10MG/5ML |

| | | | |
|------------|--------------|-----|------|
| N07961 002 | Oct 15, 1984 | Mar | CTEC |
| N40169 001 | Mar 24, 2005 | Mar | NEWA |

DIETHYLPROPION HYDROCHLORIDE

TABLET; ORAL
 DIETHYLPROPION HCL

@ ABC HOLDING 25MG
 @ 25MG

| | | | |
|------------|--------------|-----|------|
| N88267 001 | Aug 25, 1983 | Feb | DISC |
| N88268 001 | Aug 25, 1983 | Feb | DISC |

TABLET; ORAL

TENUATE

| | | | | | | | | | |
|--|---|----------------|------|--|------------|--|--|-----|------|
| | + | AVENTIS PHARMS | 25MG | | N11722 002 | | | Feb | CTEC |
|--|---|----------------|------|--|------------|--|--|-----|------|

DIHYDROERGOTAMINE MESYLATE

INJECTABLE; INJECTION

D.H.E. 45

| | | | | | | | | | |
|----|---|---------|--------|--|------------|--|--|-----|------|
| AP | + | VALEANT | 1MG/ML | | N05929 001 | | | Apr | CAHN |
|----|---|---------|--------|--|------------|--|--|-----|------|

SPRAY, METERED; NASAL

MIGRANAL

| | | | | | | | | | |
|--|---|---------|-----------|--|------------|--------------|--|-----|------|
| | + | VALEANT | 0.5MG/INH | | N20148 001 | Dec 08, 1997 | | Apr | CAHN |
|--|---|---------|-----------|--|------------|--------------|--|-----|------|

DILTIAZEM HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL

CARDIZEM CD

| | | | | | | | | |
|-----|-----|---|---------|-------|------------|--------------|-----|------|
| >D> | AB3 | + | BIOVAIL | 120MG | N20062 001 | Aug 10, 1992 | May | CRLD |
| >A> | AB3 | | | 120MG | N20062 001 | Aug 10, 1992 | May | CRLD |
| >D> | AB3 | + | | 180MG | N20062 002 | Dec 27, 1991 | May | CRLD |
| >A> | AB3 | | | 180MG | N20062 002 | Dec 27, 1991 | May | CRLD |
| >D> | AB3 | + | | 240MG | N20062 003 | Dec 27, 1991 | May | CRLD |
| >A> | AB3 | | | 240MG | N20062 003 | Dec 27, 1991 | May | CRLD |
| >D> | AB3 | + | | 300MG | N20062 004 | Dec 27, 1991 | May | CRLD |
| >A> | AB3 | | | 300MG | N20062 004 | Dec 27, 1991 | May | CRLD |

DILACOR XR

| | | | | | | | | |
|-----|-----|---|-------------|-------|------------|--------------|-----|------|
| >D> | AB2 | + | WATSON LABS | 120MG | N20092 001 | May 29, 1992 | May | CRLD |
| >A> | AB2 | | | 120MG | N20092 001 | May 29, 1992 | May | CRLD |
| >D> | AB2 | + | | 180MG | N20092 002 | May 29, 1992 | May | CRLD |
| >A> | AB2 | | | 180MG | N20092 002 | May 29, 1992 | May | CRLD |

DILTIAZEM HCL

| | | | | | | | | |
|-----|--|---|-------|------|------------|--------------|-----|------|
| >D> | | + | MYLAN | 60MG | N74910 001 | May 02, 1997 | May | CRLD |
| >A> | | | | 60MG | N74910 001 | May 02, 1997 | May | CRLD |
| >D> | | + | | 90MG | N74910 002 | May 02, 1997 | May | CRLD |
| >A> | | | | 90MG | N74910 002 | May 02, 1997 | May | CRLD |

INJECTABLE; INJECTION

CARDIZEM

| | | | | | | | | |
|----|---|-------------------|-----------|--|------------|--------------|-----|------|
| AP | + | BIOVAIL LABS INTL | 5MG/ML | | N20027 001 | Oct 24, 1991 | Mar | CAHN |
| | + | | 25MG/VIAL | | N20027 003 | Aug 18, 1995 | Mar | CAHN |

TABLET, EXTENDED RELEASE; ORAL

CARDIZEM LA

| | | | | | | | | |
|--|--|---|-------------------|-------|------------|--------------|-----|------|
| | | | BIOVAIL LABS INTL | 120MG | N21392 001 | Feb 06, 2003 | Mar | CAHN |
| | | | | 180MG | N21392 002 | Feb 06, 2003 | Mar | CAHN |
| | | | | 240MG | N21392 003 | Feb 06, 2003 | Mar | CAHN |
| | | | | 300MG | N21392 004 | Feb 06, 2003 | Mar | CAHN |
| | | | | 360MG | N21392 005 | Feb 06, 2003 | Mar | CAHN |
| | | + | | 420MG | N21392 006 | Feb 06, 2003 | Mar | CAHN |

TABLET; ORAL

CARDIZEM

| | | | | | | | | |
|----|---|--|-------------------|-------|------------|--------------|-----|------|
| AB | | | BIOVAIL LABS INTL | 30MG | N18602 001 | Nov 05, 1982 | Mar | CAHN |
| AB | | | | 60MG | N18602 002 | Nov 05, 1982 | Mar | CAHN |
| AB | | | | 90MG | N18602 003 | Dec 08, 1986 | Mar | CAHN |
| AB | + | | | 120MG | N18602 004 | Dec 08, 1986 | Mar | CAHN |

DILTIAZEM HCL

| | | | | | | | | |
|----|--|--|-------------|-------|------------|--------------|-----|------|
| AB | | | TEVA PHARMS | 30MG | N74067 001 | Nov 05, 1992 | Mar | CAHN |
| AB | | | | 60MG | N74067 002 | Nov 05, 1992 | Mar | CAHN |
| AB | | | | 90MG | N74067 003 | Nov 05, 1992 | Mar | CAHN |
| AB | | | | 120MG | N74067 004 | Nov 05, 1992 | Mar | CAHN |

DIPYRIDAMOLE

TABLET; ORAL

PERSANTINE

| | | | | | | | | | |
|-----|----|---|----------------------|------|--------|-----|--------------|-----|------|
| >D> | AB | + | BOEHRINGER INGELHEIM | 50MG | N12836 | 004 | Feb 06, 1987 | May | CRLD |
| >A> | AB | | | 50MG | N12836 | 004 | Feb 06, 1987 | May | CRLD |
| >D> | AB | | | 75MG | N12836 | 005 | Feb 06, 1987 | May | CRLD |
| >A> | AB | + | | 75MG | N12836 | 005 | Feb 06, 1987 | May | CRLD |

DOXAZOSIN MESYLATE

TABLET, EXTENDED RELEASE; ORAL

CARDURA XL

| | | | | | | | | | |
|--|--|---|--------|-------------|--------|-----|--------------|-----|------|
| | | | PFIZER | EQ 4MG BASE | N21269 | 001 | Feb 22, 2005 | Feb | NEWA |
| | | + | | EQ 8MG BASE | N21269 | 002 | Feb 22, 2005 | Feb | NEWA |

DOXEPIN HYDROCHLORIDE

CONCENTRATE; ORAL

DOXEPIN HCL

| | | | | | | | | | |
|----|--|--|-------------|-----------------|--------|-----|--------------|-----|------|
| AA | | | TEVA PHARMS | EQ 10MG BASE/ML | N71609 | 001 | Nov 09, 1987 | Mar | CAHN |
|----|--|--|-------------|-----------------|--------|-----|--------------|-----|------|

DOXYCYCLINE

CAPSULE; ORAL

DOXYCYCLINE

| | | | | | | | | | |
|----|--|--|-----------|--------------|--------|-----|--------------|-----|------|
| AB | | | PAR PHARM | EQ 75MG BASE | N65055 | 004 | Apr 18, 2005 | Mar | NEWA |
| AB | | | RANBAXY | EQ 75MG BASE | N65053 | 003 | Sep 10, 2003 | Mar | CTEC |

DOXYCYCLINE HYCLATE

CAPSULE; ORAL

DOXYCYCLINE HYCLATE

| | | | | | | | | | |
|--|--|---|-----------|--------------|--------|-----|--------------|-----|------|
| | | + | WEST WARD | EQ 20MG BASE | N65103 | 001 | May 13, 2005 | Apr | NEWA |
|--|--|---|-----------|--------------|--------|-----|--------------|-----|------|

| | | | | | | | | | |
|-----|--|---|----------|---------------|--------|-----|--------------|-----|------|
| >A> | | | | | | | | | |
| >A> | | | | | | | | | |
| >A> | | | FAULDING | EQ 75MG BASE | N50795 | 001 | May 06, 2005 | May | NEWA |
| >A> | | + | | EQ 100MG BASE | N50795 | 002 | May 06, 2005 | May | NEWA |

TABLET; ORAL

DOXYCYCLINE HYCLATE

| | | | | | | | | | |
|----|--|---|-------------------|--------------|--------|-----|--------------|-----|------|
| AB | | | COREPHARMA | EQ 20MG BASE | N65182 | 001 | May 13, 2005 | Apr | NEWA |
| AB | | | IVAX PHARMS | EQ 20MG BASE | N65163 | 001 | May 13, 2005 | Apr | NEWA |
| AB | | | MUTUAL PHARMA | EQ 20MG BASE | N65134 | 001 | May 13, 2005 | Apr | NEWA |
| | | | PERIOSTAT | | | | | | |
| AB | | + | COLLAGENEX PHARMS | EQ 20MG BASE | N50783 | 001 | Feb 02, 2001 | Apr | CFTG |

ENALAPRIL MALEATE

TABLET; ORAL

ENALAPRIL MALEATE

| | | | | | | | | | |
|--|--|--|-------------|-------|--------|-----|--------------|-----|------|
| | | | @ APOTHECON | 2.5MG | N75583 | 001 | Aug 22, 2000 | Feb | DISC |
| | | | @ | 5MG | N75583 | 002 | Aug 22, 2000 | Feb | DISC |
| | | | @ | 10MG | N75583 | 003 | Aug 22, 2000 | Feb | DISC |
| | | | @ | 20MG | N75583 | 004 | Aug 22, 2000 | Feb | DISC |

VASOTEC

| | | | | | | | | | |
|----|--|---|-------------------|-------|--------|-----|--------------|-----|------|
| AB | | | BIOVAIL LABS INTL | 2.5MG | N18998 | 005 | Jul 26, 1988 | Mar | CAHN |
| AB | | | | 5MG | N18998 | 001 | Dec 24, 1985 | Mar | CAHN |
| AB | | | | 10MG | N18998 | 002 | Dec 24, 1985 | Mar | CAHN |
| AB | | + | | 20MG | N18998 | 003 | Dec 24, 1985 | Mar | CAHN |

ENALAPRIL MALEATE; HYDROCHLOROTHIAZIDE

| | | | | | | | |
|----|-------------------|------------|--|------------|--------------|-----|------|
| | TABLET; ORAL | | | | | | |
| | VASERETIC | | | | | | |
| AB | BIOVAIL LABS INTL | 5MG;12.5MG | | N19221 003 | Jul 12, 1995 | Mar | CAHN |
| AB | + | 10MG;25MG | | N19221 001 | Oct 31, 1986 | Mar | CAHN |

ENALAPRILAT

| | | | | | | | |
|----|-----------------------|-----------|--|------------|--------------|-----|------|
| | INJECTABLE; INJECTION | | | | | | |
| | VASOTEC | | | | | | |
| AP | BIOVAIL LABS INTL | 1.25MG/ML | | N19309 001 | Feb 09, 1988 | Mar | CAHN |

ENTECAVIR

| | | | | | | | |
|---|----------------------|-----------|--|------------|--------------|-----|------|
| | SOLUTION; ORAL | | | | | | |
| | BARACLUDE | | | | | | |
| + | BRISTOL MYERS SQUIBB | 0.05MG/ML | | N21798 001 | Mar 29, 2005 | Mar | NEWA |
| | TABLET; ORAL | | | | | | |
| | BARACLUDE | | | | | | |
| | BRISTOL MYERS SQUIBB | 0.5MG | | N21797 001 | Mar 29, 2005 | Mar | NEWA |
| + | | 1MG | | N21797 002 | Mar 29, 2005 | Mar | NEWA |

EPINEPHRINE

| | | | | | | | |
|---|----------------------|--------------------|--|------------|--------------|-----|------|
| | INJECTABLE; IM-SC | | | | | | |
| | TWINJECT 0.30 | | | | | | |
| + | HOLLISTER STIER LABS | EQ 0.3MG /DELIVERY | | N20800 001 | May 30, 2003 | Feb | CTNA |

EPROSARTAN MESYLATE

| | | | | | | | |
|-----|--------------|---------------|--|------------|--------------|-----|------|
| | TABLET; ORAL | | | | | | |
| | TEVETEN | | | | | | |
| >D> | BIOVAIL | EQ 300MG BASE | | N20738 004 | Dec 22, 1997 | May | CAHN |
| >D> | | EQ 400MG BASE | | N20738 005 | Dec 22, 1997 | May | CAHN |
| >D> | + | EQ 600MG BASE | | N20738 006 | May 27, 1999 | May | CAHN |
| >A> | KOS LIFE | EQ 300MG BASE | | N20738 004 | Dec 22, 1997 | May | CAHN |
| >A> | | EQ 400MG BASE | | N20738 005 | Dec 22, 1997 | May | CAHN |
| >A> | + | EQ 600MG BASE | | N20738 006 | May 27, 1999 | May | CAHN |

EPROSARTAN MESYLATE; HYDROCHLOROTHIAZIDE

| | | | | | | | |
|-----|--------------|--------------|--|------------|--------------|-----|------|
| | TABLET; ORAL | | | | | | |
| | TEVETEN HCT | | | | | | |
| >D> | BIOVAIL | 600MG;12.5MG | | N21268 001 | Nov 01, 2001 | May | CAHN |
| >D> | + | 600MG;25MG | | N21268 002 | Nov 01, 2001 | May | CAHN |
| >A> | KOS LIFE | 600MG;12.5MG | | N21268 001 | Nov 01, 2001 | May | CAHN |
| >A> | + | 600MG;25MG | | N21268 002 | Nov 01, 2001 | May | CAHN |

ERYTHROMYCIN

| | | | | | | | |
|----|-------------------|----|--|------------|--------------|-----|------|
| | SOLUTION; TOPICAL | | | | | | |
| | ERYMAX | | | | | | |
| AT | MERZ PHARMS | 2% | | N62508 002 | Jul 11, 1985 | Jan | CAHN |

ERYTHROMYCIN ESTOLATE

| | | | | | | | |
|--|-----------------------|---------------|--|------------|--|-----|------|
| | CAPSULE; ORAL | | | | | | |
| | ERYTHROMYCIN ESTOLATE | | | | | | |
| | @ BARR | EQ 250MG BASE | | N62162 002 | | Feb | DISC |

ESMOLOL HYDROCHLORIDE

INJECTABLE; INJECTION

ESMOLOL HCL

| | | | | | | |
|----|-------------|---------|------------|--------------|-----|------|
| AP | AM PHARM | 10MG/ML | N76573 001 | May 02, 2005 | Apr | NEWA |
| AP | PHARMAFORCE | 10MG/ML | N76474 001 | May 02, 2005 | Apr | NEWA |

ESOMEPRAZOLE MAGNESIUM

CAPSULE, DELAYED REL PELLETS; ORAL

NEXIUM

| | | | | | | |
|--|-------------|--------------|------------|--------------|-----|------|
| | ASTRAZENECA | EQ 20MG BASE | N21153 001 | Feb 20, 2001 | Jan | CRLD |
|--|-------------|--------------|------------|--------------|-----|------|

ESOMEPRAZOLE SODIUM

INJECTABLE; INTRAVENOUS

NEXIUM IV

| | | | | | | |
|---|-------------|-----------|------------|--------------|-----|------|
| + | ASTRAZENECA | 20MG/VIAL | N21689 001 | Mar 31, 2005 | Mar | NEWA |
| + | | 40MG/VIAL | N21689 002 | Mar 31, 2005 | Mar | NEWA |

ESTRADIOL

FILM, EXTENDED RELEASE; TRANSDERMAL

CLIMARA

| | | | | | | | |
|-----|---|--------|--------------|------------|--------------|-----|------|
| AB2 | + | BERLEX | 0.025MG/24HR | N20375 004 | Mar 05, 1999 | Jan | CFTG |
| AB2 | + | | 0.075MG/24HR | N20375 003 | Mar 23, 1998 | Jan | CFTG |

ESCLIM

| | | | | | | |
|---|----------------------|---------------|------------|--------------|-----|------|
| @ | WOMEN FIRST HLTHCARE | 0.025MG/24HR | N20847 001 | Aug 04, 1998 | Jan | DISC |
| @ | | 0.0375MG/24HR | N20847 002 | Aug 04, 1998 | Jan | DISC |
| @ | | 0.05MG/24HR | N20847 003 | Aug 04, 1998 | Jan | DISC |
| @ | | 0.075MG/24HR | N20847 004 | Aug 04, 1998 | Jan | DISC |
| @ | | 0.1MG/24HR | N20847 005 | Aug 04, 1998 | Jan | DISC |

ESTRADIOL

| | | | | | | |
|-----|--------------------|--------------|------------|--------------|-----|------|
| AB2 | MYLAN TECHNOLOGIES | 0.025MG/24HR | N75182 003 | Jan 26, 2005 | Jan | NEWA |
| AB2 | | 0.075MG/24HR | N75182 002 | Jan 26, 2005 | Jan | NEWA |

VIVELLE

| | | | | | | |
|-----|----------|--------------|------------|--------------|-----|------|
| @ | NOVARTIS | 0.025MG/24HR | N20323 005 | Aug 16, 2000 | Jan | DISC |
| AB1 | | 0.05MG/24HR | N20323 002 | Oct 28, 1994 | Jan | CRLD |
| AB1 | | 0.1MG/24HR | N20323 004 | Oct 28, 1994 | Jan | CRLD |

VIVELLE-DOT

| | | | | | | | |
|-----|---|----------|---------------|------------|--------------|-----|------|
| BX | + | NOVARTIS | 0.025MG/24HR | N20538 009 | May 03, 2002 | Jan | CRLD |
| BX | + | | 0.0375MG/24HR | N20538 005 | Jan 08, 1999 | Jan | CRLD |
| AB1 | + | | 0.05MG/24HR | N20538 006 | Jan 08, 1999 | Jan | CRLD |
| BX | + | | 0.075MG/24HR | N20538 007 | Jan 08, 1999 | Jan | CRLD |
| AB1 | + | | 0.1MG/24HR | N20538 008 | Jan 08, 1999 | Jan | CRLD |

ESTRADIOL; NORGESTIMATE

TABLET; ORAL

ESTRADIOL AND NORGESTIMATE

| | | | | | | | |
|----|------|--------------------|--------------------|--------------|--------------|------|------|
| AB | BARR | 1MG,1MG;N/A,0.09MG | N76812 001 | Apr 29, 2005 | Apr | NEWA | |
| AB | + | PREFEST | | | | | |
| AB | + | DURAMED | 1MG,1MG;N/A,0.09MG | N21040 001 | Oct 22, 1999 | Apr | CFTG |

ESTROGENS, CONJUGATED SYNTHETIC B

TABLET; ORAL

ENJUVIA

| | | | | | | |
|---|---------|--------|------------|--------------|-----|------|
| @ | DURAMED | 0.3MG | N21443 001 | Dec 20, 2004 | Mar | DISC |
| @ | | 0.45MG | N21443 002 | Dec 20, 2004 | Mar | DISC |

ESTROPIPATE

TABLET; ORAL

ORTHO-EST

| | | | | | | | |
|-----|----|----------------------|--------|------------|--------------|-----|------|
| >A> | AB | SUN PHARM INDS (IN) | 0.75MG | N89567 001 | Feb 27, 1991 | May | CAHN |
| >A> | AB | | 1.5MG | N89582 001 | Jul 17, 1991 | May | CAHN |
| >D> | AB | WOMEN FIRST HLTHCARE | 0.75MG | N89567 001 | Feb 27, 1991 | May | CAHN |
| >D> | AB | | 1.5MG | N89582 001 | Jul 17, 1991 | May | CAHN |

ETHINYL ESTRADIOL; ETHYNODIOL DIACETATE

TABLET; ORAL-28

KELNOR

| | | | | | | | |
|-----|----|------|-------------|------------|--------------|-----|------|
| >A> | AB | BARR | 0.035MG;1MG | N76785 001 | May 23, 2005 | May | NEWA |
|-----|----|------|-------------|------------|--------------|-----|------|

ETHINYL ESTRADIOL; NORETHINDRONE

TABLET; ORAL-21

BALZIVA-21

| | | | | | | | |
|-----|----|--|--|------------|--------------|-----|------|
| >D> | AB | BARR | 0.035MG;0.4MG | N76198 001 | Apr 22, 2004 | May | CRLD |
| >A> | + | | 0.035MG;0.4MG | N76198 001 | Apr 22, 2004 | May | CRLD |
| | | NORETHINDRONE AND ETHINYL ESTRADIOL (7/14) | | | | | |
| | + | WATSON LABS | 0.035MG,0.035MG;0.5MG,1MG | N71041 001 | Sep 24, 1991 | Mar | CTEC |
| | | NORTREL 7/7/7 | | | | | |
| | | BARR | 0.035MG,0.035MG,0.035MG;0.5MG,0.75MG,1MG | N75478 001 | Aug 30, 2002 | Mar | CTEC |
| >D> | | OVCON-35 | | | | | |
| >D> | AB | + WARNER CHILCOTT | 0.035MG;0.4MG | N18127 001 | | May | DISC |
| >A> | | @ | 0.035MG;0.4MG | N18127 001 | | May | DISC |

TABLET; ORAL-28

NORETHINDRONE AND ETHINYL ESTRADIOL (7/14)

| | | | | | | | |
|----|---|----------------------|---------------------------|------------|--------------|-----|------|
| | | WATSON LABS | 0.035MG,0.035MG;0.5MG,1MG | N71042 001 | Sep 24, 1991 | Mar | CTEC |
| | | ORTHO-NOVUM 10/11-28 | | | | | |
| AB | + | ORTHO MCNEIL PHARM | 0.035MG,0.035MG;0.5MG,1MG | N18354 002 | Jan 11, 1982 | Mar | CRLD |
| | | ORTHO-NOVUM 7/14-28 | | | | | |
| | | @ ORTHO MCNEIL PHARM | 0.035MG,0.035MG;0.5MG,1MG | N19004 002 | Apr 04, 1984 | Feb | DISC |
| | | OVCON-35 | | | | | |
| AB | | WARNER CHILCOTT | 0.035MG;0.4MG | N17716 001 | | Mar | CRLD |

ETHINYL ESTRADIOL; NORETHINDRONE ACETATE

TABLET; ORAL-28

NORETHINDRONE ACETATE AND ETHINYL ESTRADIOL AND FERROUS FUMARATE

| | | | | | | | |
|-----|----|--------------|--------------|------------|--------------|-----|------|
| >A> | AB | ANDRX PHARMS | 0.02MG;1MG | N77077 001 | May 20, 2005 | May | NEWA |
| | AB | | 0.03MG;1.5MG | N77075 001 | Apr 28, 2005 | Apr | NEWA |

ETHOSUXIMIDE

SYRUP; ORAL

ETHOSUXIMIDE

| | | | | | | | |
|----|--|-------------|-----------|------------|--------------|-----|------|
| AA | | TEVA PHARMS | 250MG/5ML | N81306 001 | Jul 30, 1993 | Mar | CAHN |
|----|--|-------------|-----------|------------|--------------|-----|------|

ETODOLAC

CAPSULE; ORAL

LODINE

| | | | | | | | |
|-----|----|------------------|-------|------------|--------------|-----|------|
| >D> | AB | WYETH PHARMS INC | 200MG | N18922 002 | Jan 31, 1991 | May | DISC |
| >A> | | @ | 200MG | N18922 002 | Jan 31, 1991 | May | DISC |

TABLET, EXTENDED RELEASE; ORAL

LODINE XL

| | | | | | | | |
|-----|----|------------------|-------|------------|--------------|-----|------|
| >D> | AB | WYETH PHARMS INC | 400MG | N20584 001 | Oct 25, 1996 | May | DISC |
| >A> | | @ | 400MG | N20584 001 | Oct 25, 1996 | May | DISC |

TABLET, EXTENDED RELEASE; ORAL

| | | | | | | | | | |
|-----|----|-----------|------------------|-------|--------|-----|--------------|-----|------|
| >D> | | LODINE XL | | | | | | | |
| >D> | AB | + | WYETH PHARMS INC | 500MG | N20584 | 003 | Jan 20, 1998 | May | DISC |
| >A> | | @ | | 500MG | N20584 | 003 | Jan 20, 1998 | May | DISC |

TABLET; ORAL

| | | | | | | | | | |
|-----|----|--------|------------------|-------|--------|-----|--------------|-----|------|
| >D> | | LODINE | | | | | | | |
| >D> | AB | | WYETH PHARMS INC | 400MG | N18922 | 004 | Jul 29, 1993 | May | DISC |
| >A> | | @ | | 400MG | N18922 | 004 | Jul 29, 1993 | May | DISC |
| >D> | AB | + | | 500MG | N18922 | 005 | Jun 28, 1996 | May | DISC |
| >A> | | @ | | 500MG | N18922 | 005 | Jun 28, 1996 | May | DISC |

EXENATIDE SYNTHETIC

INJECTABLE; SUBCUTANEOUS

BYETTA

| | | | | | | | |
|---|--------|-------------------------|--------|-----|--------------|-----|------|
| + | AMYLIN | 300UGM/1.2ML(250UGM/ML) | N21773 | 001 | Apr 28, 2005 | Apr | NEWA |
| + | | 600UGM/2.4ML(250UGM/ML) | N21773 | 002 | Apr 28, 2005 | Apr | NEWA |

FENOFIBRATE

TABLET; ORAL

FENOFIBRATE

| | | | | | | | | |
|-----|----|------------|-------|--------|-----|--------------|-----|------|
| AB | | TEVA | 54MG | N76433 | 001 | May 13, 2005 | Apr | NEWA |
| AB | | | 160MG | N76433 | 002 | May 13, 2005 | Apr | NEWA |
| | | TRICOR | | | | | | |
| AB | | ABBOTT | 54MG | N21203 | 001 | Sep 04, 2001 | Apr | CFTG |
| AB | + | | 160MG | N21203 | 003 | Sep 04, 2001 | Apr | CFTG |
| >A> | | TRIGLIDE | | | | | | |
| >A> | | SKYEPHARMA | 50MG | N21350 | 001 | May 07, 2005 | May | NEWA |
| >A> | BX | | 160MG | N21350 | 002 | May 07, 2005 | May | NEWA |

FENOLDOPAM MESYLATE

INJECTABLE; INJECTION

FENOLDOPAM MESYLATE

| | | | | | | | | |
|----|--|------------|-----------------|--------|-----|--------------|-----|------|
| AP | | SABEX 2002 | EQ 10MG BASE/ML | N77155 | 001 | Feb 15, 2005 | Jan | NEWA |
|----|--|------------|-----------------|--------|-----|--------------|-----|------|

FENOPROFEN CALCIUM

CAPSULE; ORAL

NALFON

| | | | | | | | | |
|----|---|------------|---------------|--------|-----|--|-----|------|
| AB | + | PEDINOL | EQ 300MG BASE | N17604 | 002 | | Apr | CAHN |
| | | NALFON 200 | | | | | | |
| AB | | PEDINOL | EQ 200MG BASE | N17604 | 003 | | Apr | CAHN |

FENTANYL

FILM, EXTENDED RELEASE; TRANSDERMAL

DURAGESIC-100

| | | | | | | | | |
|----|---|--------------------|------------|--------|-----|--------------|-----|------|
| AB | | ALZA | 100UGM/HR | N19813 | 001 | Aug 07, 1990 | Jan | CFTG |
| | | DURAGESIC-12 | | | | | | |
| | | ALZA | 12.5UGM/HR | N19813 | 005 | Feb 04, 2005 | Feb | NEWA |
| | | DURAGESIC-25 | | | | | | |
| AB | + | ALZA | 25UGM/HR | N19813 | 004 | Aug 07, 1990 | Jan | CFTG |
| | | DURAGESIC-50 | | | | | | |
| AB | | ALZA | 50UGM/HR | N19813 | 003 | Aug 07, 1990 | Jan | CFTG |
| | | DURAGESIC-75 | | | | | | |
| AB | | ALZA | 75UGM/HR | N19813 | 002 | Aug 07, 1990 | Jan | CFTG |
| | | FENTANYL | | | | | | |
| AB | | MYLAN TECHNOLOGIES | 25UGM/HR | N76258 | 001 | Jan 28, 2005 | Jan | NEWA |
| AB | | | 50UGM/HR | N76258 | 002 | Jan 28, 2005 | Jan | NEWA |
| AB | | | 75UGM/HR | N76258 | 003 | Jan 28, 2005 | Jan | NEWA |

FILM, EXTENDED RELEASE; TRANSDERMAL
FENTANYL

AB MYLAN TECHNOLOGIES 100UGM/HR N76258 004 Jan 28, 2005 Jan NEWA

FEXOFENADINE HYDROCHLORIDE; PSEUDOEPHEDRINE HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL
ALLEGRA-D 12 HOUR

AB + AVENTIS PHARMS 60MG;120MG N20786 001 Dec 24, 1997 Mar CFTG

FEXOFENADINE HCL AND PSEUDOEPHEDRINE HCL

AB BARR 60MG;120MG N76236 001 Apr 14, 2005 Mar NEWA

FLUCONAZOLE

INJECTABLE; INJECTION

FLUCONAZOLE IN DEXTROSE 5% IN PLASTIC CONTAINER

AP APOTEX 200MG/100ML N76888 001 Mar 25, 2005 Mar NEWA

FLUCONAZOLE IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER

AP APOTEX 200MG/100ML N76889 001 Mar 25, 2005 Mar NEWA

FLUCYTOSINE

CAPSULE; ORAL

ANCOBON

VALEANT 250MG

N17001 001 Apr CAHN

+ 500MG

N17001 002 Apr CAHN

FLUMAZENIL

INJECTABLE; INJECTION

FLUMAZENIL

AP SABEX 2002 0.5MG/5ML (0.1MG/ML) N77071 001 May 03, 2005 Apr NEWA

AP 1MG/10ML (0.1MG/ML) N77071 002 May 03, 2005 Apr NEWA

FLUOCINOLONE ACETONIDE

IMPLANT; INTRAVITREAL

RETISERT

+ BAUSCH AND LOMB 0.59MG

N21737 001 Apr 08, 2005 Apr NEWA

FLUOCINOLONE ACETONIDE; HYDROQUINONE; TRETINOIN

CREAM; TOPICAL

TRI-LUMA

>A> + GALDERMA LABS LP 0.01%;4%;0.05% N21112 001 Jan 18, 2002 May CAHN

>D> + HILL DERMAC 0.01%;4%;0.05% N21112 001 Jan 18, 2002 May CAHN

FLUOCINONIDE

CREAM; TOPICAL

VANOS

+ MEDICIS 0.1%

N21758 001 Feb 11, 2005 Feb NEWA

SOLUTION; TOPICAL

FLUOCINONIDE

AT TEVA PHARMS 0.05% N72522 001 Sep 28, 1990 Mar CAHN

FLUOROURACIL

INJECTABLE; INJECTION

FLUOROURACIL

AP + VALEANT 50MG/ML N12209 001 Apr CAHN

| | | | | | | | | | |
|-----|----|-----------------------------------|---------------|--|------------|--------------|-----|------|--|
| >D> | | <u>FLUOXETINE</u> | | | | | | | |
| >D> | | CAPSULE; ORAL | | | | | | | |
| >D> | | FLUOXETINE | | | | | | | |
| >D> | AB | RANBAXY | 40MG | | N76990 001 | Dec 13, 2004 | May | CAIN | |
| | | <u>FLUOXETINE HYDROCHLORIDE</u> | | | | | | | |
| | | CAPSULE; ORAL | | | | | | | |
| | | FLUOXETINE | | | | | | | |
| | AB | BARR | EQ 40MG BASE | | N76251 001 | May 18, 2005 | Apr | NEWA | |
| >A> | AB | RANBAXY | EQ 40MG BASE | | N76990 001 | Dec 13, 2004 | May | CAIN | |
| | | <u>FLUPHENAZINE HYDROCHLORIDE</u> | | | | | | | |
| | | CONCENTRATE; ORAL | | | | | | | |
| | | FLUPHENAZINE HCL | | | | | | | |
| | AA | TEVA PHARMS | 5MG/ML | | N73058 001 | Aug 30, 1991 | Mar | CAHN | |
| | | ELIXIR; ORAL | | | | | | | |
| | | FLUPHENAZINE HCL | | | | | | | |
| | AA | TEVA PHARMS | 2.5MG/5ML | | N81310 001 | Apr 29, 1993 | Mar | CAHN | |
| | | <u>FLUTICASONE PROPIONATE</u> | | | | | | | |
| | | AEROSOL, METERED; INHALATION | | | | | | | |
| | | FLOVENT | | | | | | | |
| | + | GLAXOSMITHKLINE | 0.044MG/INH | | N20548 001 | Mar 27, 1996 | Jan | CRLD | |
| | + | | 0.11MG/INH | | N20548 002 | Mar 27, 1996 | Jan | CRLD | |
| | | FLOVENT HFA | | | | | | | |
| | + | GLAXOSMITHKLINE | 0.044MG/INH | | N21433 003 | May 14, 2004 | Jan | CRLD | |
| | + | | 0.11MG/INH | | N21433 002 | May 14, 2004 | Jan | CRLD | |
| | | LOTION; TOPICAL | | | | | | | |
| | | CUTIVATE | | | | | | | |
| | + | GLAXOSMITHKLINE | 0.05% | | N21152 001 | Mar 31, 2005 | Mar | NEWA | |
| | | OINTMENT; TOPICAL | | | | | | | |
| | | FLUTICASONE PROPIONATE | | | | | | | |
| >A> | AB | TARO PHARM INDS | 0.005% | | N77145 001 | Jun 14, 2005 | May | NEWA | |
| | | <u>FOLIC ACID</u> | | | | | | | |
| | | TABLET; ORAL | | | | | | | |
| | | FOLIC ACID | | | | | | | |
| >A> | AA | TRIGEN | 1MG | | N40514 001 | Jun 14, 2005 | May | NEWA | |
| | | <u>FOLLITROPIN ALFA/BETA</u> | | | | | | | |
| | | INJECTABLE; SUBCUTANEOUS | | | | | | | |
| | | FOLLISTIM AQ | | | | | | | |
| | + | ORGANON USA INC | 150 IU/0.18ML | | N21211 003 | Feb 11, 2004 | Feb | NEWA | |
| | + | | 300 IU/0.36ML | | N21211 001 | Mar 23, 2004 | Jan | CPOT | |
| | + | | 600 IU/0.72ML | | N21211 002 | Mar 23, 2004 | Jan | CPOT | |
| | + | | 900 IU/1.08ML | | N21211 004 | Feb 11, 2005 | Feb | NEWA | |
| | | <u>FOMIVIRSEN SODIUM</u> | | | | | | | |
| | | INJECTABLE; INJECTION | | | | | | | |
| | | VITRAVENE PRESERVATIVE FREE | | | | | | | |
| | | @ NOVARTIS | 6.6MG/ML | | N20961 001 | Aug 26, 1998 | Feb | DISC | |

FOSCARNET SODIUM

INJECTABLE; INJECTION

| | | | | | | | | | |
|-----|----|------------------|-------------|--------|-----|--------------|-----|------|--|
| >A> | | FOSCARNET SODIUM | | | | | | | |
| >A> | AP | PHARMAFORCE | 2.4GM/100ML | N77174 | 001 | May 31, 2005 | May | NEWA | |
| | | FOSCAVIR | | | | | | | |
| >D> | + | ASTRAZENECA | 2.4GM/100ML | N20068 | 001 | Sep 27, 1991 | May | CFTG | |
| >A> | AP | + | 2.4GM/100ML | N20068 | 001 | Sep 27, 1991 | May | CFTG | |

FOSINOPRIL SODIUM

TABLET; ORAL

FOSINOPRIL SODIUM

| | | | | | | | | | |
|----|--|----------------|------|--------|-----|--------------|-----|------|--|
| AB | | APOTEX | 10MG | N76906 | 001 | May 17, 2005 | Apr | NEWA | |
| AB | | | 20MG | N76906 | 002 | May 17, 2005 | Apr | NEWA | |
| AB | | | 40MG | N76906 | 003 | May 17, 2005 | Apr | NEWA | |
| AB | | INVAGEN PHARMS | 10MG | N77222 | 001 | Apr 20, 2005 | Mar | NEWA | |
| AB | | | 20MG | N77222 | 002 | Apr 20, 2005 | Mar | NEWA | |
| AB | | | 40MG | N77222 | 003 | Apr 20, 2005 | Mar | NEWA | |

FUROSEMIDE

INJECTABLE; INJECTION

FUROSEMIDE

| | | | | | | | | | |
|----|---|------------------|---------|--------|-----|--------------|-----|------|--|
| AP | + | LUITPOLD | 10MG/ML | N18579 | 001 | Nov 30, 1983 | Feb | CRLD | |
| | | LASIX | | | | | | | |
| | | @ AVENTIS PHARMS | 10MG/ML | N16363 | 001 | | Feb | DISC | |

GABAPENTIN

CAPSULE; ORAL

GABAPENTIN

| | | | | | | | | | |
|----|--|-------------|-------|--------|-----|--------------|-----|------|--|
| AB | | APOTEX | 100MG | N75360 | 001 | Apr 06, 2005 | Mar | NEWA | |
| AB | | | 300MG | N75360 | 002 | Apr 06, 2005 | Mar | NEWA | |
| AB | | | 400MG | N75360 | 003 | Apr 06, 2005 | Mar | NEWA | |
| AB | | EON | 100MG | N75539 | 001 | Apr 06, 2005 | Mar | NEWA | |
| AB | | | 300MG | N75539 | 002 | Apr 06, 2005 | Mar | NEWA | |
| AB | | | 400MG | N75539 | 003 | Apr 06, 2005 | Mar | NEWA | |
| AB | | IVAX PHARMS | 100MG | N75477 | 001 | Mar 23, 2005 | Mar | NEWA | |
| AB | | | 300MG | N75477 | 002 | Mar 23, 2005 | Mar | NEWA | |
| AB | | | 400MG | N75477 | 003 | Mar 23, 2005 | Mar | NEWA | |

TABLET; ORAL

GABAPENTIN

| | | | | | | | | | |
|----|--|-------------|-------|--------|-----|--------------|-----|------|--|
| AB | | IVAX PHARMS | 600MG | N76017 | 004 | Apr 29, 2005 | Apr | NEWA | |
| AB | | | 800MG | N76017 | 005 | Apr 29, 2005 | Apr | NEWA | |

GALANTAMINE HYDROBROMIDE

CAPSULE, EXTENDED RELEASE; ORAL

REMINYL

| | | | | | | | | | |
|---|--|---------------------|--------------|--------|-----|--------------|-----|------|--|
| + | | JOHNSON AND JOHNSON | EQ 8MG BASE | N21615 | 001 | Dec 22, 2004 | Jan | CRLD | |
| | | | EQ 24MG BASE | N21615 | 003 | Dec 22, 2004 | Jan | CRLD | |

GATIFLOXACIN

INJECTABLE; INJECTION

TEQUIN

| | | | | | | | | | |
|---|--|--|---------------------|--------|-----|--------------|-----|------|--|
| + | | BRISTOL MYERS SQUIBB | 400MG/40ML(10MG/ML) | N21062 | 004 | Dec 17, 1999 | Mar | CPOT | |
| | | TEQUIN IN DEXTROSE 5% IN PLASTIC CONTAINER | | | | | | | |
| + | | BRISTOL MYERS SQUIBB | 200MG/100ML(2MG/ML) | N21062 | 001 | Dec 17, 1999 | Mar | CPOT | |
| + | | | 400MG/200ML(2MG/ML) | N21062 | 002 | Dec 17, 1999 | Mar | CPOT | |

GENTAMICIN SULFATE

SOLUTION/DROPS; OPHTHALMIC

| | | | | | | | | |
|-----|----|-----------|--------------------|--------------|------------|--------------|-----|------|
| >D> | | GARAMYCIN | | | | | | |
| >D> | AT | + | SCHERING | EQ 0.3% BASE | N50039 002 | | May | DISC |
| >A> | | @ | | EQ 0.3% BASE | N50039 002 | | May | DISC |
| | | | GENTAMICIN SULFATE | | | | | |
| >D> | AT | | ALTANA | EQ 3% BASE | N65121 001 | Jan 30, 2004 | May | CPOT |
| >A> | AT | | | EQ 0.3% BASE | N65121 001 | Jan 30, 2004 | May | CPOT |

GLYBURIDE; METFORMIN HYDROCHLORIDE

TABLET; ORAL

GLYBURIDE AND METFORMIN HCL

| | | | | | | | | |
|----|--|------|--------------|--|------------|--------------|-----|------|
| AB | | TEVA | 1.25MG;250MG | | N76821 001 | Jan 27, 2005 | Jan | NEWA |
| AB | | | 2.5MG;500MG | | N76821 002 | Jan 27, 2005 | Jan | NEWA |
| AB | | | 5MG;500MG | | N76821 003 | Jan 27, 2005 | Jan | NEWA |

GLYCOPYRROLATE

TABLET; ORAL

GLYCOPYRROLATE

| | | | | | | | | |
|----|---|---------------|---------------|--|------------|--------------|-----|------|
| AA | | COREPHARMA | 1MG | | N40568 001 | Dec 22, 2004 | Apr | CTEC |
| AA | | | 2MG | | N40568 002 | Dec 22, 2004 | Apr | CTEC |
| | | | ROBINUL | | | | | |
| AA | + | FIRST HORIZON | 1MG | | N12827 001 | | Apr | CTEC |
| | | | ROBINUL FORTE | | | | | |
| AA | + | FIRST HORIZON | 2MG | | N12827 002 | | Apr | CTEC |

GONADOTROPIN, CHORIONIC

INJECTABLE; INJECTION

CHORIONIC GONADOTROPIN

| | | | | | | | | |
|----|---|---|--------------------|-------------------|------------|--------------|-----|------|
| | | @ | WATSON LABS (UTAH) | 2,000 UNITS/VIAL | N17016 009 | Dec 27, 1984 | Feb | CAHN |
| | | @ | | 2,000 UNITS/VIAL | N17016 011 | Feb 16, 1990 | Feb | CAHN |
| | | @ | | 5,000 UNITS/VIAL | N17016 006 | | Feb | CAHN |
| AP | + | | | 10,000 UNITS/VIAL | N17016 007 | | Feb | CAHN |
| | | @ | | 15,000 UNITS/VIAL | N17016 010 | Feb 15, 1985 | Feb | CAHN |
| | | @ | | 20,000 UNITS/VIAL | N17016 004 | | Feb | CAHN |

GRISEOFULVIN, MICROCRYSTALLINE

SUSPENSION; ORAL

GRIFULVIN V

| | | | | | | | | |
|----|---|---------|--------------|--|------------|--------------|-----|------|
| AB | + | J AND J | 125MG/5ML | | N62483 001 | Jan 26, 1984 | Feb | CFTG |
| | | | GRISEOFULVIN | | | | | |
| AB | | STIEFEL | 125MG/5ML | | N65200 001 | Mar 02, 2005 | Feb | NEWA |

GUANABENZ ACETATE

TABLET; ORAL

GUANABENZ ACETATE

| | | | | | | | | |
|----|--|-------------|-------------|--|------------|--------------|-----|------|
| AB | | TEVA PHARMS | EQ 4MG BASE | | N74267 001 | Jun 01, 1994 | Mar | CAHN |
| AB | | | EQ 8MG BASE | | N74267 002 | Jun 01, 1994 | Mar | CAHN |

HALOBETASOL PROPIONATE

OINTMENT; TOPICAL

HALOBETASOL PROPIONATE

| | | | | | | | | |
|-----|----|--|--------------------|-------|------------|--------------|-----|------|
| >A> | AB | | ALPHARMA US PHARMS | 0.05% | N77109 001 | Jun 14, 2005 | May | NEWA |
|-----|----|--|--------------------|-------|------------|--------------|-----|------|

HALOPERIDOL LACTATE

CONCENTRATE; ORAL

HALOPERIDOL

| | | | | | | | |
|----|---|-------------|----------------|------------|--------------|-----|------|
| AA | + | TEVA PHARMS | EQ 2MG BASE/ML | N71617 001 | Dec 01, 1988 | Mar | CAHN |
|----|---|-------------|----------------|------------|--------------|-----|------|

HOMATROPINE METHYLBROMIDE; HYDROCODONE BITARTRATE

SYRUP; ORAL

HYDROCODONE BITARTRATE AND HOMATROPINE METHYLBROMIDE

| | | | | | | | |
|----|--|-------------|--------------------|------------|--------------|-----|------|
| AA | | IVAX PHARMS | 1.5MG/5ML; 5MG/5ML | N40285 001 | Jul 19, 1999 | Jan | CAHN |
|----|--|-------------|--------------------|------------|--------------|-----|------|

HYDRALAZINE HYDROCHLORIDE

TABLET; ORAL

HYDRALAZINE HCL

@ ABC HOLDING

10MG

N88846 001 Feb 26, 1985 Feb DISC

@

25MG

N88847 001 Feb 26, 1985 Feb DISC

@

50MG

N88848 001 Feb 26, 1985 Feb DISC

@

100MG

N88849 001 Feb 26, 1985 Feb DISC

HYDROCHLOROTHIAZIDE

TABLET; ORAL

HYDROCHLOROTHIAZIDE

@ ABC HOLDING

25MG

N85683 001

Feb DISC

@

50MG

N83965 001

Feb DISC

@

50MG

N85672 001

Feb DISC

| | | | | | | | |
|----|---|-------------|------|------------|--|-----|------|
| AB | + | IVAX PHARMS | 50MG | N83177 002 | | Apr | CRLD |
|----|---|-------------|------|------------|--|-----|------|

@

100MG

N85022 001

Apr DISC

HYDROCHLOROTHIAZIDE; IRBESARTAN

TABLET; ORAL

AVALIDE

SANOFI SYNTHELABO

12.5MG; 300MG

N20758 003 Aug 31, 1998 Mar CRLD

+

25MG; 300MG

N20758 004 Mar 15, 2005 Mar NEWA

HYDROCHLOROTHIAZIDE; PROPRANOLOL HYDROCHLORIDE

TABLET; ORAL

INDERIDE-40/25

| | | | | | | | |
|-----|----|------------------|------------|------------|--|-----|------|
| >D> | AB | WYETH PHARMS INC | 25MG; 40MG | N18031 001 | | May | CRLD |
|-----|----|------------------|------------|------------|--|-----|------|

| | | | | | | | |
|-----|----|---|------------|------------|--|-----|------|
| >A> | AB | + | 25MG; 40MG | N18031 001 | | May | CRLD |
|-----|----|---|------------|------------|--|-----|------|

| | | | | | | | |
|-----|--|----------------|--|--|--|--|--|
| >D> | | INDERIDE-80/25 | | | | | |
|-----|--|----------------|--|--|--|--|--|

| | | | | | | | |
|-----|----|---|------------------|------------|------------|-----|------|
| >D> | AB | + | WYETH PHARMS INC | 25MG; 80MG | N18031 002 | May | DISC |
|-----|----|---|------------------|------------|------------|-----|------|

| | | | | | | | |
|-----|--|---|------------|------------|--|-----|------|
| >A> | | @ | 25MG; 80MG | N18031 002 | | May | DISC |
|-----|--|---|------------|------------|--|-----|------|

HYDROCHLOROTHIAZIDE; QUINAPRIL HYDROCHLORIDE

TABLET; ORAL

QUINAPRIL HCL AND HYDROCHLOROTHIAZIDE

| | | | | | | | |
|----|--|-------|----------------------|------------|--------------|-----|------|
| AB | | MYLAN | 12.5MG; EQ 10MG BASE | N77093 001 | Mar 28, 2005 | Mar | NEWA |
|----|--|-------|----------------------|------------|--------------|-----|------|

| | | | | | | | |
|----|--|--|----------------------|------------|--------------|-----|------|
| AB | | | 12.5MG; EQ 20MG BASE | N77093 002 | Mar 28, 2005 | Mar | NEWA |
|----|--|--|----------------------|------------|--------------|-----|------|

| | | | | | | | |
|----|--|--|--------------------|------------|--------------|-----|------|
| AB | | | 25MG; EQ 20MG BASE | N77093 003 | Mar 28, 2005 | Mar | NEWA |
|----|--|--|--------------------|------------|--------------|-----|------|

HYDROCHLOROTHIAZIDE; VALSARTAN

TABLET; ORAL

DIOVAN HCT

NOVARTIS

12.5MG; 160MG

N20818 002 Mar 06, 1998 Mar CRLD

+

25MG; 160MG

N20818 003 Jan 17, 2002 Mar CRLD

HYDROCORTISONE

ENEMA; RECTAL

HYDROCORTISONE

| | | | | | | |
|----|-------------|------------|------------|--------------|-----|------|
| AB | TEVA PHARMS | 100MG/60ML | N74171 001 | May 27, 1994 | Mar | CAHN |
|----|-------------|------------|------------|--------------|-----|------|

OINTMENT; TOPICAL

CORTRIL

| | | | | | | | |
|-----|----|---|---------------|------|------------|-----|------|
| >D> | AT | + | PFIPHARMECS | 1% | N09176 001 | May | DISC |
| >D> | AT | + | | 2.5% | N09176 002 | May | DISC |
| >A> | | @ | PFIZER GLOBAL | 1% | N09176 001 | May | DISC |
| >A> | | @ | | 2.5% | N09176 002 | May | DISC |

HYDROCORTISONE VALERATE

CREAM; TOPICAL

HYDROCORTISONE VALERATE

| | | | | | | |
|----|-------------|------|------------|--------------|-----|------|
| AB | TEVA PHARMS | 0.2% | N74489 001 | Aug 12, 1998 | Mar | CAHN |
|----|-------------|------|------------|--------------|-----|------|

HYDROMORPHONE HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE; ORAL

PALLADONE

| | | | | | | |
|--|------------------|------|------------|--------------|-----|------|
| | PURDUE PHARMA LP | 16MG | N21044 002 | Sep 24, 2004 | Feb | CRLD |
| | + | 32MG | N21044 004 | Sep 24, 2004 | Feb | CRLD |

HYDROXYCHLOROQUINE SULFATE

TABLET; ORAL

HYDROXYCHLOROQUINE SULFATE

| | | | | | | |
|----|-------------|-------|------------|--------------|-----|------|
| AB | TEVA PHARMS | 200MG | N40081 001 | Sep 30, 1994 | Mar | CAHN |
|----|-------------|-------|------------|--------------|-----|------|

HYDROXYPROGESTERONE CAPROATE

INJECTABLE; INJECTION

HYDROXYPROGESTERONE CAPROATE

| | | | | | | |
|--|---------------|----------|------------|--|-----|------|
| | @ WATSON LABS | 125MG/ML | N17439 001 | | Mar | CAHN |
| | @ | 250MG/ML | N17439 002 | | Mar | CAHN |

HYDROXYZINE HYDROCHLORIDE

TABLET; ORAL

HYDROXYZINE HCL

| | | | | | | | |
|-----|----|----------------|------|------------|--------------|-----|------|
| >D> | AB | ABLE | 10MG | N40559 001 | Jul 22, 2004 | May | DISC |
| >A> | | @ | 10MG | N40559 001 | Jul 22, 2004 | May | DISC |
| >D> | AB | | 25MG | N40562 001 | Jul 22, 2004 | May | DISC |
| >A> | | @ | 25MG | N40562 001 | Jul 22, 2004 | May | DISC |
| >D> | AB | | 50MG | N40563 001 | Jul 22, 2004 | May | DISC |
| >A> | | @ | 50MG | N40563 001 | Jul 22, 2004 | May | DISC |
| >A> | AB | VINTAGE PHARMS | 10MG | N40579 001 | May 27, 2005 | May | NEWA |
| >A> | AB | | 25MG | N40574 001 | May 27, 2005 | May | NEWA |
| >A> | AB | | 50MG | N40580 001 | May 27, 2005 | May | NEWA |

IBANDRONATE SODIUM

TABLET; ORAL

BONIVA

| | | | | | | |
|---|-------|---------------|------------|--------------|-----|------|
| + | ROCHE | EQ 2.5MG BASE | N21455 001 | May 16, 2003 | Feb | CMFD |
| | | EQ 150MG BASE | N21455 002 | Mar 24, 2005 | Mar | NEWA |
| + | | EQ 150MG BASE | N21455 002 | Mar 24, 2005 | Apr | CRLD |

IMIPRAMINE HYDROCHLORIDE

TABLET; ORAL

IMIPRAMINE HCL

| | | | | | |
|---|------|------|------------|-----|------|
| @ | TEVA | 10MG | N83729 001 | Feb | DISC |
| @ | | 25MG | N83729 004 | Feb | DISC |
| @ | | 50MG | N83729 003 | Feb | DISC |

INDOMETHACIN

CAPSULE, EXTENDED RELEASE; ORAL

INDOMETHACIN

| | | | | | | | |
|-----|----|------|------|------------|--------------|-----|------|
| >D> | AB | ABLE | 75MG | N76114 001 | Feb 06, 2002 | May | DISC |
| >A> | | @ | 75MG | N76114 001 | Feb 06, 2002 | May | DISC |

CAPSULE; ORAL

INDOMETHACIN

| | | | | | | | |
|-----|----|------|------|------------|--------------|-----|------|
| >D> | AB | ABLE | 25MG | N76666 001 | Dec 17, 2003 | May | DISC |
| >A> | | @ | 25MG | N76666 001 | Dec 17, 2003 | May | DISC |
| >D> | AB | | 50MG | N76666 002 | Dec 17, 2003 | May | DISC |
| >A> | | @ | 50MG | N76666 002 | Dec 17, 2003 | May | DISC |

IPRATROPIUM BROMIDE

SOLUTION; INHALATION

IPRATROPIUM BROMIDE

| | | | | | | | |
|----|--|------------|-------|------------|--------------|-----|------|
| AN | | BREATH LTD | 0.02% | N76291 001 | May 09, 2005 | Apr | NEWA |
|----|--|------------|-------|------------|--------------|-----|------|

IRON DEXTRAN

INJECTABLE; INJECTION

INFED

| | | | | | | | |
|----|---|--------------------|-----------------|------------|--|-----|------|
| BP | + | WATSON LABS (UTAH) | EQ 50MG IRON/ML | N17441 001 | | Feb | CAHN |
|----|---|--------------------|-----------------|------------|--|-----|------|

IRON SUCROSE

INJECTABLE; INTRAVENOUS

VENOFER

| | | | | | | |
|---|----------|--------------------------------------|------------|--------------|-----|------|
| + | LUITPOLD | EQ 100MG BASE/5ML(EQ 20MG BASE/ML) | N21135 001 | Nov 06, 2000 | Mar | CPOT |
| | | EQ 50MG BASE/2.5ML(EQ 20MG BASE/ML) | N21135 002 | Mar 20, 2005 | Mar | NEWA |
| | | EQ 75MG BASE/3.75ML(EQ 20MG BASE/ML) | N21135 003 | Mar 29, 2005 | Mar | NEWA |

ISRADIPINE

TABLET, EXTENDED RELEASE; ORAL

DYNACIRC CR

| | | | | | | |
|--|----------------|-----|------------|--------------|-----|------|
| | RELIANT PHARMS | 5MG | N20336 001 | Jun 01, 1994 | Mar | CRLD |
|--|----------------|-----|------------|--------------|-----|------|

KANAMYCIN SULFATE

CAPSULE; ORAL

KANTREX

| | | | | | | |
|---|-----------|---------------|------------|--------------|-----|------|
| @ | APOTHECON | EQ 500MG BASE | N62726 001 | Mar 06, 1987 | Feb | DISC |
|---|-----------|---------------|------------|--------------|-----|------|

KETOCONAZOLE

SHAMPOO; TOPICAL

KETOCONAZOLE

| | | | | | | | |
|----|--|---------|----|------------|--------------|-----|------|
| AB | | QLT USA | 2% | N76942 001 | Apr 11, 2005 | Mar | NEWA |
|----|--|---------|----|------------|--------------|-----|------|

KETOPROFEN

CAPSULE, EXTENDED RELEASE; ORAL
ORUVAIL

| | | | | | | | |
|-----|----|------------------|-------|------------|--------------|-----|------|
| >D> | AB | WYETH PHARMS INC | 100MG | N19816 003 | Feb 08, 1995 | May | DISC |
| >A> | | @ | 100MG | N19816 003 | Feb 08, 1995 | May | DISC |
| >D> | AB | | 150MG | N19816 002 | Feb 08, 1995 | May | DISC |
| >A> | | @ | 150MG | N19816 002 | Feb 08, 1995 | May | DISC |

LACTULOSE

SOLUTION; ORAL
EVALOSE

| | | | | | | | |
|----|--|-------------|-----------|------------|--------------|-----|------|
| AA | | TEVA PHARMS | 10GM/15ML | N73497 001 | May 28, 1993 | Mar | CAHN |
|----|--|-------------|-----------|------------|--------------|-----|------|

SOLUTION; ORAL, RECTAL
HEPTALAC

| | | | | | | | |
|----|--|-------------|-----------|------------|--------------|-----|------|
| AA | | TEVA PHARMS | 10GM/15ML | N73504 001 | May 28, 1993 | Mar | CAHN |
|----|--|-------------|-----------|------------|--------------|-----|------|

LEPIRUDIN RECOMBINANT

INJECTABLE; INJECTION
REFLUDAN

| | | | | | | | |
|--|---|--------|-----------|------------|--------------|-----|------|
| | + | BERLEX | 50MG/VIAL | N20807 001 | Mar 06, 1998 | Mar | CAIN |
|--|---|--------|-----------|------------|--------------|-----|------|

LEUCOVORIN CALCIUM

INJECTABLE; INJECTION
LEUCOVORIN CALCIUM PRESERVATIVE FREE

| | | | | | | | |
|----|---|-----------|-----------------|------------|--------------|-----|------|
| AP | + | BEDFORD | EQ 10MG BASE/ML | N40347 001 | Apr 25, 2000 | Apr | CRLD |
| | | @ HOSPIRA | EQ 10MG BASE/ML | N40147 001 | Jun 25, 1997 | Apr | DISC |

LEUPROLIDE ACETATE

INJECTABLE; SUBCUTANEOUS
ELIGARD

| | | | | | | | |
|--|---|---------|-------------|------------|--------------|-----|------|
| | + | QLT USA | 22.5MG/VIAL | N21379 001 | Jul 24, 2002 | Jan | CAHN |
|--|---|---------|-------------|------------|--------------|-----|------|

LEVALBUTEROL TARTRATE

AEROSOL, METERED; INHALATION
XOPENEX HFA

| | | | | | | | |
|--|---|----------|---------------------|------------|--------------|-----|------|
| | + | SEPRACOR | EQ 0.045MG BASE/INH | N21730 001 | Mar 11, 2005 | Mar | NEWA |
|--|---|----------|---------------------|------------|--------------|-----|------|

LEVOFLOXACIN

TABLET; ORAL
LEVAQUIN

| | | | | | | | |
|----|---|--------------------|-------|------------|--------------|-----|------|
| | | ORTHO MCNEIL PHARM | 250MG | N20634 001 | Dec 20, 1996 | Mar | CTEC |
| | | | 500MG | N20634 002 | Dec 20, 1996 | Mar | CTEC |
| AB | + | | 750MG | N20634 003 | Sep 08, 2000 | Jan | CFTG |

| | | | | | | | |
|----|--|----------------------|-------|------------|--------------|-----|------|
| AB | | LEVOFLOXACIN TEVA | 750MG | N76361 003 | Jan 26, 2005 | Jan | NEWA |
|----|--|----------------------|-------|------------|--------------|-----|------|

LEVOTHYROXINE SODIUM**

**Refer to Preface Section 1.3 Levothyroxine Sodium for amplifying information

TABLET; ORAL

LEVOTHYROXINE SODIUM

| | | | | | | | |
|-----|-----|----------|---------|------------|--------------|-----|------|
| >A> | AB2 | GENPHARM | 0.025MG | N76752 001 | Jun 16, 2005 | May | NEWA |
| >A> | AB2 | | 0.05MG | N76752 002 | Jun 16, 2005 | May | NEWA |
| >A> | AB2 | | 0.075MG | N76752 003 | Jun 16, 2005 | May | NEWA |
| >A> | AB2 | | 0.088MG | N76752 004 | Jun 16, 2005 | May | NEWA |
| >A> | AB2 | | 0.1MG | N76752 005 | Jun 16, 2005 | May | NEWA |
| >A> | AB2 | | 0.112MG | N76752 006 | Jun 16, 2005 | May | NEWA |

TABLET; ORALLEVOTHYROXINE SODIUM

| | | | | | | | |
|-----|-----|----------|---------|------------|--------------|-----|------|
| >A> | AB2 | GENPHARM | 0.125MG | N76752 007 | Jun 16, 2005 | May | NEWA |
| >A> | AB2 | | 0.15MG | N76752 008 | Jun 16, 2005 | May | NEWA |
| >A> | AB2 | | 0.175MG | N76752 009 | Jun 16, 2005 | May | NEWA |
| >A> | AB2 | | 0.2MG | N76752 010 | Jun 16, 2005 | May | NEWA |
| >A> | AB2 | | 0.3MG | N76752 011 | Jun 16, 2005 | May | NEWA |

LIDOCAINE HYDROCHLORIDEINJECTABLE; INJECTIONLIDOCAINE HCL PRESERVATIVE FREE

| | | | | | | | |
|----|--|----------|----|------------|--|-----|------|
| AP | | AM PHARM | 2% | N17584 001 | | Apr | CAHN |
| AP | | | 4% | N17584 002 | | Apr | CAHN |

JELLY; TOPICALLIDOCAINE HCL

| | | | | | | | |
|----|--|-------------|----|------------|--------------|-----|------|
| AT | | TEVA PHARMS | 2% | N81318 001 | Apr 29, 1993 | Mar | CAHN |
|----|--|-------------|----|------------|--------------|-----|------|

LIOTHYRONINE SODIUMTABLET; ORALCYTOMEL

| | | | | | | | |
|-----|--|--------------|-----------------|------------|--|-----|------|
| >D> | | JONES PHARMA | EQ 0.005MG BASE | N10379 001 | | May | CAHN |
| >D> | | | EQ 0.025MG BASE | N10379 002 | | May | CAHN |
| >D> | | + | EQ 0.05MG BASE | N10379 003 | | May | CAHN |
| >A> | | KING PHARMS | EQ 0.005MG BASE | N10379 001 | | May | CAHN |
| >A> | | | EQ 0.025MG BASE | N10379 002 | | May | CAHN |
| >A> | | + | EQ 0.05MG BASE | N10379 003 | | May | CAHN |

LITHIUM CARBONATECAPSULE; ORALLITHIUM CARBONATE

| | | | | | | | |
|-----|----|----------|-------|------------|--------------|-----|------|
| >D> | AB | ABLE | 150MG | N76823 001 | Jun 29, 2004 | May | DISC |
| >A> | | @ | 150MG | N76823 001 | Jun 29, 2004 | May | DISC |
| >D> | AB | | 300MG | N76121 001 | Sep 27, 2001 | May | DISC |
| >A> | | @ | 300MG | N76121 001 | Sep 27, 2001 | May | DISC |
| >D> | AB | | 300MG | N76823 002 | Jun 29, 2004 | May | DISC |
| >A> | | @ | 300MG | N76823 002 | Jun 29, 2004 | May | DISC |
| >D> | AB | | 600MG | N76823 003 | Jun 29, 2004 | May | DISC |
| >A> | | @ | 600MG | N76823 003 | Jun 29, 2004 | May | DISC |
| >D> | AB | + ROXANE | 600MG | N17812 003 | Jan 28, 1987 | May | CTEC |
| >A> | | + | 600MG | N17812 003 | Jan 28, 1987 | May | CTEC |

TABLET, EXTENDED RELEASE; ORALLITHIUM CARBONATE

| | | | | | | | |
|-----|----|------|-------|------------|--------------|-----|------|
| >D> | AB | ABLE | 300MG | N76382 001 | Apr 21, 2003 | May | DISC |
| >A> | | @ | 300MG | N76382 001 | Apr 21, 2003 | May | DISC |

LORAZEPAMSOLUTION; ORALLORAZEPAMROXANE

0.5MG/5ML

N74648 001 Mar 18, 1997 Jan CMFD

MAFENIDE ACETATECREAM; TOPICALSULFAMYLON

+ MYLAN BERTEK

EQ 85MG BASE/GM

N16763 001

Apr CAHN

MANGAFODIPIR TRISODIUMINJECTABLE; INJECTION
TESLASCAN

| | | | | | |
|-----------------|-----------|------------|--------------|-----|------|
| @ GE HEALTHCARE | 37.9MG/ML | N20652 001 | Nov 26, 1997 | Jan | DISC |
|-----------------|-----------|------------|--------------|-----|------|

MEBENDAZOLETABLET, CHEWABLE; ORAL
MEBENDAZOLE

| | | | | | | |
|----|-------------|-------|------------|--------------|-----|------|
| AB | TEVA PHARMS | 100MG | N73580 001 | Jan 04, 1995 | Mar | CAHN |
|----|-------------|-------|------------|--------------|-----|------|

MECLIZINE HYDROCHLORIDETABLET; ORAL
MECLIZINE HCL

| | | | | | |
|---------------|--------|------------|--|-----|------|
| @ ABC HOLDING | 12.5MG | N85253 001 | | Feb | DISC |
|---------------|--------|------------|--|-----|------|

| | | | | | |
|---|------|------------|--|-----|------|
| @ | 25MG | N85252 001 | | Feb | DISC |
|---|------|------------|--|-----|------|

MEGESTROL ACETATESUSPENSION; ORAL
MEGESTROL ACETATE

| | | | | | | |
|----|-------------|---------|------------|--------------|-----|------|
| AB | TEVA PHARMS | 40MG/ML | N75681 001 | May 05, 2003 | Mar | CAHN |
|----|-------------|---------|------------|--------------|-----|------|

MEMANTINE HYDROCHLORIDESOLUTION; ORAL
NAMENDA

| | | | | | | |
|---|-------------|--------|------------|--------------|-----|------|
| + | FOREST LABS | 2MG/ML | N21627 001 | Apr 18, 2005 | Apr | NEWA |
|---|-------------|--------|------------|--------------|-----|------|

MEQUINOL; TRETINOINSOLUTION; TOPICAL
SOLAGE

| | | | | | | |
|---|---------|----------|------------|--------------|-----|------|
| + | BARRIER | 2%;0.01% | N20922 001 | Dec 10, 1999 | Feb | CAHN |
|---|---------|----------|------------|--------------|-----|------|

METAPROTERENOL SULFATESYRUP; ORAL
METAPROTERENOL SULFATE

| | | | | | |
|---------------|----------|------------|--------------|-----|------|
| @ TEVA PHARMS | 10MG/5ML | N73034 001 | Aug 30, 1991 | Mar | CAHN |
|---------------|----------|------------|--------------|-----|------|

METAXALONETABLET; ORAL
SKELAXIN

| | | | | | | |
|-----|------------------|-------|------------|--|-----|------|
| >D> | JONES PHARMA INC | 400MG | N13217 001 | | May | DISC |
|-----|------------------|-------|------------|--|-----|------|

| | | | | | | |
|-----|---|-------|------------|--|-----|------|
| >A> | @ | 400MG | N13217 001 | | May | DISC |
|-----|---|-------|------------|--|-----|------|

METFORMIN HYDROCHLORIDETABLET, EXTENDED RELEASE; ORAL
METFORMIN HCL

| | | | | | | |
|----|------------------|-------|------------|--------------|-----|------|
| AB | ANDRX PHARMS | 750MG | N76869 001 | Apr 12, 2005 | Mar | NEWA |
| AB | PUREPAC PHARM | 750MG | N76878 001 | Apr 13, 2005 | Mar | NEWA |
| AB | TEVA | 750MG | N76864 001 | Apr 12, 2005 | Mar | NEWA |
| AB | ZYDUS PHARMS USA | 500MG | N77060 001 | Apr 20, 2005 | Mar | NEWA |
| AB | | 750MG | N77078 001 | Apr 21, 2005 | Apr | NEWA |

TABLET; ORAL

METFORMIN HCL

| | | | | | | |
|----|------------------|-------|------------|--------------|-----|------|
| AB | ZYDUS PHARMS USA | 500MG | N77064 001 | Apr 18, 2005 | Mar | NEWA |
| AB | | 850MG | N77064 002 | Apr 18, 2005 | Mar | NEWA |
| AB | | 1GM | N77064 003 | Apr 18, 2005 | Mar | NEWA |

METHAMPHETAMINE HYDROCHLORIDE

TABLET; ORAL

DESOXYN

| | | | | | | | | |
|-----|----|---|---------------------|-----|------------|--------------|-----|------|
| >D> | AB | + | OVATION PHARMS | 5MG | N05378 002 | | May | CTEC |
| >A> | | | + | 5MG | N05378 002 | | May | CTEC |
| | | | METHAMPHETAMINE HCL | | | | | |
| >D> | AB | | ABLE | 5MG | N40529 001 | Feb 25, 2004 | May | DISC |
| >A> | | | @ | 5MG | N40529 001 | Feb 25, 2004 | May | DISC |

METHAZOLAMIDE

TABLET; ORAL

METHAZOLAMIDE

| | | | | | | | | |
|----|--|--|-------------|------|------------|--------------|-----|------|
| AB | | | TEVA PHARMS | 25MG | N40001 001 | Jun 30, 1993 | Mar | CAHN |
| AB | | | | 50MG | N40001 002 | Jun 30, 1993 | Mar | CAHN |

METHIMAZOLE

TABLET; ORAL

METHIMAZOLE

| | | | | | | | | |
|----|--|---|--------------|------|------------|--------------|-----|------|
| AB | | | CEDAR PHARMS | 5MG | N40547 001 | Feb 18, 2005 | Jan | NEWA |
| AB | | | | 10MG | N40547 002 | Feb 18, 2005 | Jan | NEWA |
| AB | | | | 20MG | N40547 004 | Feb 18, 2005 | Jan | NEWA |
| | | | @ GENPHARM | 20MG | N40350 003 | Jun 07, 2001 | Apr | DISC |
| AB | | + | | 20MG | N40350 003 | Jun 07, 2001 | Jan | CFTG |

METHOCARBAMOL

TABLET; ORAL

METHOCARBAMOL

| | | | | | | | | |
|-----|----|--|------|-------|------------|--------------|-----|------|
| >D> | AA | | ABLE | 500MG | N40413 001 | Mar 17, 2003 | May | DISC |
| >A> | | | @ | 500MG | N40413 001 | Mar 17, 2003 | May | DISC |
| >D> | AA | | | 750MG | N40413 002 | Mar 17, 2003 | May | DISC |
| >A> | | | @ | 750MG | N40413 002 | Mar 17, 2003 | May | DISC |

METHOTREXATE SODIUM

INJECTABLE; INJECTION

METHOTREXATE

| | | | | | | | | |
|----|--|---|--------------------------------|--------------------------------|------------|--------------|-----|------|
| | | | @ BIGMAR BIOREN PHARMS | EQ 25MG BASE/ML | N40263 001 | Feb 26, 1999 | Apr | DISC |
| AP | | + | MAYNE PHARMA USA | EQ 50MG BASE/2ML (25 MG/ML) | N11719 010 | Dec 15, 2004 | Apr | NEWA |
| | | | METHOTREXATE LPF | | | | | |
| | | | @ MAYNE PHARMA USA | EQ 25MG BASE/ML | N11719 007 | Mar 31, 1982 | Apr | DISC |
| | | | METHOTREXATE PRESERVATIVE FREE | | | | | |
| | | | @ BIGMAR BIOREN PHARMS | EQ 25MG BASE/ML | N40265 001 | Feb 26, 1999 | Apr | DISC |
| | | | @ | EQ 1GM BASE/VIAL | N40266 001 | Feb 26, 1999 | Apr | DISC |
| | | + | MAYNE PHARMA USA | EQ 20MG BASE/2ML (10 MG/ML) | N11719 014 | Apr 13, 2005 | Apr | NEWA |
| AP | | + | | EQ 500MG BASE/20ML (25 MG/ML) | N11719 013 | Apr 13, 2005 | Apr | NEWA |
| AP | | + | | ED 1GM BASE/40ML (25 MG/ML) | N11719 012 | Apr 13, 2005 | Apr | NEWA |
| AP | | + | | EQ 2.5GM BASE/100ML (25 MG/ML) | N11719 011 | Apr 13, 2005 | Apr | NEWA |
| | | | METHOTREXATE SODIUM | | | | | |
| AP | | | BEDFORD | EQ 50 MG BASE/2ML (25 ML/ML) | N89340 001 | Sep 16, 1986 | Apr | CPOT |
| AP | | | | EQ 100MG BASE/4ML (25 MG/ML) | N89341 001 | Sep 16, 1986 | Apr | CPOT |
| AP | | | | EQ 200MG BASE/8ML (25 MG/ML) | N89342 001 | Sep 16, 1986 | Apr | CPOT |
| AP | | | | EQ 250MG BASE/10ML (25 MG/ML) | N89343 001 | Sep 16, 1986 | Apr | CPOT |
| | | | @ MAYNE PHARMA USA | EQ 20MG BASE/VIAL | N11719 001 | | Mar | DISC |
| | | | @ | EQ 25MG BASE/ML | N11719 005 | | Apr | DISC |
| | | | @ NORBROOK | EQ 25MG BASE/ML | N88648 001 | May 09, 1986 | Apr | DISC |
| | | | @ PHARMACHEMIE USA | EQ 25MG BASE/ML | N89158 001 | Jul 08, 1988 | Apr | DISC |

INJECTABLE; INJECTION

MEXATE-AQ

| | | | | | | |
|---|---------------|-----------------|------------|--------------|-----|------|
| @ | BRISTOL MYERS | EQ 25MG BASE/ML | N88760 001 | Feb 14, 1985 | Apr | DISC |
|---|---------------|-----------------|------------|--------------|-----|------|

METHYL AMINOLEVULINATE HYDROCHLORIDE

CREAM; TOPICAL

>D> METHYL AMINOLEVULINATE

| | | | | | | | |
|-----|---|---------------|-------|------------|--------------|-----|------|
| >D> | + | PHOTOCURE ASA | 16.8% | N21415 001 | Jul 27, 2004 | May | CTNA |
|-----|---|---------------|-------|------------|--------------|-----|------|

>A> METVIXIA

| | | | | | | | |
|-----|---|---------------|-------|------------|--------------|-----|------|
| >A> | + | PHOTOCURE ASA | 16.8% | N21415 001 | Jul 27, 2004 | May | CTNA |
|-----|---|---------------|-------|------------|--------------|-----|------|

METHYLDOPA

TABLET; ORAL

ALDOMET

| | | | | | | |
|---|-------|-------|------------|--|-----|------|
| @ | MERCK | 500MG | N13400 002 | | Jan | DISC |
|---|-------|-------|------------|--|-----|------|

METHYLDOPA

| | | | | | | | |
|----|---|-------|-------|------------|--------------|-----|------|
| AB | + | MYLAN | 500MG | N70076 001 | Apr 18, 1985 | Jan | CRLD |
|----|---|-------|-------|------------|--------------|-----|------|

METHYLDOPATE HYDROCHLORIDE

INJECTABLE; INJECTION

ALDOMET

| | | | | | | |
|---|-------|---------|------------|--|-----|------|
| @ | MERCK | 50MG/ML | N13401 001 | | Jan | DISC |
|---|-------|---------|------------|--|-----|------|

METHYLDOPATE HCL

| | | | | | | | |
|----|---|----------|---------|------------|--------------|-----|------|
| AP | + | LUITPOLD | 50MG/ML | N71279 001 | Oct 02, 1987 | Jan | CRLD |
|----|---|----------|---------|------------|--------------|-----|------|

METHYLERGONOVINE MALEATE

TABLET; ORAL

METHERGINE

| | | | | | | |
|---|----------|-------|------------|--|-----|------|
| + | NOVARTIS | 0.2MG | N06035 003 | | Jan | CRLD |
|---|----------|-------|------------|--|-----|------|

METHYLPHENIDATE HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL

METHYLPHENIDATE HCL

| | | | | | | | |
|-----|----|------|------|------------|--------------|-----|------|
| >D> | AB | ABLE | 20MG | N76032 001 | May 09, 2001 | May | DISC |
|-----|----|------|------|------------|--------------|-----|------|

| | | | | | | | |
|-----|--|---|------|------------|--------------|-----|------|
| >A> | | @ | 20MG | N76032 001 | May 09, 2001 | May | DISC |
|-----|--|---|------|------------|--------------|-----|------|

TABLET; ORAL

METHYLPHENIDATE HCL

| | | | | | | | |
|-----|----|------|-----|------------|--------------|-----|------|
| >D> | AB | ABLE | 5MG | N40404 001 | Mar 29, 2001 | May | DISC |
|-----|----|------|-----|------------|--------------|-----|------|

| | | | | | | | |
|-----|--|---|-----|------------|--------------|-----|------|
| >A> | | @ | 5MG | N40404 001 | Mar 29, 2001 | May | DISC |
|-----|--|---|-----|------------|--------------|-----|------|

| | | | | | | | |
|-----|----|--|------|------------|--------------|-----|------|
| >D> | AB | | 10MG | N40404 002 | Mar 29, 2001 | May | DISC |
|-----|----|--|------|------------|--------------|-----|------|

| | | | | | | | |
|-----|--|---|------|------------|--------------|-----|------|
| >A> | | @ | 10MG | N40404 002 | Mar 29, 2001 | May | DISC |
|-----|--|---|------|------------|--------------|-----|------|

| | | | | | | | |
|-----|----|--|------|------------|--------------|-----|------|
| >D> | AB | | 20MG | N40404 003 | Mar 29, 2001 | May | DISC |
|-----|----|--|------|------------|--------------|-----|------|

| | | | | | | | |
|-----|--|---|------|------------|--------------|-----|------|
| >A> | | @ | 20MG | N40404 003 | Mar 29, 2001 | May | DISC |
|-----|--|---|------|------------|--------------|-----|------|

METHYLPREDNISOLONE ACETATE

INJECTABLE; INJECTION

DEPO-MEDROL

| | | | | | | | |
|----|---|----------------------|---------|------------|--|-----|------|
| AB | + | PHARMACIA AND UPJOHN | 40MG/ML | N11757 001 | | Feb | CFTG |
|----|---|----------------------|---------|------------|--|-----|------|

| | | | | | | | |
|----|---|--|---------|------------|--|-----|------|
| AB | + | | 80MG/ML | N11757 004 | | Feb | CFTG |
|----|---|--|---------|------------|--|-----|------|

METHYLPREDNISOLONE ACETATE

| | | | | | | | |
|----|--|--------------|---------|------------|--------------|-----|------|
| AB | | SICOR PHARMS | 40MG/ML | N40557 001 | Feb 23, 2005 | Feb | NEWA |
|----|--|--------------|---------|------------|--------------|-----|------|

| | | | | | | | |
|----|--|--|---------|------------|--------------|-----|------|
| AB | | | 80MG/ML | N40557 002 | Feb 23, 2005 | Feb | NEWA |
|----|--|--|---------|------------|--------------|-----|------|

METOLAZONE

| | | | | | | | | |
|----|--------------|-------|--|------------|--|-----|------|--|
| | TABLET; ORAL | | | | | | | |
| | ZAROXOLYN | | | | | | | |
| AB | UCB | 2.5MG | | N17386 001 | | Mar | CAHN | |
| AB | + | 5MG | | N17386 002 | | Mar | CAHN | |
| AB | + | 10MG | | N17386 003 | | Mar | CAHN | |

METOPROLOL TARTRATE

| | | | | | | | | |
|----|---------------------|-------|--|------------|--------------|-----|------|--|
| | TABLET; ORAL | | | | | | | |
| | METOPROLOL TARTRATE | | | | | | | |
| AB | TEVA PHARMS | 50MG | | N74333 001 | Jan 27, 1994 | Mar | CAHN | |
| AB | | 100MG | | N74333 002 | Jan 27, 1994 | Mar | CAHN | |

METRONIDAZOLE

| | | | | | | | | |
|-----|--------------------------------|---------------|---------------|------------|--------------|--------------|------|------|
| | CAPSULE; ORAL | | | | | | | |
| | METRONIDAZOLE | | | | | | | |
| >D> | AB | ABLE | 375MG | N76505 001 | Nov 13, 2003 | May | DISC | |
| >A> | | @ | 375MG | N76505 001 | Nov 13, 2003 | May | DISC | |
| | GEL; VAGINAL | | | | | | | |
| | METROGEL-VAGINAL | | | | | | | |
| >D> | + | 3M | 0.75% | N20208 001 | Aug 17, 1992 | May | CTEC | |
| >A> | BX | + | 0.75% | N20208 001 | Aug 17, 1992 | May | CTEC | |
| >A> | | METRONIDAZOLE | | | | | | |
| >A> | BX | TEVA PHARMS | 0.75% | N21806 001 | May 20, 2005 | May | NEWA | |
| | TABLET, EXTENDED RELEASE; ORAL | | | | | | | |
| | FLAGYL ER | | | | | | | |
| >D> | AB | + | GD SEARLE LLC | 750MG | N20868 001 | Nov 26, 1997 | May | CTEC |
| >A> | | + | | 750MG | N20868 001 | Nov 26, 1997 | May | CTEC |
| | METRONIDAZOLE | | | | | | | |
| >D> | AB | ABLE | 750MG | N76462 001 | Jun 25, 2003 | May | DISC | |
| >A> | | @ | 750MG | N76462 001 | Jun 25, 2003 | May | DISC | |
| | TABLET; ORAL | | | | | | | |
| | METRONIDAZOLE | | | | | | | |
| >D> | AB | ABLE | 250MG | N76519 001 | Jun 27, 2003 | May | DISC | |
| >A> | | @ | 250MG | N76519 001 | Jun 27, 2003 | May | DISC | |
| >D> | AB | | 500MG | N76519 002 | Jun 27, 2003 | May | DISC | |
| >A> | | @ | 500MG | N76519 002 | Jun 27, 2003 | May | DISC | |

MICAFUNGIN SODIUM

| | | | | | | | | |
|--|---------------------------|----------|-----------|------------|--------------|-----|------|--|
| | INJECTABLE; IV (INFUSION) | | | | | | | |
| | MYCAMINE | | | | | | | |
| | + | ASTELLAS | 50MG/VIAL | N21506 002 | Mar 16, 2005 | Mar | NEWA | |

MIDAZOLAM HYDROCHLORIDE

| | | | | | | | | |
|----|-----------------------|----------------|--|------------|--------------|-----|------|--|
| | INJECTABLE; INJECTION | | | | | | | |
| | MIDAZOLAM HCL | | | | | | | |
| AP | HOSPIRA | EQ 1MG BASE/ML | | N75293 001 | Jun 20, 2000 | Mar | CMFD | |
| AP | | EQ 5MG BASE/ML | | N75293 002 | Jun 20, 2000 | Mar | CMFD | |
| AP | INTL MEDICATED | EQ 1MG BASE/ML | | N76144 001 | Jan 26, 2005 | Jan | NEWA | |
| AP | | EQ 5MG BASE/ML | | N76144 002 | Jan 26, 2005 | Jan | NEWA | |
| | SYRUP; ORAL | | | | | | | |
| | MIDAZOLAM HCL | | | | | | | |
| AA | PADDOCK | EQ 2MG BASE/ML | | N76379 001 | May 02, 2005 | Apr | NEWA | |

MINOCYCLINE HYDROCHLORIDE

CAPSULE; ORAL

MINOCIN

| | | | | | | | |
|-----|----|-----------------------|--------------------|------------|--------------|-----|------|
| >D> | AB | WYETH PHARMS INC | EQ 75MG BASE | N50649 003 | Feb 12, 2001 | May | DISC |
| >A> | | @ | EQ 75MG BASE | N50649 003 | Feb 12, 2001 | May | DISC |
| >D> | | INJECTABLE; INJECTION | | | | | |
| >D> | | MINOCIN | | | | | |
| >D> | + | WYETH PHARMS INC | EQ 100MG BASE/VIAL | N50444 001 | | May | DISC |
| >A> | | @ | EQ 100MG BASE/VIAL | N50444 001 | | May | DISC |

MOMETASONE FUROATE

CREAM; TOPICAL

ELOCON

| | | | | | | | |
|----|---|--------------------|------|------------|--------------|-----|------|
| AB | + | SCHERING | 0.1% | N19625 001 | May 06, 1987 | Jan | CFTG |
| | | MOMETASONE FUROATE | | | | | |
| AB | | ALTANA | 0.1% | N76171 001 | Apr 08, 2005 | Mar | NEWA |
| AB | | TARO | 0.1% | N76679 001 | Dec 21, 2004 | Jan | NEWA |

LOTION; TOPICAL

ELOCON

| | | | | | | | |
|----|---|--------------------|------|------------|--------------|-----|------|
| AB | + | SCHERING | 0.1% | N19796 001 | Mar 30, 1989 | Mar | CFTG |
| | | MOMETASONE FUROATE | | | | | |
| AB | | AGIS INDS | 0.1% | N77180 001 | Apr 06, 2005 | Mar | NEWA |

OINTMENT; TOPICAL

MOMETASONE FUROATE

| | | | | | | | |
|----|--|--------|------|------------|--------------|-----|------|
| AB | | ALTANA | 0.1% | N77061 001 | Mar 28, 2005 | Mar | NEWA |
|----|--|--------|------|------------|--------------|-----|------|

POWDER; INHALATION

ASMANEX TWISTHALER

| | | | | | | | |
|---|--|----------|------------|------------|--------------|-----|------|
| + | | SCHERING | 0.22MG/INH | N21067 001 | Mar 30, 2005 | Mar | NEWA |
|---|--|----------|------------|------------|--------------|-----|------|

MOMETASONE FUROATE MONOHYDRATE

SPRAY, METERED; NASAL

NASONEX

| | | | | | | | |
|---|--|-----------------|----------------------|------------|--------------|-----|------|
| + | | SCHERING PLOUGH | EQ 0.05MG BASE/SPRAY | N20762 001 | Oct 01, 1997 | Apr | CAHN |
| + | | SHIRE | EQ 0.05MG BASE/SPRAY | N20762 001 | Oct 01, 1997 | Mar | CAHN |

MORPHINE SULFATE

CAPSULE, EXTENDED RELEASE; ORAL

AVINZA

| | | | | | | | |
|----|--|--------|------|------------|--------------|-----|------|
| BX | | LIGAND | 30MG | N21260 001 | Mar 20, 2002 | Mar | CRLD |
| BX | | | 60MG | N21260 002 | Mar 20, 2002 | Mar | CRLD |
| | | | 90MG | N21260 003 | Mar 20, 2002 | Mar | CRLD |

KADIAN

| | | | | | | | |
|----|--|--------------------|------|------------|--------------|-----|------|
| | | ALPHARMA US PHARMS | 20MG | N20616 001 | Jul 03, 1996 | Mar | CRLD |
| BX | | | 30MG | N20616 004 | Mar 09, 2001 | Mar | CRLD |
| | | | 50MG | N20616 002 | Jul 03, 1996 | Mar | CRLD |
| BX | | | 60MG | N20616 005 | Mar 09, 2001 | Mar | CRLD |

NADOLOL

TABLET; ORAL

NADOLOL

| | | | | | | | |
|----|--|-------------|-------|------------|--------------|-----|------|
| AB | | TEVA PHARMS | 80MG | N74368 001 | Aug 31, 1994 | Mar | CAHN |
| AB | | | 120MG | N74368 002 | Aug 31, 1994 | Mar | CAHN |
| AB | | | 160MG | N74368 003 | Aug 31, 1994 | Mar | CAHN |

NALOXONE HYDROCHLORIDE

INJECTABLE; INJECTION

NALOXONE HCL

| | | | | | | |
|----|---------|----------|------------|--------------|-----|------|
| AP | HOSPIRA | 0.4MG/ML | N70172 001 | Sep 24, 1986 | Mar | CMFD |
|----|---------|----------|------------|--------------|-----|------|

NAPROXEN

>A> TABLET, DELAYED RELEASE; ORAL

>A> NAPROXEN

| | | | | | | | |
|-----|----|------------|-------|------------|--------------|-----|------|
| >A> | AB | ALPHAPHARM | 375MG | N75390 001 | Apr 19, 2001 | May | CDFR |
|-----|----|------------|-------|------------|--------------|-----|------|

| | | | | | | | |
|-----|----|--|-------|------------|--------------|-----|------|
| >A> | AB | | 500MG | N75390 002 | Apr 19, 2001 | May | CDFR |
|-----|----|--|-------|------------|--------------|-----|------|

>D> TABLET, EXTENDED RELEASE; ORAL

>D> NAPROXEN

| | | | | | | | |
|-----|----|--------------|-------|------------|--------------|-----|------|
| >D> | AB | + ALPHAPHARM | 375MG | N75390 001 | Apr 19, 2001 | May | CDFR |
|-----|----|--------------|-------|------------|--------------|-----|------|

| | | | | | | | |
|-----|----|---|-------|------------|--------------|-----|------|
| >D> | AB | + | 500MG | N75390 002 | Apr 19, 2001 | May | CDFR |
|-----|----|---|-------|------------|--------------|-----|------|

TABLET; ORAL

NAPROXEN

| | | | | | | |
|----|-----------------|-------|------------|--------------|-----|------|
| AB | PERRIGO R AND D | 250MG | N77339 001 | Apr 27, 2005 | Apr | NEWA |
|----|-----------------|-------|------------|--------------|-----|------|

| | | | | | | |
|----|--|-------|------------|--------------|-----|------|
| AB | | 375MG | N77339 002 | Apr 27, 2005 | Apr | NEWA |
|----|--|-------|------------|--------------|-----|------|

| | | | | | | |
|----|--|-------|------------|--------------|-----|------|
| AB | | 500MG | N77339 003 | Apr 27, 2005 | Apr | NEWA |
|----|--|-------|------------|--------------|-----|------|

| | | | | | | |
|----|-------------|-------|------------|--------------|-----|------|
| AB | TEVA PHARMS | 250MG | N74207 001 | Dec 21, 1993 | Mar | CAHN |
|----|-------------|-------|------------|--------------|-----|------|

| | | | | | | |
|----|--|-------|------------|--------------|-----|------|
| AB | | 375MG | N74207 002 | Dec 21, 1993 | Mar | CAHN |
|----|--|-------|------------|--------------|-----|------|

| | | | | | | |
|----|--|-------|------------|--------------|-----|------|
| AB | | 500MG | N74207 003 | Dec 21, 1993 | Mar | CAHN |
|----|--|-------|------------|--------------|-----|------|

NAPROXEN SODIUM

TABLET; ORAL

NAPROXEN SODIUM

| | | | | | | | |
|-----|----|------|---------------|------------|--------------|-----|------|
| >D> | AB | ABLE | EQ 250MG BASE | N76544 001 | Aug 22, 2003 | May | DISC |
|-----|----|------|---------------|------------|--------------|-----|------|

| | | | | | | | |
|-----|--|---|---------------|------------|--------------|-----|------|
| >A> | | @ | EQ 250MG BASE | N76544 001 | Aug 22, 2003 | May | DISC |
|-----|--|---|---------------|------------|--------------|-----|------|

| | | | | | | | |
|-----|----|--|---------------|------------|--------------|-----|------|
| >D> | AB | | EQ 500MG BASE | N76544 002 | Aug 22, 2003 | May | DISC |
|-----|----|--|---------------|------------|--------------|-----|------|

| | | | | | | | |
|-----|--|---|---------------|------------|--------------|-----|------|
| >A> | | @ | EQ 500MG BASE | N76544 002 | Aug 22, 2003 | May | DISC |
|-----|--|---|---------------|------------|--------------|-----|------|

| | | | | | | |
|----|-------------|---------------|------------|--------------|-----|------|
| AB | TEVA PHARMS | EQ 250MG BASE | N74289 001 | Jan 27, 1994 | Mar | CAHN |
|----|-------------|---------------|------------|--------------|-----|------|

| | | | | | | |
|----|--|---------------|------------|--------------|-----|------|
| AB | | EQ 500MG BASE | N74289 002 | Jan 27, 1994 | Mar | CAHN |
|----|--|---------------|------------|--------------|-----|------|

NEFAZODONE HYDROCHLORIDE

TABLET; ORAL

NEFAZODONE HCL

| | | | | | | | |
|-----|----|------|-------|------------|--------------|-----|------|
| >D> | AB | TEVA | 250MG | N76037 005 | Sep 16, 2003 | May | CRLD |
|-----|----|------|-------|------------|--------------|-----|------|

| | | | | | | | |
|-----|----|---|-------|------------|--------------|-----|------|
| >A> | AB | + | 250MG | N76037 005 | Sep 16, 2003 | May | CRLD |
|-----|----|---|-------|------------|--------------|-----|------|

>D> SERZONE

| | | | | | | | |
|-----|----|----------------------|------|------------|--------------|-----|------|
| >D> | AB | BRISTOL MYERS SQUIBB | 50MG | N20152 001 | Dec 22, 1994 | May | DISC |
|-----|----|----------------------|------|------------|--------------|-----|------|

| | | | | | | | |
|-----|--|---|------|------------|--------------|-----|------|
| >A> | | @ | 50MG | N20152 001 | Dec 22, 1994 | May | DISC |
|-----|--|---|------|------------|--------------|-----|------|

| | | | | | | | |
|-----|----|--|-------|------------|--------------|-----|------|
| >D> | AB | | 100MG | N20152 002 | Dec 22, 1994 | May | DISC |
|-----|----|--|-------|------------|--------------|-----|------|

| | | | | | | | |
|-----|--|---|-------|------------|--------------|-----|------|
| >A> | | @ | 100MG | N20152 002 | Dec 22, 1994 | May | DISC |
|-----|--|---|-------|------------|--------------|-----|------|

| | | | | | | | |
|-----|----|--|-------|------------|--------------|-----|------|
| >D> | AB | | 150MG | N20152 003 | Dec 22, 1994 | May | DISC |
|-----|----|--|-------|------------|--------------|-----|------|

| | | | | | | | |
|-----|--|---|-------|------------|--------------|-----|------|
| >A> | | @ | 150MG | N20152 003 | Dec 22, 1994 | May | DISC |
|-----|--|---|-------|------------|--------------|-----|------|

| | | | | | | | |
|-----|----|--|-------|------------|--------------|-----|------|
| >D> | AB | | 200MG | N20152 004 | Dec 22, 1994 | May | DISC |
|-----|----|--|-------|------------|--------------|-----|------|

| | | | | | | | |
|-----|--|---|-------|------------|--------------|-----|------|
| >A> | | @ | 200MG | N20152 004 | Dec 22, 1994 | May | DISC |
|-----|--|---|-------|------------|--------------|-----|------|

| | | | | | | | |
|-----|----|---|-------|------------|--------------|-----|------|
| >D> | AB | + | 250MG | N20152 005 | Dec 22, 1994 | May | DISC |
|-----|----|---|-------|------------|--------------|-----|------|

| | | | | | | | |
|-----|--|---|-------|------------|--------------|-----|------|
| >A> | | @ | 250MG | N20152 005 | Dec 22, 1994 | May | DISC |
|-----|--|---|-------|------------|--------------|-----|------|

NESIRITIDE RECOMBINANT

FOR SOLUTION; INTRAVENOUS

NATRECOR

| | | | | | | |
|---|-------|------------|------------|--------------|-----|------|
| + | SCIOS | 1.5MG/VIAL | N20920 001 | Aug 10, 2001 | Apr | CAIN |
|---|-------|------------|------------|--------------|-----|------|

NIACIN

TABLET, EXTENDED RELEASE; ORAL

NIACIN

| | | | | | | |
|---------|-------|-------|------------|--------------|-----|------|
| AB | BARR | 500MG | N76378 001 | Apr 26, 2005 | Apr | NEWA |
| AB | | 750MG | N76378 002 | Apr 26, 2005 | Apr | NEWA |
| AB | | 1GM | N76250 001 | Apr 14, 2005 | Mar | NEWA |
| NIASPAN | | | | | | |
| AB | + KOS | 500MG | N20381 002 | Jul 28, 1997 | Apr | CFTG |
| AB | + | 750MG | N20381 003 | Jul 28, 1997 | Apr | CFTG |
| AB | + | 1GM | N20381 004 | Jul 28, 1997 | Mar | CFTG |

NICARDIPINE HYDROCHLORIDE

INJECTABLE; INJECTION

CARDENE

| | | | | | | |
|---|------------|----------|------------|--------------|-----|------|
| + | ESP PHARMA | 2.5MG/ML | N19734 001 | Jan 30, 1992 | Mar | CAHN |
|---|------------|----------|------------|--------------|-----|------|

NITROFURANTOIN; NITROFURANTOIN, MACROCRYSTALLINE

CAPSULE; ORAL

NITROFURANTOIN (MONOHYDRATE/MACROCRYSTALS)

| | | | | | | |
|----|---------|-----------|------------|--------------|-----|------|
| AB | EON | 75MG;25MG | N77066 001 | Apr 05, 2005 | Mar | NEWA |
| AB | RANBAXY | 75MG;25MG | N76951 001 | Mar 30, 2005 | Mar | NEWA |

NYSTATIN

POWDER; TOPICAL

NYSTATIN

| | | | | | | |
|----|--------------|------------------|------------|--------------|-----|------|
| AT | UPSHER SMITH | 100,000 UNITS/GM | N65183 001 | May 03, 2005 | Apr | NEWA |
|----|--------------|------------------|------------|--------------|-----|------|

OCTREOTIDE ACETATE

INJECTABLE; INJECTION

OCTREOTIDE ACETATE

| | | | | | | |
|--|------------|-------------------|------------|--------------|-----|------|
| AP | BEDFORD | EQ 0.2MG BASE/ML | N76330 001 | Apr 08, 2005 | Mar | NEWA |
| AP | | EQ 1MG BASE/ML | N76330 002 | Apr 08, 2005 | Mar | NEWA |
| OCTREOTIDE ACETATE (PRESERVATIVE FREE) | | | | | | |
| AP | BEDFORD | EQ 0.05MG BASE/ML | N76313 001 | Mar 28, 2005 | Mar | NEWA |
| AP | | EQ 0.1MG BASE/ML | N76313 003 | Mar 28, 2005 | Mar | NEWA |
| AP | | EQ 0.5MG BASE/ML | N76313 002 | Mar 28, 2005 | Mar | NEWA |
| SANDOSTATIN | | | | | | |
| AP | + NOVARTIS | EQ 0.05MG BASE/ML | N19667 001 | Oct 21, 1988 | Mar | CFTG |
| AP | + | EQ 0.1MG BASE/ML | N19667 002 | Oct 21, 1988 | Mar | CFTG |
| AP | + | EQ 0.2MG BASE/ML | N19667 004 | Jun 12, 1991 | Mar | CFTG |
| AP | + | EQ 0.5MG BASE/ML | N19667 003 | Oct 21, 1988 | Mar | CFTG |
| AP | + | EQ 1MG BASE/ML | N19667 005 | Jun 12, 1991 | Mar | CFTG |

OLSALAZINE SODIUM

CAPSULE; ORAL

DIPENTUM

| | | | | | | |
|---|-----|-------|------------|--------------|-----|------|
| + | UCB | 250MG | N19715 001 | Jul 31, 1990 | Mar | CAHN |
|---|-----|-------|------------|--------------|-----|------|

OMEPRAZOLE

CAPSULE, DELAYED REL PELLETS; ORAL

PRILOSEC

| | | | | | | |
|---|-------------|------|------------|--------------|-----|------|
| + | ASTRAZENECA | 40MG | N19810 002 | Jan 15, 1998 | Apr | CRLD |
| | | 40MG | N19810 002 | Jan 15, 1998 | Mar | CTEC |

OXALIPLATIN

INJECTABLE; IV (INFUSION)

ELOXATIN

| | | | | | | | |
|--|---|-------------------|---------------------|------------|--------------|-----|------|
| | + | SANOFI | 50MG/VIAL | N21492 001 | Aug 09, 2002 | Mar | CRLD |
| | + | SANOFI SYNTHELABO | 50MG/10ML (5MG/ML) | N21759 001 | Jan 31, 2005 | Jan | NEWA |
| | + | | 100MG/20ML (5MG/ML) | N21759 002 | Jan 31, 2005 | Jan | NEWA |

OXAZEPAM

CAPSULE; ORAL

OXAZEPAM

| | | | | | | | |
|----|---|----------------------|------|------------|--------------|-----|------|
| AB | + | IVAX PHARMS | 30MG | N70945 001 | Aug 03, 1987 | Apr | CRLD |
| | | SERAX | | | | | |
| | | @ ALPHARMA US PHARMS | 10MG | N15539 002 | | Apr | DISC |
| | | @ | 15MG | N15539 004 | | Apr | DISC |
| | | @ | 30MG | N15539 006 | | Apr | DISC |

OXYMORPHONE HYDROCHLORIDE

INJECTABLE; INJECTION

NUMORPHAN

| | | | | | | | |
|-----|---|---------------------|----------|------------|--|-----|------|
| >D> | + | ENDO PHARMS | 1.5MG/ML | N11707 001 | | May | DISC |
| >A> | | @ | 1.5MG/ML | N11707 001 | | May | DISC |
| >D> | | SUPPOSITORY; RECTAL | | | | | |
| >D> | | NUMORPHAN | | | | | |
| >D> | + | ENDO PHARMS | 5MG | N11738 004 | | May | DISC |
| >A> | | @ | 5MG | N11738 004 | | May | DISC |

PACLITAXEL

FOR SUSPENSION; IV (INFUSION)

ABRAXANE

| | | | | | | | |
|--|---|---------------|------------|------------|--------------|-----|------|
| | + | AM BIOSCIENCE | 100MG/VIAL | N21660 001 | Jan 07, 2005 | Jan | NEWA |
|--|---|---------------|------------|------------|--------------|-----|------|

PAMIDRONATE DISODIUM

INJECTABLE; INJECTION

PAMIDRONATE DISODIUM

| | | | | | | | |
|-----|----|------------------|-----------------------|------------|--------------|-----|------|
| >D> | AP | BEDFORD | 30MG /10ML(3MG/ML) | N21113 001 | Mar 04, 2002 | May | CRLD |
| >A> | AP | + | 30MG /10ML(3MG/ML) | N21113 001 | Mar 04, 2002 | May | CRLD |
| >D> | AP | MAYNE PHARMA USA | EQ 30MG /10ML(3MG/ML) | N75841 001 | Jun 27, 2002 | May | CRLD |
| >A> | AP | + | EQ 30MG /10ML(3MG/ML) | N75841 001 | Jun 27, 2002 | May | CRLD |
| >D> | AP | | EQ 60MG /10ML(6MG/ML) | N75841 002 | Jun 27, 2002 | May | CRLD |
| >A> | AP | + | EQ 60MG /10ML(6MG/ML) | N75841 002 | Jun 27, 2002 | May | CRLD |
| >D> | AP | | EQ 90MG /10ML(9MG/ML) | N75841 003 | Jun 27, 2002 | May | CRLD |
| >A> | AP | + | EQ 90MG /10ML(9MG/ML) | N75841 003 | Jun 27, 2002 | May | CRLD |

PARICALCITOL

| | | | | | | | |
|-----|--|---------------|------|------------|--------------|-----|------|
| >A> | | CAPSULE; ORAL | | | | | |
| >A> | | ZEMPLAR | | | | | |
| >A> | | ABBOTT | 1UGM | N21606 001 | May 26, 2005 | May | NEWA |
| >A> | | | 2UGM | N21606 002 | May 26, 2005 | May | NEWA |
| >A> | | + | 4UGM | N21606 003 | May 26, 2005 | May | NEWA |

PEMOLINE

TABLET, CHEWABLE; ORAL

PEMOLINE

| | | | | | | | |
|----|--|-------------|--------|------------|--------------|-----|------|
| AB | | TEVA PHARMS | 37.5MG | N75555 001 | Feb 18, 2000 | Mar | CAHN |
|----|--|-------------|--------|------------|--------------|-----|------|

TABLET; ORAL

PEMOLINE

| | | | | | | |
|----|-------------|---------|------------|--------------|-----|------|
| AB | TEVA PHARMS | 18.75MG | N75030 003 | Feb 22, 2000 | Mar | CAHN |
| AB | | 37.5MG | N75030 001 | Jan 29, 1999 | Mar | CAHN |
| AB | | 75MG | N75030 002 | Jan 29, 1999 | Mar | CAHN |

PENTOBARBITAL SODIUM

CAPSULE; ORAL

SODIUM PENTOBARBITAL

@ VALEANT PHARM INTL

100MG

N83264 001

Jan DISC

PHENDIMETRAZINE TARTRATE

TABLET; ORAL

BONTRIL PDM

| | | | | | | |
|----|--------------------------|------|------------|--------------|-----|------|
| AA | + VALEANT | 35MG | N85272 001 | | Feb | CRLD |
| | CAM-METRAZINE | | | | | |
| | @ ABC HOLDING | 35MG | N83922 001 | | Feb | DISC |
| | @ | 35MG | N85318 001 | | Feb | DISC |
| | @ | 35MG | N85320 001 | | Feb | DISC |
| | @ | 35MG | N85321 001 | | Feb | DISC |
| | @ | 35MG | N85511 001 | | Feb | DISC |
| | @ CAMALL | 35MG | N85756 001 | | Feb | DISC |
| | PHENDIMETRAZINE TARTRATE | | | | | |
| | @ ABC HOLDING | 35MG | N85761 001 | | Feb | DISC |
| | @ | 35MG | N85941 001 | Jun 27, 1983 | Feb | DISC |
| | @ EON | 35MG | N85830 001 | | Feb | DISC |
| | X-TROZINE | | | | | |
| | @ SHIRE RICHWOOD | 35MG | N86553 001 | | Feb | DISC |
| | @ | 35MG | N86554 001 | | Feb | DISC |

PHENTERMINE HYDROCHLORIDE

CAPSULE; ORAL

ONA-MAST

@ MAST MM

30MG

N86511 001

Feb DISC

@

30MG

N86516 001

Feb DISC

PHENTERMINE HCL

@ ABC HOLDING

18.75MG

N88576 001 May 23, 1984

Feb DISC

@

30MG

N85417 001

Feb DISC

@

30MG

N86732 002

Feb DISC

@

30MG

N87215 001

Feb DISC

@

37.5MG

N87915 001 Dec 22, 1983

Feb DISC

@

37.5MG

N87918 001 Dec 22, 1983

Feb DISC

@

37.5MG

N87930 001 Oct 14, 1983

Feb DISC

@

37.5MG

N88610 001 Jun 04, 1984

Feb DISC

@

37.5MG

N88611 001 Jun 04, 1984

Feb DISC

@

37.5MG

N88625 001 Aug 23, 1984

Feb DISC

| | | | | | | | |
|-----|----|----------|------|------------|--------------|-----|------|
| >D> | AA | ABLE | 15MG | N40497 001 | Mar 13, 2003 | May | DISC |
| >A> | | @ | 15MG | N40497 001 | Mar 13, 2003 | May | DISC |
| >D> | AA | | 30MG | N40403 001 | Aug 30, 2001 | May | DISC |
| >A> | | @ | 30MG | N40403 001 | Aug 30, 2001 | May | DISC |
| >D> | AA | | 30MG | N40427 001 | Aug 30, 2001 | May | DISC |
| >A> | | @ | 30MG | N40427 001 | Aug 30, 2001 | May | DISC |
| | | @ CAMALL | 15MG | N86735 001 | | Feb | DISC |
| | | @ | 30MG | N87226 001 | | Feb | DISC |

TABLET; ORAL

ONA MAST

@ MAST MM

8MG

N86260 001

Feb DISC

TABLET; ORAL

| | | | | | | | | |
|-----|----|-----------------|--------|--|--------|-----|--------------|----------|
| | | PHENTERMINE HCL | | | | | | |
| | | @ ABC HOLDING | 8MG | | N83923 | 001 | | Feb DISC |
| | | @ | 8MG | | N85319 | 001 | | Feb DISC |
| | | @ | 37.5MG | | N87805 | 001 | Dec 06, 1982 | Feb DISC |
| | | @ | 37.5MG | | N88596 | 001 | Apr 04, 1984 | Feb DISC |
| >D> | AA | ABLE | 37.5MG | | N40402 | 001 | Aug 30, 2001 | May DISC |
| >A> | | @ | 37.5MG | | N40402 | 001 | Aug 30, 2001 | May DISC |
| | AA | LANNETT | 37.5MG | | N40555 | 001 | Apr 15, 2005 | Mar NEWA |

PHENTERMINE RESIN COMPLEX

CAPSULE, EXTENDED RELEASE; ORAL

| | | | | | | | | |
|--|--|---------|--------------|--|--------|-----|--|----------|
| | | IONAMIN | | | | | | |
| | | UCB | EQ 15MG BASE | | N11613 | 004 | | Mar CAHN |
| | | + | EQ 30MG BASE | | N11613 | 002 | | Mar CAHN |

PHENYTOIN SODIUM

INJECTABLE; INJECTION

| | | | | | | | | |
|----|---|------------------|---------|--|--------|-----|--------------|----------|
| | | PHENYTOIN | | | | | | |
| AP | + | ELKINS SINN | 50MG/ML | | N84307 | 001 | | Mar CTEC |
| | | PHENYTOIN SODIUM | | | | | | |
| AP | | HOSPIRA | 50MG/ML | | N89521 | 001 | Mar 17, 1987 | Mar CMFD |
| AP | | | 50MG/ML | | N89744 | 001 | Dec 18, 1987 | Mar CMFD |

PIROXICAM

CAPSULE; ORAL

| | | | | | | | | |
|----|--|-------------|------|--|--------|-----|--------------|----------|
| | | PIROXICAM | | | | | | |
| AB | | TEVA PHARMS | 10MG | | N74103 | 001 | Aug 28, 1992 | Mar CAHN |
| AB | | | 20MG | | N74103 | 002 | Aug 28, 1992 | Mar CAHN |

POTASSIUM CHLORIDE

INJECTABLE; INJECTION

| | | | | | | | | |
|----|--|---|--------------|--|--------|-----|--------------|----------|
| | | POTASSIUM CHLORIDE 10MEQ IN PLASTIC CONTAINER | | | | | | |
| AP | | HOSPIRA | 14.9MG/ML | | N20161 | 005 | Nov 30, 1992 | Mar CMFD |
| AP | | | 745MG/100ML | | N20161 | 001 | Nov 30, 1992 | Mar CMFD |
| | | POTASSIUM CHLORIDE 20MEQ IN PLASTIC CONTAINER | | | | | | |
| AP | | HOSPIRA | 1.49GM/100ML | | N20161 | 002 | Nov 30, 1992 | Mar CMFD |

POTASSIUM CITRATE

TABLET, EXTENDED RELEASE; ORAL

| | | | | | | | | |
|--|--|----------------|-------|--|--------|-----|--------------|----------|
| | | UROCIT-K | | | | | | |
| | | MISSION PHARMA | 5MEQ | | N19071 | 001 | Aug 30, 1985 | Jan CTNA |
| | | + | 10MEQ | | N19071 | 002 | Aug 31, 1992 | Jan CTNA |

PRAMLINTIDE ACETATE

INJECTABLE; SUBCUTANEOUS

| | | | | | | | | |
|--|--|--------|--------|------------------------------------|--------|-----|--------------|----------|
| | | SYMLIN | | | | | | |
| | | + | AMYLIN | EQ 3MG BASE/5ML (EQ 0.6MG BASE/ML) | N21332 | 001 | Mar 16, 2005 | Mar NEWA |

PREDNISOLONE

SYRUP; ORAL

| | | | | | | | | |
|----|--|--------------|----------|--|--------|-----|--------------|----------|
| | | PREDNISOLONE | | | | | | |
| AA | | IVAX PHARMS | 15MG/5ML | | N40287 | 001 | May 28, 1999 | Jan CAHN |
| AA | | TEVA PHARMS | 15MG/5ML | | N40322 | 001 | Jan 19, 2000 | Mar CAHN |

PREDNISOLONE SODIUM PHOSPHATE

SOLUTION; ORAL

PEDIAPRED

AA + UCB EQ 5MG BASE/5ML N19157 001 May 28, 1986 Mar CAHN

PREDNISOLONE SODIUM PHOSPHATE

>A> AA KV PHARM EQ 5MG BASE/5ML N76982 001 May 24, 2005 May NEWA

>A> AA EQ 15MG BASE/5ML N76988 001 May 24, 2005 May NEWA

AA PHARM ASSOC EQ 15MG BASE/5ML N76913 001 Apr 25, 2005 Apr NEWA

PREDNISON

TABLET; ORAL

PREDNISON

>A> AB TRIGEN 1MG N40611 001 Jun 06, 2005 May NEWA

PRIMIDONE

TABLET; ORAL

MYSOLINE

AB + VALEANT 50MG N09170 003 Apr CAHN

AB 250MG N09170 002 Apr CAHN

PRIMIDONE

AB VINTAGE PHARMS 50MG N40586 001 Feb 24, 2005 Feb NEWA

AB 250MG N40586 002 Feb 24, 2005 Feb NEWA

PROCHLORPERAZINE

SUPPOSITORY; RECTAL

COMPAZINE

>D> AB GLAXOSMITHKLINE 2.5MG N11127 003 May CTEC

>A> 2.5MG N11127 003 May CTEC

>D> AB 5MG N11127 001 May CTEC

>A> 5MG N11127 001 May CTEC

PROCHLORPERAZINE

>D> AB ABLE 2.5MG N40407 001 Jul 11, 2001 May DISC

>A> @ 2.5MG N40407 001 Jul 11, 2001 May DISC

>D> AB 5MG N40407 002 Jul 11, 2001 May DISC

>A> @ 5MG N40407 002 Jul 11, 2001 May DISC

>D> AB 25MG N40407 003 Jul 11, 2001 May DISC

>A> @ 25MG N40407 003 Jul 11, 2001 May DISC

PROCHLORPERAZINE MALEATE

TABLET; ORAL

PROCHLORPERAZINE MALEATE

AB TEVA PHARMS EQ 5MG BASE N40120 001 Jul 11, 1996 Mar CAHN

AB EQ 10MG BASE N40120 002 Jul 11, 1996 Mar CAHN

PROGESTERONE

INJECTABLE; INJECTION

PROGESTERONE

AO + WATSON LABS (UTAH) 50MG/ML N17362 002 Feb CAHN

PROMETHAZINE HYDROCHLORIDE

SUPPOSITORY; RECTAL

PHENERGAN

>D> AB + WYETH PHARMS INC 50MG N11689 001 May CTEC

>A> + 50MG N11689 001 May CTEC

SUPPOSITORY; RECTALPROMETHAZINE HCL

| | | | | | | | |
|-----|----|------|--------|------------|--------------|-----|------|
| >D> | AB | ABLE | 12.5MG | N40504 001 | Apr 11, 2003 | May | DISC |
| >A> | | @ | 12.5MG | N40504 001 | Apr 11, 2003 | May | DISC |
| >D> | AB | | 25MG | N40504 002 | Apr 11, 2003 | May | DISC |
| >A> | | @ | 25MG | N40504 002 | Apr 11, 2003 | May | DISC |
| >D> | AB | | 50MG | N40449 001 | Feb 27, 2003 | May | DISC |
| >A> | | @ | 50MG | N40449 001 | Feb 27, 2003 | May | DISC |

TABLET; ORALPHENERGAN

| | | | | | | | |
|-----|----|------------------|------|------------|--|-----|------|
| >D> | AB | WYETH PHARMS INC | 25MG | N07935 003 | | May | CTEC |
| >A> | | | 25MG | N07935 003 | | May | CTEC |
| >D> | AB | + | 50MG | N07935 004 | | May | DISC |
| >A> | | @ | 50MG | N07935 004 | | May | DISC |

PROMETHAZINE HCL

| | | | | | | | |
|-----|----|------|--------|------------|--------------|-----|------|
| >D> | | ABLE | 12.5MG | N40558 001 | Jul 01, 2004 | May | DISC |
| >A> | | @ | 12.5MG | N40558 001 | Jul 01, 2004 | May | DISC |
| | | | 12.5MG | N40558 001 | Jul 01, 2004 | Jan | CTEC |
| >D> | AB | | 25MG | N40558 002 | Jul 01, 2004 | May | DISC |
| >A> | | @ | 25MG | N40558 002 | Jul 01, 2004 | May | DISC |
| >D> | AB | | 50MG | N40558 003 | Jul 01, 2004 | May | DISC |
| >A> | | @ | 50MG | N40558 003 | Jul 01, 2004 | May | DISC |

PROPOFOLINJECTABLE; INJECTIONPROPOFOL

| | | | | | | | |
|----|--|---------|---------|------------|--------------|-----|------|
| AB | | BEDFORD | 10MG/ML | N74848 001 | Apr 19, 2005 | Mar | NEWA |
|----|--|---------|---------|------------|--------------|-----|------|

PROPRANOLOL HYDROCHLORIDETABLET; ORALINDERAL

| | | | | | | | |
|----|--|------------------|------|------------|--|-----|------|
| AB | | WYETH PHARMS INC | 10MG | N16418 001 | | Apr | CRLD |
|----|--|------------------|------|------------|--|-----|------|

QUAZEPAMTABLET; ORALDORAL

| | | | | | | | |
|-----|--|---------------------|-------|------------|--------------|-----|------|
| >D> | | MEDPOINTE PHARM HLC | 7.5MG | N18708 003 | Feb 26, 1987 | May | DISC |
| >A> | | @ | 7.5MG | N18708 003 | Feb 26, 1987 | May | DISC |

QUINAPRIL HYDROCHLORIDETABLET; ORALQUINAPRIL HCL

| | | | | | | | |
|----|--|-----------|--------------|------------|--------------|-----|------|
| AB | | EON | EQ 5MG BASE | N76803 001 | Mar 02, 2005 | Feb | NEWA |
| AB | | | EQ 10MG BASE | N76803 002 | Mar 02, 2005 | Feb | NEWA |
| AB | | | EQ 20MG BASE | N76803 003 | Mar 02, 2005 | Feb | NEWA |
| AB | | | EQ 40MG BASE | N76803 004 | Mar 02, 2005 | Feb | NEWA |
| AB | | PAR PHARM | EQ 5MG BASE | N76036 001 | Jan 28, 2005 | Jan | NEWA |
| AB | | | EQ 10MG BASE | N76036 002 | Jan 28, 2005 | Jan | NEWA |
| AB | | | EQ 20MG BASE | N76036 003 | Jan 28, 2005 | Jan | NEWA |
| AB | | | EQ 40MG BASE | N76036 004 | Jan 28, 2005 | Jan | NEWA |

QUINIDINE SULFATETABLET, EXTENDED RELEASE; ORALQUINIDINE SULFATE

| | | | | | | | |
|---|--|-------------|-------|------------|--------------|-----|------|
| + | | TEVA PHARMS | 300MG | N40045 001 | Jun 30, 1994 | Mar | CAHN |
|---|--|-------------|-------|------------|--------------|-----|------|

RANITIDINE HYDROCHLORIDE

INJECTABLE; INJECTION
RANITIDINE HCL

AP BEN VENUE EQ 25MG BASE/ML N74777 001 Mar 02, 2005 Feb NEWA

RESERPINE; TRICHLORMETHIAZIDE

TABLET; ORAL
NAQUIVAL
@ SCHERING

0.1MG;4MG

N12265 003 Feb DISC

SIROLIMUS

TABLET; ORAL
RAPAMUNE

>D> WYETH PHARMS INC 2MG N21110 002 Aug 22, 2002 May CRLD
>A> + 2MG N21110 002 Aug 22, 2002 May CRLD
>D> + 5MG N21110 003 Feb 23, 2004 May DISC
>A> @ 5MG N21110 003 Feb 23, 2004 May DISC

SODIUM BENZOATE; SODIUM PHENYLACETATE

SOLUTION; IV (INFUSION)
AMMONUL

+ UCYCLYD 10%;10% (5GM/50ML;5GM/50ML)

N20645 001 Feb 17, 2005 Feb NEWA

SODIUM CHLORIDE

SOLUTION; IRRIGATION
SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER

AT HOSPIRA 450MG/100ML N18380 001 Mar CMFD

SOMATREM

INJECTABLE; INJECTION
PROTROPIN

@ GENENTECH 5MG/VIAL
@ 10MG/VIAL

N19107 001 Oct 17, 1985 Mar DISC
N19107 002 Oct 24, 1989 Mar DISC

SOMATROPIN RECOMBINANT

INJECTABLE; SUBCUTANEOUS
SEROSTIM LQ

SERONO 6MG/0.05VIAL

N20604 005 Feb 11, 2005 Feb NEWA

SUCCINYLCHOLINE CHLORIDE

INJECTABLE; INJECTION
ANECTINE

>D> + SABEX 2002 500MG/VIAL N08453 001 May DISC
>A> @ 500MG/VIAL N08453 001 May DISC
>D> + 1GM/VIAL N08453 004 May DISC
>A> @ 1GM/VIAL N08453 004 May DISC

SULFAMETHOXAZOLE; TRIMETHOPRIM

TABLET; ORAL
SULFAMETHOXAZOLE AND TRIMETHOPRIM

AB INTERPHARM 400MG;80MG N76899 001 Jan 27, 2005 Jan NEWA
AB 800MG;160MG N76899 002 Jan 27, 2005 Jan NEWA

TACROLIMUS

CAPSULE; ORAL

PROGRAF

| | | | | | | | |
|-----|---|-------------------|-------------|------------|--------------|-----|------|
| >D> | + | ASTELLAS | EQ 1MG BASE | N50708 001 | Apr 08, 1994 | May | CRLD |
| >A> | | | EQ 1MG BASE | N50708 001 | Apr 08, 1994 | May | CRLD |
| | + | FUJISAWA HLTHCARE | EQ 1MG BASE | N50708 001 | Apr 08, 1994 | Jan | CRLD |

TAMOXIFEN CITRATE

TABLET; ORAL

TAMOXIFEN CITRATE

| | | | | | | | |
|--|---|--------------|--------------|------------|--------------|-----|------|
| | @ | PHARMACHEMIE | EQ 10MG BASE | N74539 001 | Mar 31, 2003 | Feb | DISC |
|--|---|--------------|--------------|------------|--------------|-----|------|

TECHNETIUM TC-99M MEDRONATE KIT

INJECTABLE; INJECTION

OSTEOLITE

| | | | | | | | |
|-----|----|-----|-----|------------|--|-----|------|
| >D> | | | | | | | |
| >D> | AP | CIS | N/A | N17972 001 | | May | DISC |
| >A> | | @ | N/A | N17972 001 | | May | DISC |

TELITHROMYCIN

TABLET; ORAL

KETEK

| | | | | | | | |
|--|--|----------------|-------|------------|--------------|-----|------|
| | | AVENTIS PHARMS | 300MG | N21144 002 | Feb 09, 2005 | Feb | NEWA |
|--|--|----------------|-------|------------|--------------|-----|------|

TERBUTALINE SULFATE

TABLET; ORAL

TERBUTALINE SULFATE

| | | | | | | | |
|----|--|---------|-------|------------|--------------|-----|------|
| AB | | LANNETT | 2.5MG | N77152 001 | Mar 25, 2005 | Mar | NEWA |
| AB | | | 5MG | N77152 002 | Mar 25, 2005 | Mar | NEWA |

TERCONAZOLE

CREAM; VAGINAL

TERCONAZOLE

| | | | | | | | |
|----|--|--------|------|------------|--------------|-----|------|
| AB | | ALTANA | 0.4% | N76712 001 | Feb 18, 2005 | Jan | NEWA |
|----|--|--------|------|------------|--------------|-----|------|

TESTOSTERONE CYPIONATE

INJECTABLE; INJECTION

TESTOSTERONE CYPIONATE

| | | | | | | | |
|----|--|---------|----------|------------|--------------|-----|------|
| AO | | PADDOCK | 200MG/ML | N40530 001 | Jan 31, 2005 | Jan | NEWA |
|----|--|---------|----------|------------|--------------|-----|------|

TETRACYCLINE HYDROCHLORIDE

CAPSULE; ORAL

SUMYCIN

| | | | | | | | |
|--|---|-----------|-------|------------|--|-----|------|
| | @ | APOTHECON | 250MG | N60429 001 | | Mar | DISC |
|--|---|-----------|-------|------------|--|-----|------|

| | | | | | | | |
|--|---|--|-------|------------|--|-----|------|
| | @ | | 500MG | N60429 003 | | Mar | DISC |
|--|---|--|-------|------------|--|-----|------|

TETRACYCLINE HCL

| | | | | | | | |
|----|---|-------------|-------|------------|--|-----|------|
| AB | + | IVAX PHARMS | 500MG | N60704 002 | | Mar | CRLD |
| | @ | MAST MM | 250MG | N62085 001 | | Feb | DISC |

THEOPHYLLINE

CAPSULE, EXTENDED RELEASE; ORAL

THEOPHYLLINE

| | | | | | | | |
|--|--|-------------|-------|------------|--------------|-----|------|
| | | INWOOD LABS | 125MG | N40052 002 | Feb 14, 1994 | Apr | CTEC |
|--|--|-------------|-------|------------|--------------|-----|------|

TABLET, EXTENDED RELEASE; ORAL

THEOPHYLLINE

| | | | | | | | |
|-----|----|------|-------|------------|--------------|-----|------|
| >D> | AB | ABLE | 300MG | N40548 001 | Apr 30, 2004 | May | DISC |
|-----|----|------|-------|------------|--------------|-----|------|

TABLET, EXTENDED RELEASE; ORALTHEOPHYLLINE

| | | | | | | | |
|-----|----|--------|-------|------------|--------------|-----|------|
| >A> | | @ ABLE | 300MG | N40548 001 | Apr 30, 2004 | May | DISC |
| >D> | AB | | 400MG | N40543 001 | Apr 27, 2004 | May | DISC |
| >A> | | @ | 400MG | N40543 001 | Apr 27, 2004 | May | DISC |
| >D> | AB | | 450MG | N40546 001 | Apr 30, 2004 | May | DISC |
| >A> | | @ | 450MG | N40546 001 | Apr 30, 2004 | May | DISC |
| >D> | AB | | 600MG | N40539 001 | Apr 27, 2004 | May | DISC |
| >A> | | @ | 600MG | N40539 001 | Apr 27, 2004 | May | DISC |

UNIPHYL

| | | | | | | | | |
|-----|----|---|------------------|-------|------------|--------------|-----|------|
| >D> | AB | + | PURDUE FREDERICK | 400MG | N87571 001 | Sep 01, 1982 | May | CTEC |
| >A> | | + | | 400MG | N87571 001 | Sep 01, 1982 | May | CTEC |
| >D> | AB | + | | 600MG | N40086 001 | Apr 15, 1996 | May | CTEC |
| >A> | | + | | 600MG | N40086 001 | Apr 15, 1996 | May | CTEC |

THIORIDAZINE HYDROCHLORIDECONCENTRATE; ORALTHIORIDAZINE HCL

| | | | | | | | |
|----|---|-------------|----------|------------|--------------|-----|------|
| AA | + | TEVA PHARMS | 30MG/ML | N89602 001 | Nov 09, 1987 | Mar | CAHN |
| AA | + | | 100MG/ML | N89603 001 | Nov 09, 1987 | Mar | CAHN |

THIOTHIXENE HYDROCHLORIDECONCENTRATE; ORALTHIOTHIXENE HCL

| | | | | | | | |
|----|--|-------------|----------------|------------|--------------|-----|------|
| AA | | TEVA PHARMS | EQ 5MG BASE/ML | N71554 001 | Oct 16, 1987 | Mar | CAHN |
|----|--|-------------|----------------|------------|--------------|-----|------|

TOLTERODINE TARTRATECAPSULE, EXTENDED RELEASE; ORALDETROL LA

PHARMACIA AND UPJOHN 2MG

| | | | |
|------------|--------------|-----|------|
| N21228 001 | Dec 22, 2000 | Apr | CRLD |
|------------|--------------|-----|------|

TOREMIFENE CITRATETABLET; ORALFARESTON

+ GTX INC EQ 60MG BASE

| | | | |
|------------|--------------|-----|------|
| N20497 001 | May 29, 1997 | Jan | CAHN |
|------------|--------------|-----|------|

TORSEMIDETABLET; ORALTORSEMIDE

| | | | | | | | |
|-----|----|--------|-------|------------|--------------|-----|------|
| >A> | AB | APOTEX | 5MG | N76894 001 | May 31, 2005 | May | NEWA |
| >A> | AB | | 10MG | N76894 002 | May 31, 2005 | May | NEWA |
| >A> | AB | | 20MG | N76894 003 | May 31, 2005 | May | NEWA |
| >A> | AB | | 100MG | N76894 004 | May 31, 2005 | May | NEWA |
| | AB | ROXANE | 5MG | N76943 001 | Mar 01, 2005 | Feb | NEWA |
| | AB | | 10MG | N76943 002 | Mar 01, 2005 | Feb | NEWA |
| | AB | | 20MG | N76943 003 | Mar 01, 2005 | Feb | NEWA |

TRAMADOL HYDROCHLORIDE

| | | | | | | | |
|-----|--|-------------------------------------|--|--|--|--|--|
| >A> | | TABLET, ORALLY DISINTEGRATING; ORAL | | | | | |
|-----|--|-------------------------------------|--|--|--|--|--|

| | | | | | | | |
|-----|--|------------------------|--|--|--|--|--|
| >A> | | TRAMADOL HYDROCHLORIDE | | | | | |
|-----|--|------------------------|--|--|--|--|--|

| | | | | | | | |
|-----|---|---------|------|------------|--------------|-----|------|
| >A> | + | BIOVAIL | 50MG | N21693 001 | May 05, 2005 | May | NEWA |
|-----|---|---------|------|------------|--------------|-----|------|

TRETINOIN

| | | | | | | | |
|-----|--|---------------------------|--|--|--|--|--|
| >D> | | CREAM, AUGMENTED; TOPICAL | | | | | |
|-----|--|---------------------------|--|--|--|--|--|

| | | | | | | | |
|-----|--|--------|--|--|--|--|--|
| >D> | | RENOVA | | | | | |
|-----|--|--------|--|--|--|--|--|

| | | | | | | | |
|-----|---|---------------------|-------|------------|--------------|-----|------|
| >D> | + | JOHNSON AND JOHNSON | 0.05% | N19963 001 | Dec 29, 1995 | May | CDFR |
|-----|---|---------------------|-------|------------|--------------|-----|------|

| | | | | | | | | |
|-----------------------------------|---------------------------------|------------------|-----------------|--------|-----|--------------|-----|------|
| >A> | CREAM; TOPICAL | | | | | | | |
| >A> | RENOVA | | | | | | | |
| >A> | + JOHNSON AND JOHNSON | 0.05% | | N19963 | 001 | Dec 29, 1995 | May | CDFR |
| | SOLUTION; TOPICAL | | | | | | | |
| | TRETINOIN | | | | | | | |
| AT | TEVA PHARMS | 0.05% | | N74873 | 001 | Jun 19, 1998 | Mar | CAHN |
| <u>TRICHLORMETHIAZIDE</u> | | | | | | | | |
| | TABLET; ORAL | | | | | | | |
| | NAQUA | | | | | | | |
| | @ SCHERING | 2MG | | N12265 | 001 | | Feb | DISC |
| | @ | 4MG | | N12265 | 002 | | Feb | DISC |
| | TRICHLORMETHIAZIDE | | | | | | | |
| | @ ABC HOLDING | 4MG | | N85568 | 001 | | Feb | DISC |
| | @ PAR PHARM | 2MG | | N87007 | 001 | | Feb | DISC |
| | @ | 4MG | | N87005 | 001 | | Feb | DISC |
| <u>TRIMETHOPRIM HYDROCHLORIDE</u> | | | | | | | | |
| | SOLUTION; ORAL | | | | | | | |
| | PRIMSOL | | | | | | | |
| | @ TARO PHARMS NORTH | EQ 25MG BASE/5ML | | N74374 | 001 | Jun 23, 1995 | Jan | CAHN |
| | + | EQ 50MG BASE/5ML | | N74973 | 001 | Jan 24, 2000 | Jan | CAHN |
| <u>URSODIOL</u> | | | | | | | | |
| | CAPSULE; ORAL | | | | | | | |
| | URSODIOL | | | | | | | |
| AB | TEVA PHARMS | 300MG | | N75592 | 001 | May 25, 2000 | Mar | CAHN |
| <u>VALPROIC ACID</u> | | | | | | | | |
| | SYRUP; ORAL | | | | | | | |
| | VALPROIC ACID | | | | | | | |
| AA | TEVA PHARMS | 250MG/5ML | | N73178 | 001 | Aug 25, 1992 | Mar | CAHN |
| <u>VERAPAMIL HYDROCHLORIDE</u> | | | | | | | | |
| | CAPSULE, EXTENDED RELEASE; ORAL | | | | | | | |
| | VERELAN PM | | | | | | | |
| >A> | ELAN DRUG | 100MG | | N20943 | 001 | Nov 25, 1998 | May | CAHN |
| >A> | | 200MG | | N20943 | 002 | Nov 25, 1998 | May | CAHN |
| >A> | + | 300MG | | N20943 | 003 | Nov 25, 1998 | May | CAHN |
| >D> | ELAN PHARM | 100MG | | N20943 | 001 | Nov 25, 1998 | May | CAHN |
| | | 100MG | | N20943 | 001 | Nov 25, 1998 | Mar | CRLD |
| >D> | | 200MG | | N20943 | 002 | Nov 25, 1998 | May | CAHN |
| | | 200MG | | N20943 | 002 | Nov 25, 1998 | Mar | CRLD |
| >D> | + | 300MG | | N20943 | 003 | Nov 25, 1998 | May | CAHN |
| | INJECTABLE; INJECTION | | | | | | | |
| | VERAPAMIL HCL | | | | | | | |
| >D> | AP HOSPIRA | 2.5MG/ML | | N70739 | 001 | May 06, 1987 | May | DISC |
| >A> | @ | 2.5MG/ML | | N70739 | 001 | May 06, 1987 | May | DISC |
| >D> | AP | 2.5MG/ML | | N70740 | 001 | May 06, 1987 | May | DISC |
| >A> | @ | 2.5MG/ML | | N70740 | 001 | May 06, 1987 | May | DISC |
| <u>VINORELBINE TARTRATE</u> | | | | | | | | |
| | INJECTABLE; INJECTION | | | | | | | |
| | VINORELBINE TARTRATE | | | | | | | |
| AP | AM PHARM | EQ 10MG BASE/ML | | N76849 | 001 | Apr 18, 2005 | Mar | NEWA |
| >A> | AP | MAYNE PHARMA USA | EQ 10MG BASE/ML | N76827 | 001 | Jun 02, 2005 | May | NEWA |

ZIPRASIDONE HYDROCHLORIDE

CAPSULE; ORAL

GEODON

| | | | | | | | |
|-----|---|--------|--------------|------------|--------------|-----|------|
| >D> | + | PFIZER | 20MG | N20825 001 | Feb 05, 2001 | May | CPOT |
| >A> | + | | EQ 20MG BASE | N20825 001 | Feb 05, 2001 | May | CPOT |
| >D> | | | 40MG | N20825 002 | Feb 05, 2001 | May | CPOT |
| >A> | | | EQ 40MG BASE | N20825 002 | Feb 05, 2001 | May | CPOT |
| >D> | | | 60MG | N20825 003 | Feb 05, 2001 | May | CPOT |
| >A> | | | EQ 60MG BASE | N20825 003 | Feb 05, 2001 | May | CPOT |
| >D> | | | 80MG | N20825 004 | Feb 05, 2001 | May | CPOT |
| >A> | | | EQ 80MG BASE | N20825 004 | Feb 05, 2001 | May | CPOT |

PRESCRIPTION DRUG PRODUCT LIST - 25TH EDITION

OTC DRUG PRODUCT LIST - CUMULATIVE SUPPLEMENT 5 - May 2005

2-1

ASPIRIN

TABLET; ORAL

BAYER EXTRA STRENGTH ASPIRIN FOR MIGRAINE PAIN

BAYER 500MG N21317 001 Oct 18, 2001 Mar CMFD

BENTOQUATAM

LOTION; TOPICAL

IVY BLOCK

+ STAND HOMEOPATH 5% N20532 001 Aug 26, 1996 Apr CAHN

CHLORHEXIDINE GLUCONATE

CLOTH; TOPICAL

CHLORHEXIDINE GLUCONATE

+ SAGE PRODS 2% N21669 001 Apr 25, 2005 Apr NEWA

CHLORHEXIDINE GLUCONATE; ISOPROPYL ALCOHOL

SPONGE; TOPICAL

CHLORAPREP ONE-STEP FREPP

+ MEDI FLEX INC 2%;70% N20832 001 Jul 14, 2000 Apr CTNA

CHLORAPREP WITH TINT

+ MEDI FLEX INC 2%;70% N20832 002 May 03, 2005 Apr NEWA

CLOTRIMAZOLE

TABLET; VAGINAL

GYNIX

TEVA PHARMS 100MG N73249 001 Feb 13, 1998 Mar CAHN

DEXTROMETHORPHAN POLISTIREX

SUSPENSION, EXTENDED RELEASE; ORAL

DELSYM

+ UCB EQ 30MG HBR/5ML N18658 001 Oct 08, 1982 Apr CAHN

FAMOTIDINE

TABLET; ORAL

FAMOTIDINE

PERRIGO 10MG N75400 001 Mar 18, 2005 Mar NEWA

WOCKHARDT 10MG N77146 001 Mar 07, 2005 Feb NEWA

IBUPROFEN

CAPSULE; ORAL

IBUPROFEN

>D> BANNER PHARMACAPS 200MG N21472 001 Oct 18, 2002 May CRLD

>A> + 200MG N21472 001 Oct 18, 2002 May CRLD

TABLET; ORAL

IBUPROFEN

>A> PERRIGO R AND D 200MG N77349 001 Jun 21, 2005 May NEWA

LOPERAMIDE HYDROCHLORIDE

SOLUTION; ORAL

IMODIUM A-D

+ MCNEIL 1MG/7.5ML N19487 002 Jul 08, 2004 Apr NEWA

LORATADINE

SYRUP; ORAL

CLARITIN HIVES RELIEF

@ SCHERING

1MG/ML

N20641 003 Nov 19, 2003 Jan DISC

MICONAZOLE NITRATE

CREAM; VAGINAL

MICONAZOLE 3

TARO

4%

N76773 001 Mar 02, 2005 Feb NEWA

NICOTINE POLACRILEX

GUM, CHEWING; BUCCAL

NICOTINE POLACRILEX

@ WATSON LABS

EQ 2MG BASE

N76568 001 Jul 29, 2004 Apr DISC

@

EQ 4MG BASE

N76569 002 Jul 29, 2004 Apr DISC

NICOTINE POLACRILEX (MINT)

WATSON LABS

EQ 2MG BASE

N76569 001 Jul 29, 2004 Apr CTNA

EQ 4MG BASE

N76568 002 Jul 29, 2004 Apr CTNA

**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 2005

NO MAY 2005 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 2005 ADDITIONS

**PRESCRIPTION AND OTC DRUG PRODUCT
PATENT AND EXCLUSIVITY DATA**

See report footnote for information regarding report content

| APPL/PROD NO | PATENT NO | PATENT EXPIRATION DATE | PATENT CODES | EXCLUSIVITY CODE(S) | EXCLUSIVITY EXPIRATION DATE |
|---|-----------------|---------------------------|-----------------|------------------------|--|
| <u>ABACAVIR SULFATE; LAMIVUDINE; ZIDOVUDINE - TRIZIVIR</u> | | | | | |
| 021205 001 | >A> 4724232 | Sep 17, 2005 | | U-248 | |
| | >A> 4818538 | Sep 17, 2005 | DP | | |
| | >A> 4828838 | Sep 17, 2005 | DP | | |
| | >A> 4833130 | Sep 17, 2005 | | U-248 | |
| | >A> 4837208 | Sep 17, 2005 | | U-248 | |
| | >A> 5034394 | Jun 26, 2009 | DS DP | | |
| | >A> 5034394*PED | Dec 26, 2009 | | | |
| | >A> 5047407 | Nov 17, 2009 | DS DP | U-248 | |
| | >A> 5047407*PED | May 17, 2010 | | | |
| | >A> 5905082 | May 18, 2016 | DS DP | U-248 | |
| | >A> 5905082*PED | Nov 18, 2016 | | | |
| | >A> 6180639 | Jan 30, 2018 | | U-248 | |
| | >A> 6180639*PED | Jul 30, 2018 | | U-248 | |
| | >A> 6294540 | May 14, 2018 | DS DP | U-65 | |
| | >A> 6294540*PED | Nov 14, 2018 | | U-65 | |
| | >A> 6417191 | Mar 28, 2016 | DP | U-248 | |
| <u>ALBUTEROL SULFATE - ALBUTEROL SULFATE HFA</u> | | | | | |
| 021457 001 | 5605674 | Feb 25, 2014 | DP | | |
| | 5695743 | Jul 06, 2010 | DP | U-491 | |
| | 5766573 | Nov 28, 2009 | | U-356 | |
| | 6352684 | Nov 28, 2009 | DP | | |
| <u>ALENDRONATE SODIUM; CHOLECALCIFEROL - FOSAMAX PLUS D</u> | | | | | |
| 021762 001 | >A> 4621077 | Aug 06, 2007 | | U-648 | |
| | >A> 4621077*PED | Feb 06, 2008 | | | |
| | >A> 5358941 | Dec 02, 2012 | DP | | |
| | >A> 5358941*PED | Jun 02, 2013 | | | |
| | >A> 5681590 | Dec 02, 2012 | DP | | |
| | >A> 5681590*PED | Jun 02, 2013 | | | |
| | >A> 5994329 | Jul 17, 2018 | | U-647 | |
| | >A> 5994329*PED | Jan 17, 2019 | | | |
| | >A> 6090410 | Dec 02, 2012 | DP | | |
| | >A> 6090410*PED | Jun 02, 2013 | DP | | |
| <u>ALPRAZOLAM - NIRAVAM</u> | | | | | |
| 021726 001 | 6024981 | Apr 09, 2018 | DP | | |
| | 6221392 | Apr 09, 2018 | DP | | |
| <u>ALPRAZOLAM - NIRAVAM</u> | | | | | |
| 021726 002 | 6024981 | Apr 09, 2018 | DP | | |
| | 6221392 | Apr 09, 2018 | DP | | |
| <u>ALPRAZOLAM - NIRAVAM</u> | | | | | |
| 021726 003 | 6024981 | Apr 09, 2018 | DP | | |
| | 6221392 | Apr 09, 2018 | DP | | |
| <u>ALPRAZOLAM - NIRAVAM</u> | | | | | |
| 021726 004 | 6024981 | Apr 09, 2018 | DP | | |
| | 6221392 | Apr 09, 2018 | DP | | |
| <u>ALPRAZOLAM - XANAX</u> | | | | | |
| 018276 004 | >A> 5061494 | Dec 12, 2008 | | | |
| <u>ARIPIPIRAZOLE - ABILIFY</u> | | | | | |
| 021713 001 | | | | I-437 I-401 NCE | Sep 29, 2007 Aug 28, 2006 Nov 15, 2007 |
| <u>ARSENIC TRIOXIDE - TRISENOX</u> | | | | | |
| 021248 001 | 6855339 | Nov 10, 2018 | | U-617 | |
| | 6861076 | Nov 10, 2018 | | U-617 | |
| | >A> 6884439 | Nov 10, 2018 | | U-651 | |
| <u>ATOMOXETINE HYDROCHLORIDE - STRATTERA</u> | | | | | |
| 021411 007 | 5658590 | Jan 11, 2015 | | U-494 | |
| | 5658590*PED | Jul 11, 2015 | | NCE PED | Nov 26, 2007 May 26, 2008 |
| <u>ATOMOXETINE HYDROCHLORIDE - STRATTERA</u> | | | | | |
| 021411 008 | 5658590 | Jan 11, 2015 | | U-494 | |
| | 5658590*PED | Jul 11, 2015 | | NCE PED | Nov 26, 2007 May 26, 2008 |
| <u>BEXAROTENE - TARGRETIN</u> | | | | | |
| 021055 001 | 6043279 | Apr 22, 2012 | | U-509 | |
| | 6320074 | Apr 22, 2012 | DS | U-509 | |

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|---|-----------------|---------------------------|-----------------|------------------------|--------------------------------|
| <u>BEXAROTENE - TARGRETIN</u> | | | | | |
| 021056 001 | 6043279 | Apr 22, 2012 | | U-510 | |
| | 6320074 | Apr 22, 2012 | DS | U-510 | |
| <u>BORTEZOMIB - VELCADE</u> | | | | | |
| 021602 001 | | | | I-452 | Mar 25, 2008 |
| <u>BROMFENAC SODIUM - XIBROM</u> | | | | | |
| 021664 001 | | | | NP | Mar 24, 2008 |
| <u>BUDESONIDE - ENTOCORT EC</u> | | | | | |
| 021324 001 | >A> 6423340 | Nov 15, 2010 | | I-454 | Apr 29, 2008 |
| | >A> 6423340*PED | May 11, 2011 | | | |
| <u>CANDESARTAN CILEXETIL - ATACAND</u> | | | | | |
| 020838 001 | | | | >A> I-456 | May 18, 2008 |
| | | | | >A> I-455 | May 18, 2008 |
| | | | | I-448 | Feb 22, 2008 |
| <u>CANDESARTAN CILEXETIL - ATACAND</u> | | | | | |
| 020838 002 | | | | >A> I-456 | May 18, 2008 |
| | | | | >A> I-455 | May 18, 2008 |
| | | | | I-448 | Feb 22, 2008 |
| <u>CANDESARTAN CILEXETIL - ATACAND</u> | | | | | |
| 020838 003 | | | | >A> I-456 | May 18, 2008 |
| | | | | >A> I-455 | May 18, 2008 |
| | | | | I-448 | Feb 22, 2008 |
| <u>CANDESARTAN CILEXETIL - ATACAND</u> | | | | | |
| 020838 004 | | | | >A> I-456 | May 18, 2008 |
| | | | | >A> I-455 | May 18, 2008 |
| | | | | I-448 | Feb 22, 2008 |
| <u>CARBAMAZEPINE - CARBATROL</u> | | | | | |
| 020712 003 | 5326570 | Jul 05, 2011 | | U-215 | |
| | 5912013 | Jun 15, 2016 | | U-277 | |
| <u>CARBAMAZEPINE - EQUETRO</u> | | | | | |
| 021710 001 | 5326570 | Jul 23, 2011 | | U-627 | |
| | 5912013 | Jun 15, 2016 | DP | DP | |
| <u>CARBAMAZEPINE - EQUETRO</u> | | | | | |
| 021710 002 | 5326570 | Jul 23, 2011 | | U-627 | |
| | 5912013 | Jun 15, 2016 | DP | DP | |
| <u>CARBAMAZEPINE - EQUETRO</u> | | | | | |
| 021710 003 | 5326570 | Jul 23, 2011 | | U-627 | |
| | 5912013 | Jun 15, 2016 | DP | DP | |
| <u>CARBIDOPA; ENTACAPONE; LEVODOPA - STALEVO 100</u> | | | | | |
| 021485 002 | 5446194 | Oct 19, 2013 | DS | | |
| <u>CARBIDOPA; ENTACAPONE; LEVODOPA - STALEVO 150</u> | | | | | |
| 021485 003 | 5446194 | Oct 19, 2013 | DS | | |
| <u>CARBIDOPA; ENTACAPONE; LEVODOPA - STALEVO 50</u> | | | | | |
| 021485 001 | 5446194 | Oct 19, 2013 | DS | | |
| <u>CETRORELIX - CETROTIDE</u> | | | | | |
| 021197 001 | 6863891 | Feb 19, 2013 | | U-426 | |
| <u>CETRORELIX - CETROTIDE</u> | | | | | |
| 021197 002 | 6863891 | Feb 19, 2013 | | U-426 | |
| <u>CHLORHEXIDINE GLUCONATE - CHLORHEXIDINE GLUCONATE</u> | | | | | |
| 021669 001 | | | | >A> NDF | Apr 25, 2008 |
| <u>CHLORHEXIDINE GLUCONATE; ISOPROPYL ALCOHOL - CHLORAPREP ONE-STEP FREPP</u> | | | | | |
| 020832 001 | >A> 5538353 | Aug 25, 2015 | | DP | |
| | >A> 5690958 | Sep 30, 2016 | | DP | |
| | >A> 5752363 | Apr 22, 2017 | | DP | |
| | >A> 5772346 | Apr 22, 2017 | | DP | |
| | >A> 6536975 | Nov 10, 2020 | | DP | |
| | >A> D386849 | Nov 25, 2011 | | DP | |
| | >A> D396911 | Aug 11, 2012 | | DP | |

**PRESCRIPTION AND OTC DRUG PRODUCT
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|--|-------------|---------------------------|-----------------|------------------------|--------------------------------|
| <u>CHLORHEXIDINE GLUCONATE; ISOPROPYL ALCOHOL - CHLORAPREP WITH TINT</u> | | | | | |
| 020832 002 | >A> 5538353 | Aug 25, 2015 | DP | NP | May 03, 2008 |
| | >A> 5690958 | Sep 30, 2016 | DP | | |
| | >A> 6536975 | Nov 10, 2020 | DP | | |
| | >A> 6729786 | Mar 14, 2023 | DP | | |
| <u>CIPROFLOXACIN HYDROCHLORIDE - PROQUIN XR</u> | | | | | |
| 021744 001 | | | | >A> NDF | May 19, 2008 |
| <u>CIPROFLOXACIN HYDROCHLORIDE; HYDROCORTISONE - CIPRO HC</u> | | | | | |
| 020805 001 | 4844902 | Feb 11, 2008 | DP | | |
| | 5843930 | Jul 06, 2015 | | U-646 | |
| <u>CIPROFLOXACIN; CIPROFLOXACIN HYDROCHLORIDE - CIPRO XR</u> | | | | | |
| 021473 001 | | | | >A> NC >A> PED | Dec 13, 2005 Jun 13, 2006 |
| <u>CIPROFLOXACIN; CIPROFLOXACIN HYDROCHLORIDE - CIPRO XR</u> | | | | | |
| 021473 002 | | | | >A> NC >A> PED | Dec 13, 2005 Jun 13, 2006 |
| <u>CLOFARABINE - CLOLAR</u> | | | | | |
| 021673 001 | 4918179 | Jun 14, 2005 | DS | | |
| | 5384310 | May 23, 2009 | DS | DP | |
| | 5661136 | Aug 26, 2014 | | U-626 | |
| <u>COLESTIPOL HYDROCHLORIDE - COLESTID</u> | | | | | |
| 020222 001 | 5490987 | Feb 13, 2013 | | DP | |
| <u>DAPTOMYCIN - CUBICIN</u> | | | | | |
| 021572 001 | 6852689 | Sep 24, 2019 | | U-282 | |
| <u>DAPTOMYCIN - CUBICIN</u> | | | | | |
| 021572 002 | 6852689 | Sep 24, 2019 | | U-282 | |
| <u>DARIFENACIN HYDROBROMIDE - ENABLEX</u> | | | | | |
| 021513 001 | 5096890 | Mar 13, 2010 | DS | DP | U-631 |
| | 6106864 | Aug 21, 2016 | | DP | U-630 |
| <u>DARIFENACIN HYDROBROMIDE - ENABLEX</u> | | | | | |
| 021513 002 | 5096890 | Mar 13, 2010 | DS | DP | U-631 |
| | 6106864 | Aug 21, 2016 | | DP | U-630 |
| <u>DELAVIRDINE MESYLATE - RESCRIPTOR</u> | | | | | |
| 020705 002 | >A> 6177101 | Jun 07, 2019 | | | |
| <u>DESIRUDIN RECOMBINANT - IPRIVASK</u> | | | | | |
| 021271 001 | | | | NCE | Apr 04, 2008 |
| <u>DESLORATADINE - CLARINEX</u> | | | | | |
| 021165 001 | 4659716 | Apr 21, 2006 | | U-427 | |
| | 4659716*PED | Oct 21, 2006 | | U-427 | |
| <u>DESLORATADINE - CLARINEX</u> | | | | | |
| 021300 001 | 4659716 | Apr 21, 2006 | | DP | U-611 |
| | 4659716*PED | Oct 21, 2006 | | | |
| <u>DESLORATADINE - CLARINEX</u> | | | | | |
| 021312 001 | 4659716 | Apr 21, 2006 | | U-427 | |
| | 4659716*PED | Oct 21, 2006 | | U-427 | |
| <u>DESLORATADINE; PSEUDOEPHEDRINE SULFATE - CLARINEX D 24 HOUR</u> | | | | | |
| 021605 001 | 4659716 | Apr 21, 2006 | DP | U-644 | NCE |
| | 4659716*PED | Oct 21, 2006 | | | NC |
| | 6100274 | Jul 07, 2019 | DP | | PED |
| | 6100274*PED | Jan 07, 2020 | | | Jun 21, 2007 |
| <u>DEXRAZOXANE HYDROCHLORIDE - DEXRAZOXANE</u> | | | | | |
| 076068 001 | | | | PC | Aug 27, 2005 |
| <u>DEXRAZOXANE HYDROCHLORIDE - DEXRAZOXANE</u> | | | | | |
| 076068 002 | | | | PC | Oct 19, 2005 |
| <u>DEXTROMETHORPHAN POLISTIREX - DELSYM</u> | | | | | |
| 018658 001 | 5980882 | Apr 16, 2017 | | DP | |
| <u>DICLOFENAC SODIUM; MISOPROSTOL - ARTHROTEC</u> | | | | | |
| 020607 001 | >A> 5698225 | May 03, 2010 | | U-392 | |

**PRESCRIPTION AND OTC DRUG PRODUCT
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| APPL/PROD NO | PATENT NO | PATENT EXPIRATION DATE | PATENT CODES | EXCLUSIVITY CODE(S) | EXCLUSIVITY EXPIRATION DATE |
|---|-------------|---------------------------|-----------------|------------------------|--------------------------------|
| <u>DICLOFENAC SODIUM; MISOPROSTOL - ARTHROTEC</u> | | | | | |
| 020607 002 | >A> 5698225 | May 03, 2010 | U-392 | | |
| <u>DIVALPROEX SODIUM - DEPAKOTE ER</u> | | | | | |
| 021168 001 | 6720004 | Dec 18, 2018 | DP | | |
| <u>DIVALPROEX SODIUM - DEPAKOTE ER</u> | | | | | |
| 021168 002 | 6720004 | Dec 18, 2018 | DP | | |
| <u>DOFETILIDE - TIKOSYN</u> | | | | | |
| 020931 001 | >A> 4959366 | Sep 25, 2012 | DS DP | U-652 | |
| <u>DOFETILIDE - TIKOSYN</u> | | | | | |
| 020931 002 | >A> 4959366 | Sep 25, 2012 | DS DP | U-652 | |
| <u>DOFETILIDE - TIKOSYN</u> | | | | | |
| 020931 003 | >A> 4959366 | Sep 25, 2012 | DS DP | U-652 | |
| <u>DOXAZOSIN MESYLATE - CARDURA XL</u> | | | | | |
| 021269 001 | | | | NDF | Feb 22, 2008 |
| <u>DOXAZOSIN MESYLATE - CARDURA XL</u> | | | | | |
| 021269 002 | 4837111 | Mar 21, 2008 | DP | NDF | Feb 22, 2008 |
| <u>DOXERCALCIFEROL - HECTOROL</u> | | | | | |
| 020862 001 | >A> 6903083 | Jul 18, 2021 | DS DP | | |
| <u>DOXERCALCIFEROL - HECTOROL</u> | | | | | |
| 020862 002 | >A> 6903083 | Jul 18, 2021 | DS DP | | |
| <u>DOXERCALCIFEROL - HECTOROL</u> | | | | | |
| 021027 001 | >A> 6903083 | Jul 18, 2021 | DS DP | | |
| <u>ENOXAPARIN SODIUM - LOVENOX</u> | | | | | |
| 020164 001 | >A> RE38743 | Feb 14, 2012 | DS DP | U-545 | |
| <u>ENOXAPARIN SODIUM - LOVENOX</u> | | | | | |
| 020164 002 | >A> RE38743 | Feb 14, 2012 | DS DP | U-545 | |
| <u>ENOXAPARIN SODIUM - LOVENOX</u> | | | | | |
| 020164 003 | >A> RE38743 | Feb 14, 2012 | DS DP | U-545 | |
| <u>ENOXAPARIN SODIUM - LOVENOX</u> | | | | | |
| 020164 004 | >A> RE38743 | Feb 14, 2012 | DS DP | U-545 | |
| <u>ENOXAPARIN SODIUM - LOVENOX</u> | | | | | |
| 020164 005 | >A> RE38743 | Feb 14, 2012 | DS DP | U-545 | |
| <u>ENOXAPARIN SODIUM - LOVENOX</u> | | | | | |
| 020164 006 | >A> RE38743 | Feb 14, 2012 | DS DP | U-545 | |
| <u>ENOXAPARIN SODIUM - LOVENOX</u> | | | | | |
| 020164 007 | >A> RE38743 | Feb 14, 2012 | DS DP | U-545 | |
| <u>ENOXAPARIN SODIUM - LOVENOX</u> | | | | | |
| 020164 008 | >A> RE38743 | Feb 14, 2012 | DS DP | U-545 | |
| <u>ENOXAPARIN SODIUM - LOVENOX</u> | | | | | |
| 020164 009 | >A> RE38743 | Feb 14, 2012 | DS DP | U-545 | |
| <u>ENTACAPONE - COMTAN</u> | | | | | |
| 020796 001 | 5446194 | Oct 19, 2013 | DS | | |
| <u>ENTECAVIR - BARACLUDE</u> | | | | | |
| 021797 001 | 5206244 | Oct 18, 2010 | DS | NCE | Mar 29, 2010 |
| <u>ENTECAVIR - BARACLUDE</u> | | | | | |
| 021797 002 | 5206244 | Oct 18, 2010 | DS | NCE | Mar 29, 2010 |
| <u>ENTECAVIR - BARACLUDE</u> | | | | | |
| 021798 001 | 5206244 | Oct 18, 2010 | DS | NCE | Mar 29, 2010 |
| <u>EPINEPHRINE; LIDOCAINE HYDROCHLORIDE - LIDOSITE TOPICAL SYSTEM KIT</u> | | | | | |
| 021504 001 | 6862473 | Sep 30, 2013 | DP | | |
| <u>EPLERENONE - INSPRA</u> | | | | | |
| 021437 001 | 4559332 | Apr 09, 2006 | DS DP | U-537 | |
| <u>EPLERENONE - INSPRA</u> | | | | | |
| 021437 002 | 4559332 | Apr 09, 2006 | DS DP | U-537 | |
| <u>EPLERENONE - INSPRA</u> | | | | | |
| 021437 003 | 4559332 | Apr 09, 2006 | DS DP | U-537 | |

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| APPL/PROD NO | PATENT NO | PATENT EXPIRATION DATE | PATENT CODES | | | EXCLUSIVITY CODE(S) | EXCLUSIVITY EXPIRATION DATE |
|--|-------------|---------------------------|-----------------|----|-------|------------------------|--------------------------------|
| <u>ERTAPENEM SODIUM - INVANZ</u> | | | | | | | |
| 021337 001 | 5478820 | Feb 02, 2013 | | | | NCE | Nov 21, 2006 |
| | 5478820*PED | Aug 02, 2013 | | | | PED | May 21, 2007 |
| | 5652233 | Feb 02, 2013 | | | | | |
| | 5652233*PED | Aug 02, 2013 | | | | | |
| | 5952323 | May 15, 2017 | | | | | |
| | 5952323*PED | Nov 15, 2017 | | | | | |
| <u>ESMOLOL HYDROCHLORIDE - ESMOLOL HCL</u> | | | | | | | |
| 076323 001 | | | | | | PC | May 01, 2005 |
| <u>ESOMEPRAZOLE MAGNESIUM - NEXIUM</u> | | | | | | | |
| 021153 001 | 4738974 | Apr 19, 2006 | DS | DP | U-635 | | |
| | 4738974 | Apr 19, 2006 | DS | DP | U-373 | | |
| | 4738974*PED | Oct 19, 2006 | | | U-373 | | |
| | 6875872 | May 27, 2014 | DS | | | | |
| | 6875872*PED | Nov 27, 2014 | | | | | |
| <u>ESOMEPRAZOLE MAGNESIUM - NEXIUM</u> | | | | | | | |
| 021153 002 | 4738974 | Apr 19, 2006 | DS | DP | U-635 | | |
| | 4738974 | Apr 19, 2006 | DS | DP | U-373 | | |
| | 4738974*PED | Oct 19, 2006 | | | U-373 | | |
| | 6875872 | May 27, 2014 | DS | | | | |
| | 6875872*PED | Nov 27, 2014 | | | | | |
| <u>ESOMEPRAZOLE SODIUM - NEXIUM IV</u> | | | | | | | |
| 021689 001 | 5877192 | May 27, 2014 | | | U-643 | NE | Mar 31, 2008 |
| | 5877192*PED | Nov 27, 2014 | | | | | |
| | 6143771 | May 27, 2014 | | DP | U-643 | | |
| <u>ESOMEPRAZOLE SODIUM - NEXIUM IV</u> | | | | | | | |
| 021689 002 | 5877192 | May 27, 2014 | | | U-643 | NE | Mar 31, 2008 |
| | 5877192*PED | Nov 27, 2014 | | | | | |
| | 6143771 | May 27, 2014 | | DP | U-643 | | |
| <u>ESTROGENS, CONJUGATED SYNTHETIC B - ENJUVIA</u> | | | | | | | |
| 021443 001 | 6660726 | Mar 08, 2021 | DS | DP | U-284 | NP | Dec 20, 2007 |
| | 6660726 | Mar 08, 2021 | DS | DP | U-196 | | |
| | 6855703 | Feb 12, 2021 | DS | DP | U-284 | | |
| <u>ESTROGENS, CONJUGATED SYNTHETIC B - ENJUVIA</u> | | | | | | | |
| 021443 002 | 6660726 | Mar 08, 2021 | DS | DP | U-284 | NP | Dec 20, 2007 |
| | 6660726 | Mar 08, 2021 | DS | DP | U-196 | | |
| | 6855703 | Feb 12, 2021 | DS | DP | U-284 | | |
| <u>ESTROGENS, CONJUGATED SYNTHETIC B - ENJUVIA</u> | | | | | | | |
| 021443 003 | 6660726 | Mar 08, 2021 | DS | DP | U-284 | | |
| | 6660726 | Mar 08, 2021 | DS | DP | U-196 | | |
| | 6855703 | Feb 12, 2021 | DS | DP | U-284 | | |
| <u>ESTROGENS, CONJUGATED SYNTHETIC B - ENJUVIA</u> | | | | | | | |
| 021443 004 | 6660726 | Mar 08, 2021 | DS | DP | U-284 | | |
| | 6660726 | Mar 08, 2021 | DS | DP | U-196 | | |
| | 6855703 | Feb 12, 2021 | DS | DP | U-284 | | |
| <u>ESZOPICLONE - LUNESTA</u> | | | | | | | |
| 021476 001 | 6319926 | Jan 16, 2012 | | | U-620 | | |
| | 6444673 | Jan 16, 2012 | DS | DP | | | |
| | 6864257 | Aug 30, 2012 | | | U-629 | | |
| <u>ESZOPICLONE - LUNESTA</u> | | | | | | | |
| 021476 002 | 6319926 | Jan 16, 2012 | | | U-620 | | |
| | 6444673 | Jan 16, 2012 | DS | DP | | | |
| | 6864257 | Aug 30, 2012 | | | U-629 | | |
| <u>ESZOPICLONE - LUNESTA</u> | | | | | | | |
| 021476 003 | 6319926 | Jan 16, 2012 | | | U-620 | | |
| | 6444673 | Jan 16, 2012 | DS | DP | | | |
| | 6864257 | Aug 30, 2012 | | | U-629 | | |
| <u>ETHINYL ESTRADIOL; NORGESTIMATE - ORTHO CYCLEN-21</u> | | | | | | | |
| 019653 001 | | | | | | >A> M-41 | May 13, 2008 |
| | | | | | | >A> PED | Nov 13, 2008 |
| <u>ETHINYL ESTRADIOL; NORGESTIMATE - ORTHO CYCLEN-28</u> | | | | | | | |
| 019653 002 | | | | | | >A> M-41 | May 13, 2008 |
| | | | | | | >A> PED | Nov 13, 2008 |

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|--|-------------|---------------------------|-----------------|------------------------|--------------------------------|
| <u>ETHINYL ESTRADIOL; NORGESTIMATE - ORTHO TRI-CYCLEN</u> | | | | | |
| 019697 001 | | | | >A> M-41 >A> PED | May 13, 2008 Nov 13, 2008 |
| <u>ETHINYL ESTRADIOL; NORGESTIMATE - ORTHO TRI-CYCLEN</u> | | | | | |
| 019697 002 | | | | >A> M-41 >A> PED | May 13, 2008 Nov 13, 2008 |
| <u>EXEMESTANE - AROMASIN</u> | | | | | |
| 020753 001 | >A> 4808616 | Apr 01, 2011 | DS DP | U-658 | |
| <u>EXENATIDE SYNTHETIC - BYETTA</u> | | | | | |
| 021773 001 | >A> 5424286 | May 24, 2013 | | U-653 | NCE |
| | >A> 6858576 | Jan 06, 2017 | | U-656 | |
| | >A> 6872700 | Jan 14, 2020 | | U-654 | Apr 28, 2010 |
| <u>EXENATIDE SYNTHETIC - BYETTA</u> | | | | | |
| 021773 002 | >A> 5424286 | May 24, 2013 | | U-653 | NCE |
| | >A> 6858576 | Jan 06, 2017 | | U-656 | |
| | >A> 6872700 | Jan 14, 2020 | | U-654 | Apr 28, 2010 |
| <u>FAMOTIDINE - FLUXID</u> | | | | | |
| 021712 001 | 6024981 | Apr 09, 2018 | | DP | |
| | 6221392 | Apr 09, 2018 | | DP | |
| <u>FAMOTIDINE - FLUXID</u> | | | | | |
| 021712 002 | 6024981 | Apr 09, 2018 | | DP | |
| | 6221392 | Apr 09, 2018 | | DP | |
| <u>FENTANYL - DURAGESIC-12</u> | | | | | |
| 019813 005 | | | | NPP PED | May 20, 2006 Nov 20, 2006 |
| <u>FENTANYL CITRATE - ACTIQ</u> | | | | | |
| 020747 001 | 5785989 | May 01, 2005 | | | |
| <u>FENTANYL CITRATE - ACTIQ</u> | | | | | |
| 020747 002 | 5785989 | May 01, 2005 | | | |
| <u>FENTANYL CITRATE - ACTIQ</u> | | | | | |
| 020747 003 | 5785989 | May 01, 2005 | | | |
| <u>FENTANYL CITRATE - ACTIQ</u> | | | | | |
| 020747 004 | 5785989 | May 01, 2005 | | | |
| <u>FENTANYL CITRATE - ACTIQ</u> | | | | | |
| 020747 005 | 5785989 | May 01, 2005 | | | |
| <u>FENTANYL CITRATE - ACTIQ</u> | | | | | |
| 020747 006 | 5785989 | May 01, 2005 | | | |
| <u>FLUOCINOLONE ACETONIDE - RETISERT</u> | | | | | |
| 021737 001 | | | | NDF | Apr 08, 2008 |
| <u>FLUOCINONIDE - VANOS</u> | | | | | |
| 021758 001 | >A> 6765001 | Dec 21, 2021 | | DP | NP |
| <u>FLUTICASONE PROPIONATE - CUTIVATE</u> | | | | | |
| 021152 001 | | | | NDF PED | Mar 31, 2008 Sep 30, 2008 |
| <u>FLUTICASONE PROPIONATE; SALMETEROL XINAFOATE - ADVAIR DISKUS 100/50</u> | | | | | |
| 021077 001 | 6536427 | Mar 01, 2011 | | DP | |
| <u>FLUTICASONE PROPIONATE; SALMETEROL XINAFOATE - ADVAIR DISKUS 250/50</u> | | | | | |
| 021077 002 | 6536427 | Mar 01, 2011 | | DP | |
| <u>FLUTICASONE PROPIONATE; SALMETEROL XINAFOATE - ADVAIR DISKUS 500/50</u> | | | | | |
| 021077 003 | 6536427 | Mar 01, 2011 | | DP | |
| <u>FONDAPARINUX SODIUM - ARIXTRA</u> | | | | | |
| 021345 001 | | | | >A> I-457 | May 26, 2008 |
| <u>FONDAPARINUX SODIUM - ARIXTRA</u> | | | | | |
| 021345 002 | | | | >A> I-457 | May 26, 2008 |
| <u>FONDAPARINUX SODIUM - ARIXTRA</u> | | | | | |
| 021345 003 | | | | >A> I-457 | May 26, 2008 |
| <u>FONDAPARINUX SODIUM - ARIXTRA</u> | | | | | |
| 021345 004 | | | | >A> I-457 | May 26, 2008 |

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|--|-------------|---------------------------|-----------------|------------------------|--------------------------------|
| <u>GALANTAMINE HYDROBROMIDE - REMINYL</u> | | | | | |
| 021169 001 | 6358527 | Jun 06, 2017 | DP U-322 | | |
| <u>GALANTAMINE HYDROBROMIDE - REMINYL</u> | | | | | |
| 021169 002 | 6358527 | Jun 06, 2017 | DP U-322 | | |
| <u>GALANTAMINE HYDROBROMIDE - REMINYL</u> | | | | | |
| 021169 003 | 6358527 | Jun 06, 2017 | DP U-322 | | |
| <u>GALANTAMINE HYDROBROMIDE - REMINYL</u> | | | | | |
| 021615 001 | >A> 4663318 | Dec 14, 2008 | | U-322 | |
| <u>GALANTAMINE HYDROBROMIDE - REMINYL</u> | | | | | |
| 021615 002 | >A> 4663318 | Dec 14, 2008 | | U-322 | |
| <u>GALANTAMINE HYDROBROMIDE - REMINYL</u> | | | | | |
| 021615 003 | >A> 4663318 | Dec 14, 2008 | | U-322 | |
| <u>GEMCITABINE HYDROCHLORIDE - GEMZAR</u> | | | | | |
| 020509 001 | 4808614 | May 15, 2010 | DS | I-428 | May 19, 2007 |
| | 4808614*PED | Nov 15, 2010 | | M-40 | Apr 26, 2008 |
| | 5464826 | Nov 07, 2012 | | PED | Oct 26, 2008 |
| | 5464826*PED | May 07, 2013 | | PED | Nov 19, 2007 |
| <u>GEMCITABINE HYDROCHLORIDE - GEMZAR</u> | | | | | |
| 020509 002 | 4808614 | May 15, 2010 | DS | I-428 | May 19, 2007 |
| | 4808614*PED | Nov 15, 2010 | | M-40 | Apr 26, 2008 |
| | 5464826 | Nov 07, 2012 | | PED | Oct 26, 2008 |
| | 5464826*PED | May 07, 2013 | | PED | Nov 19, 2007 |
| <u>GLIPIZIDE - GLUCOTROL XL</u> | | | | | |
| 020329 001 | >A> 5545413 | Jul 02, 2008 | | U-111 | |
| <u>GLIPIZIDE - GLUCOTROL XL</u> | | | | | |
| 020329 002 | >A> 5545413 | Jul 02, 2008 | | U-111 | |
| <u>GLIPIZIDE - GLUCOTROL XL</u> | | | | | |
| 020329 003 | >A> 5545413 | Jul 02, 2008 | | U-111 | |
| <u>GLYBURIDE - GLYNASE</u> | | | | | |
| 020051 001 | >A> 4735805 | Mar 11, 2007 | | | |
| <u>GLYBURIDE - GLYNASE</u> | | | | | |
| 020051 002 | >A> 4735805 | Mar 11, 2007 | | | |
| <u>GLYBURIDE - GLYNASE</u> | | | | | |
| 020051 003 | >A> 4735805 | Mar 11, 2007 | | | |
| <u>GLYBURIDE - GLYNASE</u> | | | | | |
| 020051 004 | >A> 4735805 | Mar 11, 2007 | | | |
| <u>GRANISETRON HYDROCHLORIDE - KYTRIL</u> | | | | | |
| 020239 003 | 4886808 | Dec 29, 2007 | DS DP | U-89 | I-369 |
| <u>GRANISETRON HYDROCHLORIDE - KYTRIL</u> | | | | | |
| 020239 004 | | | | | I-369 |
| <u>HYDROCHLOROTHIAZIDE; IRBESARTAN - AVALIDE</u> | | | | | |
| 020758 004 | 5270317 | Sep 30, 2011 | DS DP | | |
| | 5270317*PED | Mar 30, 2012 | | | |
| | 5994348 | Jun 07, 2015 | | DP | |
| | 5994348*PED | Dec 07, 2015 | | | |
| <u>HYDROCHLOROTHIAZIDE; LOSARTAN POTASSIUM - HYZAAR</u> | | | | | |
| 020387 001 | 5138069 | Aug 11, 2009 | DS | | |
| | >A> 5153197 | Oct 06, 2009 | | DP U-3 | |
| | >A> 5153197 | Oct 06, 2009 | | DP U-538 | |
| <u>HYDROCHLOROTHIAZIDE; LOSARTAN POTASSIUM - HYZAAR</u> | | | | | |
| 020387 002 | 5138069 | Aug 11, 2009 | DS | | |
| | >A> 5153197 | Oct 06, 2009 | | DP U-3 | |
| | >A> 5153197 | Oct 06, 2009 | | DP U-538 | |
| <u>HYDROCHLOROTHIAZIDE; OLMESARTAN MEDOXOMIL - BENICAR HCT</u> | | | | | |
| 021532 002 | 6878703 | Nov 19, 2021 | | U-3 | |
| <u>HYDROCHLOROTHIAZIDE; OLMESARTAN MEDOXOMIL - BENICAR HCT</u> | | | | | |
| 021532 003 | 6878703 | Nov 19, 2021 | | U-3 | |
| <u>HYDROCHLOROTHIAZIDE; OLMESARTAN MEDOXOMIL - BENICAR HCT</u> | | | | | |
| 021532 005 | 6878703 | Nov 19, 2021 | | U-3 | |

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|---|-----------------|---------------------------|-----------------|------------------------|--------------------------------|
| <u>IBANDRONATE SODIUM - BONIVA</u> | | | | | |
| 021455 002 | 4927814 | Jul 09, 2007 | DS DP | U-642 | D-96 |
| | 6294196 | Oct 07, 2019 | DP | | NS |
| | | | | | NCE |
| | | | | | Mar 24, 2008 |
| | | | | | Mar 24, 2008 |
| | | | | | May 16, 2008 |
| <u>IMATINIB MESYLATE - GLEEVEC</u> | | | | | |
| 021335 001 | 5521184 | Jan 04, 2015 | | | |
| | >A> 6894051 | May 23, 2019 | DS DP | U-649 | |
| <u>IMATINIB MESYLATE - GLEEVEC</u> | | | | | |
| 021335 002 | 5521184 | Jan 04, 2015 | | | |
| | >A> 6894051 | May 23, 2019 | DS DP | U-649 | |
| <u>IMATINIB MESYLATE - GLEEVEC</u> | | | | | |
| 021588 001 | 5521184 | Jan 04, 2015 | | | |
| | >A> 6894051 | May 23, 2019 | DS DP | U-649 | |
| <u>IMATINIB MESYLATE - GLEEVEC</u> | | | | | |
| 021588 002 | 5521184 | Jan 04, 2015 | | | |
| | >A> 6894051 | May 23, 2019 | DS DP | U-649 | |
| <u>INSULIN ASPART PROTAMINE RECOMBINANT; INSULIN ASPART RECOMBINANT - NOVOLOG MIX 70/30</u> | | | | | |
| 021172 001 | >A> 5618913 | Apr 08, 2014 | | | |
| | >A> 5618913*PED | Oct 08, 2014 | | | |
| <u>INSULIN ASPART RECOMBINANT - NOVOLOG</u> | | | | | |
| 020986 001 | >A> 5618913 | Apr 08, 2014 | | | >A> NCE |
| | >A> 5618913*PED | Oct 08, 2014 | | | >A> PED |
| | >A> 5866538 | Jun 20, 2017 | | | |
| | >A> 5866538*PED | Dec 20, 2017 | | | |
| <u>ITRACONAZOLE - ITRACONAZOLE</u> | | | | | |
| 076104 001 | | | | PC | Aug 08, 2005 |
| <u>LANSOPRAZOLE - PREVACID</u> | | | | | |
| 021428 001 | >A> 6328994 | May 17, 2019 | | | |
| <u>LANSOPRAZOLE - PREVACID</u> | | | | | |
| 021428 002 | >A> 6328994 | May 17, 2019 | | | |
| <u>LETROZOLE - FEMARA</u> | | | | | |
| 020726 001 | | | | I-446 | Oct 29, 2007 |
| <u>LEUPROLIDE ACETATE - ELIGARD</u> | | | | | |
| 021731 001 | 4938763 | Oct 03, 2008 | DP | U-621 | |
| | 5278201 | Jan 11, 2011 | DP | | |
| | 5324519 | Jun 28, 2011 | DP | | |
| | 5599552 | Feb 04, 2014 | DP | U-621 | |
| | 5739176 | Oct 03, 2008 | DP | U-621 | |
| | 6395293 | Sep 28, 2013 | DP | | |
| | 6565874 | Oct 28, 2018 | DP | U-621 | |
| | 6626870 | Mar 27, 2020 | DP | | |
| | 6773714 | Oct 28, 2018 | | U-621 | |
| | RE37950 | Oct 03, 2008 | DP | U-621 | |
| <u>LEVALBUTEROL TARTRATE - XOPENEX HFA</u> | | | | | |
| 021730 001 | 5225183 | Jul 06, 2010 | DP | | NP |
| | 5362755 | Nov 08, 2011 | | U-636 | Mar 11, 2008 |
| | 5439670 | Jul 06, 2010 | DP | | |
| | 5547994 | Aug 20, 2013 | | U-636 | |
| | 5605674 | Feb 25, 2014 | DP | | |
| | 5695743 | Jul 06, 2010 | DP | U-636 | |
| | 5760090 | Jan 05, 2010 | | U-636 | |
| | 5836299 | Nov 17, 2017 | DP | | |
| | 5844002 | Jan 05, 2010 | | U-636 | |
| | 6083993 | Jan 05, 2010 | | U-636 | |
| | 6352684 | Nov 28, 2009 | DP | | |

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|--|-------------|---------------------------|-----------------|------------------------|--------------------------------|
| <u>LINEZOLID - ZYVOX</u> | | | | | |
| 021130 001 | 5688792 | Nov 18, 2014 | DS | U-319 | I-431 Jun 23, 2007 |
| | 5688792*PED | May 18, 2015 | | | I-402 Jul 22, 2006 |
| | 6514529 | Mar 15, 2021 | | DP | NPP Dec 19, 2005 |
| | 6514529*PED | Sep 15, 2021 | | | NCE Apr 18, 2005 |
| | 6559305 | Jan 29, 2021 | DS | | PED Dec 23, 2007 |
| | 6559305*PED | Jul 29, 2021 | | | PED Jan 22, 2007 |
| | | | | | PED Jun 19, 2006 |
| | | | | | PED Oct 18, 2005 |
| <u>LINEZOLID - ZYVOX</u> | | | | | |
| 021130 002 | 5688792 | Nov 18, 2014 | DS | U-319 | I-431 Jun 23, 2007 |
| | 5688792*PED | May 18, 2015 | | | I-402 Jul 22, 2006 |
| | 6514529 | Mar 15, 2021 | | DP | NPP Dec 19, 2005 |
| | 6514529*PED | Sep 15, 2021 | | | NCE Apr 18, 2005 |
| | 6559305 | Jan 29, 2021 | DS | | PED Dec 23, 2007 |
| | 6559305*PED | Jul 29, 2021 | | | PED Jan 22, 2007 |
| | | | | | PED Jun 19, 2006 |
| | | | | | PED Oct 18, 2005 |
| <u>LINEZOLID - ZYVOX</u> | | | | | |
| 021131 001 | 5688792 | Nov 18, 2014 | | U-319 | I-431 Jun 23, 2007 |
| | 5688792*PED | May 18, 2015 | | | I-402 Jul 22, 2006 |
| | 6559305 | Jan 29, 2021 | DS | | NPP Dec 19, 2005 |
| | 6559305*PED | Jul 29, 2021 | | | NCE Apr 18, 2005 |
| | | | | | PED Dec 23, 2007 |
| | | | | | PED Jan 22, 2007 |
| | | | | | PED Jun 19, 2006 |
| | | | | | PED Oct 18, 2005 |
| <u>LINEZOLID - ZYVOX</u> | | | | | |
| 021132 001 | 5688792 | Nov 18, 2014 | DS | U-319 | I-431 Jun 23, 2007 |
| | 5688792*PED | May 18, 2015 | | | I-402 Jul 22, 2006 |
| | 6559305 | Jan 29, 2021 | DS | | NPP Dec 19, 2005 |
| | 6559305*PED | Jul 29, 2021 | | | NCE Apr 18, 2005 |
| | | | | | PED Dec 23, 2007 |
| | | | | | PED Jan 22, 2007 |
| | | | | | PED Jun 19, 2006 |
| | | | | | PED Oct 18, 2005 |
| <u>LOPINAVIR; RITONAVIR - KALETRA</u> | | | | | |
| 021226 001 | | | | | >A> D-99 Apr 29, 2008 |
| <u>LOPINAVIR; RITONAVIR - KALETRA</u> | | | | | |
| 021251 001 | | | | | >A> D-99 Apr 29, 2008 |
| <u>LOVASTATIN - ALTOPREV</u> | | | | | |
| 021316 001 | 6485748 | Dec 12, 2017 | | DP | |
| <u>LOVASTATIN - ALTOPREV</u> | | | | | |
| 021316 002 | 6485748 | Dec 12, 2017 | | DP | |
| <u>LOVASTATIN - ALTOPREV</u> | | | | | |
| 021316 003 | 6485748 | Dec 12, 2017 | | DP | |
| <u>LOVASTATIN - ALTOPREV</u> | | | | | |
| 021316 004 | 6485748 | Dec 12, 2017 | | DP | |
| <u>MEDROXYPROGESTERONE ACETATE - DEPO-SUBQ PROVERA 104</u> | | | | | |
| 021583 001 | 6495534 | May 15, 2020 | | DP | I-451 Mar 25, 2008 |
| <u>MELOXICAM - MOBIC</u> | | | | | |
| 020938 001 | | | | | I-430 Jul 16, 2007 |
| | | | | | NCE Apr 13, 2005 |
| | | | | | PED Jan 16, 2008 |
| | | | | | PED Oct 13, 2005 |
| <u>MELOXICAM - MOBIC</u> | | | | | |
| 020938 002 | | | | | >A> I-430 Jul 16, 2007 |
| | | | | | >A> NCE Apr 13, 2005 |
| | | | | | >A> PED Jan 16, 2008 |
| | | | | | >A> PED Oct 13, 2005 |

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|---|-------------|---------------------------|-----------------|------------------------|--------------------------------|
| <u>MELOXICAM - MOBIC</u> | | | | | |
| 021530 001 | 6184220 | Mar 25, 2019 | DP | I-430 | Jul 16, 2007 |
| | 6184220*PED | Sep 25, 2019 | | NCE | Apr 13, 2005 |
| | | | | PED | Jan 16, 2008 |
| | | | | PED | Oct 13, 2005 |
| <u>MEMANTINE HYDROCHLORIDE - NAMENDA</u> | | | | | |
| 021627 001 | | | | >A> NCE | Oct 16, 2008 |
| <u>METFORMIN HYDROCHLORIDE - FORTAMET</u> | | | | | |
| 021574 001 | 6866866 | Mar 17, 2021 | DP | | |
| <u>METFORMIN HYDROCHLORIDE - FORTAMET</u> | | | | | |
| 021574 002 | 6866866 | Mar 17, 2021 | DP | | |
| <u>METFORMIN HYDROCHLORIDE - METFORMIN HCL</u> | | | | | |
| 076863 001 | | | | PC | Apr 12, 2005 |
| <u>METFORMIN HYDROCHLORIDE - RIOMET</u> | | | | | |
| 021591 001 | >A> 6890957 | Sep 14, 2023 | DP | | |
| <u>METHYLPHENIDATE HYDROCHLORIDE - RITALIN LA</u> | | | | | |
| 021284 001 | >A> 6228398 | Nov 01, 2019 | DP | U-472 | |
| <u>METHYLPHENIDATE HYDROCHLORIDE - RITALIN LA</u> | | | | | |
| 021284 002 | >A> 6228398 | Nov 01, 2019 | DP | U-472 | |
| <u>METHYLPHENIDATE HYDROCHLORIDE - RITALIN LA</u> | | | | | |
| 021284 003 | >A> 6228398 | Nov 01, 2019 | DP | U-472 | |
| <u>METHYLPHENIDATE HYDROCHLORIDE - RITALIN LA</u> | | | | | |
| 021284 004 | >A> 6228398 | Nov 01, 2019 | DP | | |
| <u>METOPROLOL SUCCINATE - TOPROL-XL</u> | | | | | |
| 019962 001 | 4927640 | May 22, 2007 | DP | D-95 | Feb 15, 2008 |
| | 4957745 | Sep 18, 2007 | DP | U-107 | |
| | 5001161 | Sep 18, 2007 | DP | | |
| | 5081154 | Sep 18, 2007 | DS | | |
| <u>METOPROLOL SUCCINATE - TOPROL-XL</u> | | | | | |
| 019962 002 | 4927640 | May 22, 2007 | DP | D-95 | Feb 15, 2008 |
| | 4957745 | Sep 18, 2007 | DP | U-107 | |
| | 5001161 | Sep 18, 2007 | DP | | |
| | 5081154 | Sep 18, 2007 | DS | | |
| <u>METOPROLOL SUCCINATE - TOPROL-XL</u> | | | | | |
| 019962 003 | 4927640 | May 22, 2007 | DP | D-95 | Feb 15, 2008 |
| | 4957745 | Sep 18, 2007 | DP | U-107 | |
| | 5001161 | Sep 18, 2007 | DP | | |
| | 5081154 | Sep 18, 2007 | DS | | |
| <u>METOPROLOL SUCCINATE - TOPROL-XL</u> | | | | | |
| 019962 004 | 4927640 | May 22, 2007 | DP | D-95 | Feb 15, 2008 |
| | 4957745 | Sep 18, 2007 | DP | U-107 | |
| | 5001161 | Sep 18, 2007 | DP | U-107 | |
| | 5081154 | Sep 18, 2007 | DS | U-107 | |
| <u>MICAFUNGIN SODIUM - MYCAMINE</u> | | | | | |
| 021506 002 | >A> 5376634 | Dec 27, 2011 | DS DP | NCE | Mar 16, 2010 |
| | >A> 6107458 | Sep 29, 2015 | DS DP | U-650 | |
| | >A> 6265536 | Sep 29, 2015 | DS DP | U-650 | |
| | >A> 6774104 | Jan 08, 2021 | DP | U-650 | |
| <u>MODAFINIL - PROVIGIL</u> | | | | | |
| 020717 001 | | | | I-449 | Jan 23, 2007 |
| <u>MODAFINIL - PROVIGIL</u> | | | | | |
| 020717 002 | | | | I-449 | Jan 23, 2007 |

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|--|-----------|---------------------------|-----------------|------------------------|--------------------------------|
| <u>MOMETASONE FUROATE - ASMANEX TWISTHALER</u> | | | | | |
| 021067 001 | 5394868 | Jun 25, 2012 | DP | NP | Mar 30, 2008 |
| | 5687710 | Nov 18, 2014 | DP | | |
| | 5829434 | Nov 03, 2015 | DP | | |
| | 5889015 | Jan 27, 2014 | | U-645 | |
| | 6057307 | Jan 27, 2014 | DP | U-645 | |
| | 6240918 | Feb 20, 2017 | DP | | |
| | 6365581 | Jan 27, 2014 | | U-645 | |
| | 6503537 | Mar 17, 2018 | DP | | |
| | 6677322 | Jan 27, 2014 | | U-645 | |
| <u>MOMETASONE FUROATE - MOMETASONE FUROATE</u> | | | | | |
| 077180 001 | | | | >A> PC | Nov 19, 2005 |
| <u>MOMETASONE FUROATE MONOHYDRATE - NASONEX</u> | | | | | |
| 020762 001 | 5837699 | Jan 27, 2014 | DP | U-625 | |
| | 6127353 | Oct 03, 2017 | DS DP | | |
| | 6723713 | Jan 27, 2014 | | U-625 | |
| <u>NATEGLINIDE - STARLIX</u> | | | | | |
| 021204 001 | 6844008 | Nov 14, 2017 | DP | U-214 | |
| | RE34878 | Sep 08, 2009 | | | |
| <u>NATEGLINIDE - STARLIX</u> | | | | | |
| 021204 002 | 6844008 | Nov 14, 2017 | DP | U-214 | |
| | RE34878 | Sep 08, 2009 | | | |
| <u>OCTREOTIDE ACETATE - OCTREOTIDE ACETATE (PRESERVATIVE FREE)</u> | | | | | |
| 076313 001 | | | | PC | Oct 02, 2005 |
| <u>OCTREOTIDE ACETATE - OCTREOTIDE ACETATE (PRESERVATIVE FREE)</u> | | | | | |
| 076313 002 | | | | PC | Oct 02, 2005 |
| <u>OCTREOTIDE ACETATE - OCTREOTIDE ACETATE (PRESERVATIVE FREE)</u> | | | | | |
| 076313 003 | | | | PC | Oct 02, 2005 |
| <u>OCTREOTIDE ACETATE - SANDOSTATIN</u> | | | | | |
| 019667 005 | 5753618 | Jul 08, 2008 | | | |
| <u>OLMESARTAN MEDOXOMIL - BENICAR</u> | | | | | |
| 021286 001 | 6878703 | Nov 19, 2021 | | U-3 | |
| <u>OLMESARTAN MEDOXOMIL - BENICAR</u> | | | | | |
| 021286 003 | 6878703 | Nov 19, 2021 | | U-3 | |
| <u>OLMESARTAN MEDOXOMIL - BENICAR</u> | | | | | |
| 021286 004 | 6878703 | Nov 19, 2021 | | U-3 | |
| <u>OMEPRAZOLE - ZEGERID</u> | | | | | |
| 021706 001 | 5840737 | Jul 16, 2016 | DS | U-624 | |
| | 5840737 | Jul 16, 2016 | DS | U-623 | |
| | 6489346 | Jul 16, 2016 | DS DP | U-624 | |
| | 6489346 | Jul 16, 2016 | DS DP | U-623 | |
| | 6645988 | Jul 16, 2016 | DS DP | | |
| | 6699885 | Jul 16, 2016 | | U-624 | |
| | 6699885 | Jul 16, 2016 | | U-623 | |
| | 6780882 | Jul 16, 2016 | DS DP | | |
| <u>ONDANSETRON HYDROCHLORIDE - ZOFTRAN</u> | | | | | |
| 020007 001 | | | | D-98 | Mar 25, 2008 |
| | | | | D-97 | Mar 25, 2008 |
| | | | | PED | Sep 25, 2008 |
| | | | | PED | Sep 25, 2008 |
| <u>ONDANSETRON HYDROCHLORIDE - ZOFTRAN PRESERVATIVE FREE</u> | | | | | |
| 020007 003 | | | | D-98 | Mar 25, 2008 |
| | | | | D-97 | Mar 25, 2008 |
| | | | | PED | Sep 25, 2008 |
| | | | | PED | Sep 25, 2008 |
| <u>OXALIPLATIN - ELOXATIN</u> | | | | | |
| 021759 001 | | | | I-441 | Nov 04, 2007 |
| | | | | NCE | Aug 09, 2007 |
| <u>OXALIPLATIN - ELOXATIN</u> | | | | | |
| 021759 002 | | | | I-441 | Nov 04, 2007 |
| | | | | NCE | Aug 09, 2007 |

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|-------------------------------------|-----------|---------------------------|-----------------|------------------------|--------------------------------|
| <u>OXCARBAZEPINE - TRILEPTAL</u> | | | | | |
| 021014 | 001 | | | NCE PED | Jan 14, 2005 Jul 14, 2005 |
| <u>OXCARBAZEPINE - TRILEPTAL</u> | | | | | |
| 021014 | 002 | | | NCE PED | Jan 14, 2005 Jul 14, 2005 |
| <u>OXCARBAZEPINE - TRILEPTAL</u> | | | | | |
| 021014 | 003 | | | NCE PED | Jan 14, 2005 Jul 14, 2005 |
| <u>OXCARBAZEPINE - TRILEPTAL</u> | | | | | |
| 021285 | 001 | | | NCE PED | Jan 14, 2005 Jul 14, 2005 |
| <u>PACLITAXEL - ABRAXANE</u> | | | | | |
| 021660 | 001 | 5439686 | Feb 22, 2013 | DP | NP Jan 07, 2008 |
| | | 5498421 | Mar 12, 2013 | DP U-634 | |
| | | 6096331 | Feb 22, 2013 | DP U-633 | |
| | | 6506405 | Feb 22, 2013 | DP U-633 | |
| | | 6537579 | Feb 22, 2013 | U-632 | |
| | | 6749868 | Feb 22, 2013 | DP | |
| | | 6753006 | Feb 22, 2013 | DP | |
| <u>PARICALCITOL - ZEMPLAR</u> | | | | | |
| 021606 | 001 | | | >A> NDF | May 26, 2008 |
| <u>PARICALCITOL - ZEMPLAR</u> | | | | | |
| 021606 | 002 | | | >A> NDF | May 26, 2008 |
| <u>PARICALCITOL - ZEMPLAR</u> | | | | | |
| 021606 | 003 | | | >A> NDF | May 26, 2008 |
| <u>PEGAPTANIB SODIUM - MACUGEN</u> | | | | | |
| 021756 | 001 | 5919455 | Oct 27, 2013 | DS | U-622 |
| | | 5932462 | Aug 03, 2016 | DS | |
| | | 6011020 | Jan 04, 2017 | DS | |
| | >A> | 6051698 | Oct 17, 2012 | DS | |
| | | 6113906 | Oct 27, 2013 | DS | |
| | | 6147204 | Jun 11, 2010 | DS | |
| | | 6426335 | Jun 11, 2010 | DS | |
| <u>PRAMLINTIDE ACETATE - SYMLIN</u> | | | | | |
| 021332 | 001 | 5175145 | Dec 29, 2009 | | NCE Mar 16, 2010 |
| | | 5686411 | Nov 11, 2014 | DS DP | |
| | | 5814600 | Sep 29, 2015 | | |
| | | 5998367 | Mar 08, 2011 | DS DP | |
| | | 6114304 | Sep 05, 2017 | | |
| | | 6410511 | Jan 09, 2018 | DP | |
| | | 6608029 | Sep 07, 2013 | | |
| | | 6610824 | Mar 08, 2011 | DS | |
| | | | | | |
| <u>PREGABALIN - LYRICA</u> | | | | | |
| 021446 | 001 | 6001876 | Jul 16, 2017 | | U-55 |
| | | 6197819 | Mar 06, 2018 | DS DP | |
| <u>PREGABALIN - LYRICA</u> | | | | | |
| 021446 | 002 | 6001876 | Jul 16, 2017 | | U-55 |
| | | 6197819 | Mar 06, 2018 | DS DP | |
| <u>PREGABALIN - LYRICA</u> | | | | | |
| 021446 | 003 | 6001876 | Jul 16, 2017 | | U-55 |
| | | 6197819 | Mar 06, 2018 | DS DP | |
| <u>PREGABALIN - LYRICA</u> | | | | | |
| 021446 | 004 | 6001876 | Jul 16, 2017 | | U-55 |
| | | 6197819 | Mar 06, 2018 | DS DP | |
| <u>PREGABALIN - LYRICA</u> | | | | | |
| 021446 | 005 | 6001876 | Jul 16, 2017 | | U-55 |
| | | 6197819 | Mar 06, 2018 | DS DP | |
| <u>PREGABALIN - LYRICA</u> | | | | | |
| 021446 | 006 | 6001876 | Jul 16, 2017 | | U-55 |
| | | 6197819 | Mar 06, 2018 | DS DP | |

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|--|-------------|---------------------------|-----------------|------------------------|--------------------------------|
| <u>PREGABALIN - LYRICA</u> | | | | | |
| 021446 007 | 6001876 | Jul 16, 2017 | | U-55 | |
| | 6197819 | Mar 06, 2018 | DS DP | | |
| <u>PREGABALIN - LYRICA</u> | | | | | |
| 021446 008 | 6001876 | Jul 16, 2017 | | U-55 | |
| | 6197819 | Mar 06, 2018 | DS DP | | |
| <u>RALOXIFENE HYDROCHLORIDE - EVISTA</u> | | | | | |
| 020815 001 | >A> 6894064 | Mar 10, 2017 | | DP U-657 | |
| <u>RIBAVIRIN - COPEGUS</u> | | | | | |
| 021511 001 | | | | I-447 | Feb 25, 2008 |
| <u>RISPERIDONE - RISPERDAL</u> | | | | | |
| 021444 004 | 4804663 | Dec 29, 2007 | DS DP | U-543 | |
| | 5648093 | Jul 15, 2014 | | DP | |
| | 6224905 | Jun 10, 2017 | | DP | |
| <u>RISPERIDONE - RISPERDAL</u> | | | | | |
| 021444 005 | 4804663 | Dec 29, 2007 | DS DP | U-543 | |
| | 5648093 | Jul 15, 2014 | | DP | |
| | 6224905 | Jun 10, 2017 | | DP | |
| <u>ROPINIROLE HYDROCHLORIDE - REQUIP</u> | | | | | |
| 020658 001 | >A> 4452808 | Dec 07, 2007 | DS DP | | |
| <u>ROPINIROLE HYDROCHLORIDE - REQUIP</u> | | | | | |
| 020658 002 | >A> 4452808 | Dec 07, 2007 | DS DP | | |
| <u>ROPINIROLE HYDROCHLORIDE - REQUIP</u> | | | | | |
| 020658 003 | >A> 4452808 | Dec 07, 2007 | DS DP | | |
| <u>ROPINIROLE HYDROCHLORIDE - REQUIP</u> | | | | | |
| 020658 004 | >A> 4452808 | Dec 07, 2007 | DS DP | | |
| <u>ROPINIROLE HYDROCHLORIDE - REQUIP</u> | | | | | |
| 020658 005 | >A> 4452808 | Dec 07, 2007 | DS DP | | |
| <u>ROPINIROLE HYDROCHLORIDE - REQUIP</u> | | | | | |
| 020658 006 | >A> 4452808 | Dec 07, 2007 | DS DP | | |
| <u>ROPINIROLE HYDROCHLORIDE - REQUIP</u> | | | | | |
| 020658 007 | >A> 4452808 | Dec 07, 2007 | DS DP | | |
| <u>ROSIGLITAZONE MALEATE - AVANDIA</u> | | | | | |
| 021071 002 | 5002953 | Aug 30, 2008 | DS DP | U-628 | I-453 Feb 28, 2008 |
| | 5002953 | Aug 30, 2008 | DS DP | U-329 | |
| | 5741803 | Apr 21, 2015 | DS DP | U-628 | |
| | 5741803 | Apr 21, 2015 | DS DP | U-329 | |
| <u>ROSIGLITAZONE MALEATE - AVANDIA</u> | | | | | |
| 021071 003 | 5002953 | Aug 30, 2008 | DS DP | U-628 | I-453 Feb 28, 2008 |
| | 5002953 | Aug 30, 2008 | DS DP | U-329 | |
| | 5741803 | Apr 21, 2015 | DS DP | U-628 | |
| | 5741803 | Apr 21, 2015 | DS DP | U-329 | |
| <u>ROSIGLITAZONE MALEATE - AVANDIA</u> | | | | | |
| 021071 004 | 5002953 | Aug 30, 2008 | DS DP | U-628 | I-453 Feb 28, 2008 |
| | 5002953 | Aug 30, 2008 | DS DP | U-329 | |
| | 5741803 | Apr 21, 2015 | DS DP | U-628 | |
| | 5741803 | Apr 21, 2015 | DS DP | U-329 | |
| <u>ROSUVASTATIN CALCIUM - CRESTOR</u> | | | | | |
| 021366 002 | 6858618 | Dec 17, 2021 | | U-618 | |
| <u>ROSUVASTATIN CALCIUM - CRESTOR</u> | | | | | |
| 021366 003 | 6858618 | Dec 17, 2021 | | U-618 | |
| <u>ROSUVASTATIN CALCIUM - CRESTOR</u> | | | | | |
| 021366 004 | 6858618 | Dec 17, 2021 | | U-618 | |
| <u>ROSUVASTATIN CALCIUM - CRESTOR</u> | | | | | |
| 021366 005 | 6858618 | Dec 17, 2021 | | U-618 | |
| <u>SIROLIMUS - RAPAMUNE</u> | | | | | |
| 021083 001 | 5536729 | Sep 30, 2013 | DP | NPP PED | Mar 11, 2008 Sep 11, 2008 |

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|--|-------------|---------------------------|-----------------|------------------------|--------------------------------|
| <u>SIROLIMUS - RAPAMUNE</u> | | | | | |
| 021110 001 | 5989591 | Mar 11, 2018 | DP | NPP PED | Mar 11, 2008 Sep 11, 2008 |
| <u>SIROLIMUS - RAPAMUNE</u> | | | | | |
| 021110 002 | 5989591 | Mar 11, 2018 | DP | NPP PED | Mar 11, 2008 Sep 11, 2008 |
| <u>SIROLIMUS - RAPAMUNE</u> | | | | | |
| 021110 003 | 5100899 | Jun 06, 2009 | | U-290 | Mar 11, 2008 |
| | 5100899*PED | Dec 06, 2009 | | | Sep 11, 2008 |
| | 5212155 | May 18, 2010 | | U-291 | |
| | 5212155*PED | Nov 18, 2010 | | | |
| | 5403833 | Apr 04, 2012 | | U-293 | |
| | 5403833*PED | Oct 04, 2012 | | | |
| | 5989591 | Mar 11, 2018 | DP | | |
| | 5989591*PED | Sep 11, 2018 | | | |
| <u>SODIUM BENZOATE; SODIUM PHENYLACETATE - AMMONUL</u> | | | | | |
| 020645 001 | | | | NDF ODE | Feb 17, 2008 Feb 17, 2012 |
| <u>SOMATROPIN RECOMBINANT - GENOTROPIN PRESERVATIVE FREE</u> | | | | | |
| 020280 001 | 4968299 | Jun 28, 2008 | DP | | |
| | 6152897 | Nov 20, 2018 | DP | | |
| <u>SOMATROPIN RECOMBINANT - GENOTROPIN PRESERVATIVE FREE</u> | | | | | |
| 020280 002 | 4968299 | Jun 28, 2008 | DP | | |
| | 6152897 | Nov 20, 2018 | DP | | |
| <u>SOMATROPIN RECOMBINANT - GENOTROPIN PRESERVATIVE FREE</u> | | | | | |
| 020280 003 | 4968299 | Jun 28, 2008 | DP | | |
| | 6152897 | Nov 20, 2018 | DP | | |
| <u>SOMATROPIN RECOMBINANT - GENOTROPIN PRESERVATIVE FREE</u> | | | | | |
| 020280 005 | 4968299 | Jun 28, 2008 | DP | | |
| | 6152897 | Nov 20, 2018 | DP | | |
| <u>SOMATROPIN RECOMBINANT - GENOTROPIN PRESERVATIVE FREE</u> | | | | | |
| 020280 008 | 4968299 | Jun 28, 2008 | DP | | |
| | 6152897 | Nov 20, 2018 | DP | | |
| <u>SOMATROPIN RECOMBINANT - GENOTROPIN PRESERVATIVE FREE</u> | | | | | |
| 020280 009 | 4968299 | Jun 28, 2008 | DP | | |
| | 6152897 | Nov 20, 2018 | DP | | |
| <u>SOMATROPIN RECOMBINANT - GENOTROPIN PRESERVATIVE FREE</u> | | | | | |
| 020280 010 | 4968299 | Jun 28, 2008 | DP | | |
| <u>SOMATROPIN RECOMBINANT - GENOTROPIN PRESERVATIVE FREE</u> | | | | | |
| 020280 011 | 4968299 | Jun 28, 2008 | DP | | |
| <u>SOMATROPIN RECOMBINANT - GENOTROPIN PRESERVATIVE FREE</u> | | | | | |
| 020280 012 | 4968299 | Jun 28, 2008 | DP | | |
| <u>SOMATROPIN RECOMBINANT - GENOTROPIN PRESERVATIVE FREE</u> | | | | | |
| 020280 013 | 4968299 | Jun 28, 2008 | DP | | |
| <u>TELITHROMYCIN - KETEK</u> | | | | | |
| 021144 002 | 5635485 | Apr 21, 2015 | DS DP | U-578 | NCE |
| | D459798 | Sep 24, 2015 | DP | | Apr 01, 2009 |
| <u>TEMOZOLOMIDE - TEMODAR</u> | | | | | |
| 021029 001 | 5260291 | Aug 11, 2013 | DS DP | U-619 | I-450 |
| | 5260291*PED | Feb 11, 2014 | | | ODE Mar 15, 2012 |
| <u>TEMOZOLOMIDE - TEMODAR</u> | | | | | |
| 021029 002 | 5260291 | Aug 11, 2013 | DS DP | U-619 | I-450 |
| | 5260291*PED | Feb 11, 2014 | | | ODE Mar 15, 2012 |
| <u>TEMOZOLOMIDE - TEMODAR</u> | | | | | |
| 021029 003 | 5260291 | Aug 11, 2013 | DS DP | U-619 | I-450 |
| | 5260291*PED | Feb 11, 2014 | | | ODE Mar 15, 2012 |
| <u>TEMOZOLOMIDE - TEMODAR</u> | | | | | |
| 021029 004 | 5260291 | Aug 11, 2013 | DS DP | U-619 | I-450 |
| | 5260291*PED | Feb 11, 2014 | | | ODE Mar 15, 2012 |

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|--------------------------------------|-----------|---------------------------|-----------------|------------------------|--------------------------------|
| <u>THALIDOMIDE - THALOMID</u> | | | | | |
| 020785 001 | 6869399 | Oct 23, 2020 | U-371 | | |
| <u>THALIDOMIDE - THALOMID</u> | | | | | |
| 020785 002 | 6869399 | Oct 23, 2020 | U-371 | | |
| <u>THALIDOMIDE - THALOMID</u> | | | | | |
| 020785 003 | 6869399 | Oct 23, 2020 | U-371 | | |
| <u>TOPIRAMATE - TOPAMAX</u> | | | | | |
| 020505 001 | | | | I-41 | Aug 11, 2007 |
| <u>TOPIRAMATE - TOPAMAX</u> | | | | | |
| 020505 002 | | | | I-41 | Aug 11, 2007 |
| <u>TOPIRAMATE - TOPAMAX</u> | | | | | |
| 020505 003 | | | | I-41 | Aug 11, 2007 |
| <u>TOPIRAMATE - TOPAMAX</u> | | | | | |
| 020505 004 | | | | I-41 | Aug 11, 2007 |
| <u>TOPIRAMATE - TOPAMAX</u> | | | | | |
| 020505 005 | | | | I-41 | Aug 11, 2007 |
| <u>TOPIRAMATE - TOPAMAX</u> | | | | | |
| 020505 006 | | | | I-41 | Aug 11, 2007 |
| <u>TOPIRAMATE - TOPAMAX SPRINKLE</u> | | | | | |
| 020844 001 | | | | I-41 | Aug 11, 2007 |
| <u>TOPIRAMATE - TOPAMAX SPRINKLE</u> | | | | | |
| 020844 002 | | | | I-41 | Aug 11, 2007 |
| <u>TOPIRAMATE - TOPAMAX SPRINKLE</u> | | | | | |
| 020844 003 | | | | I-41 | Aug 11, 2007 |
| <u>VORICONAZOLE - VFEND</u> | | | | | |
| 021266 001 | 5567817 | May 24, 2016 | DS DP | U-540 | |
| <u>VORICONAZOLE - VFEND</u> | | | | | |
| 021266 002 | 5567817 | May 24, 2016 | DS DP | U-540 | |
| <u>VORICONAZOLE - VFEND</u> | | | | | |
| 021267 001 | 5567817 | May 24, 2016 | DS DP | U-540 | |
| <u>VORICONAZOLE - VFEND</u> | | | | | |
| 021630 001 | 5567817 | May 24, 2016 | DS DP | U-540 | |
| <u>ZICONOTIDE - PRIALT</u> | | | | | |
| 021060 001 | 5364842 | Dec 30, 2011 | | U-55 | |
| | 5364842 | Dec 30, 2011 | | U-48 | |
| | 5795864 | Jun 27, 2015 | DP | | |
| | 5859186 | Dec 30, 2011 | | U-55 | |
| | 5859186 | Dec 30, 2011 | | U-48 | |
| <u>ZICONOTIDE - PRIALT</u> | | | | | |
| 021060 002 | 5364842 | Dec 30, 2011 | | U-55 | |
| | 5364842 | Dec 30, 2011 | | U-48 | |
| | 5795864 | Jun 27, 2015 | DP | | |
| | 5859186 | Dec 30, 2011 | | U-55 | |
| | 5859186 | Dec 30, 2011 | | U-48 | |
| <u>ZICONOTIDE - PRIALT</u> | | | | | |
| 021060 003 | 5364842 | Dec 30, 2011 | | U-55 | |
| | 5364842 | Dec 30, 2011 | | U-48 | |
| | 5795864 | Jun 27, 2015 | DP | | |
| | 5859186 | Dec 30, 2011 | | U-55 | |
| | 5859186 | Dec 30, 2011 | | U-48 | |
| <u>ZICONOTIDE - PRIALT</u> | | | | | |
| 021060 004 | 5364842 | Dec 30, 2011 | | U-55 | |
| | 5364842 | Dec 30, 2011 | | U-48 | |
| | 5795864 | Jun 27, 2015 | DP | | |
| | 5859186 | Dec 30, 2011 | | U-55 | |
| | 5859186 | Dec 30, 2011 | | U-48 | |

PRESCRIPTION AND OTC DRUG PRODUCT PATENT AND EXCLUSIVITY DATA

See report footnote for information regarding report content

| APPL/PROD NO | PATENT NO | PATENT EXPIRATION DATE | PATENT CODES | EXCLUSIVITY CODE(S) | EXCLUSIVITY EXPIRATION DATE |
|-----------------|-----------|---------------------------|-----------------|------------------------|--------------------------------|
|-----------------|-----------|---------------------------|-----------------|------------------------|--------------------------------|

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 submitted on FDA Form 3542 and listed after August 18, 2003 will have one to three patent codes indicating specific patent claims as submitted by the sponsor:

DS = Drug Substance claim

DP = Drug Product claim

U and number = Method of Use claim (may be multiple). Specific Method of use claims are listed at <http://www.fda.gov/cder/orange/patex.htm>

3. 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.

4. *PED and PED represent pediatric exclusivity. Patents with pediatric exclusivity granted after August 18, 2003 will be indicated with *PED as was done prior to August 18, 2003. Patents with *PED added after August 18, 2003 will not contain any information relative to the patent itself other than the *PED extension. Information related specifically to the patent will be conveyed on the original patent only.

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, 25th 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>