MISSOURI BOARD OF PHARMACY
GENERIC NEGATIVE FORMULARY
VOLUME 19 NUMBER 1
June 2009

STATE OF MISSOURI

REVISED GENERIC DRUG FORMULARY

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GENERIC DRUG NEGATIVE FORMULARY

IMPORTANT INFORMATION

In certain instances, the same drug may be listed two or more times in order to identify drug manufacturers that are considered bioequivalent to each other within a specific group. When this occurs, each group will be noted as such with the number to note it as one of two or more groups of drug manufacturers. **While each manufacturer in a particular group is bioequivalent to the other manufacturers listed in a group, one group will not be considered bioequivalent to another group. Only manufacturers within the same group can be interchanged for drug substitution purposes.**

SYNOPSIS OF GENERIC SUBSTITUTION IN MISSOURI

Missouri law provides that all prescription forms have two signature lines at the bottom of the form. Under the line appearing in the lower left corner of the form shall appear the words **"Substitution Permitted"**. Under the line appearing in the lower right corner of the form shall appear the words, **"Dispense as Written"**. By signing the prescription form on the left, above the line marked **"Substitution Permitted"**, the prescriber allows the pharmacist to substitute a less expensive drug product in the place of the drug product prescribed, within the parameters of the Negative Formulary. No prescription that originates within the state of Missouri shall be valid unless it complies with this form and is signed by the prescriber on one of these lines. When an oral, facsimile, or electronic prescription is involved, specific instructions must be provided to and recorded by the pharmacist regarding permission to engage in substitution.

The use of the Negative Formulary is very simple. In general, when a compound is listed in the Negative Formulary, substitution is **prohibited.** However, in the case of certain compounds the names of specific manufacturers are listed immediately adjacent to those compounds. This indicates that although the compound listed is generally prohibited from substitution, the drug products available from the listed manufacturers are permitted for substitution.

Approved Prescription Drug Products

This term refers to currently marketed prescription drug products approved by FDA through new drug applications (NDAs) and abbreviated new drug applications (ANDAs) under the provisions of section 505, or in the case of antibiotics, through analogous

applications known as Forms 5 or 6 under section 507 of the Federal Food, Drug and Cosmetic Act (the Act). All drug products on the list have been fully reviewed and approved for safety and effectiveness by FDA. Also, the law permits drugs to be legally marketed without such fully approved applications under certain circumstances but the drugs so marketed do not appear on the list.
For more information regarding consideration by the N.F.R.C. or if you have questions about the formulation and utilization of the Negative Formulary, you may contact:

Missouri State Board of Pharmacy
P.O. Box 625
Jefferson City, MO 65102

MISSOURI LAW GOVERNING GENERIC DRUG SUBSTITUTION

338.056. Generic substitutions may be made, when, form required for prescription blanks - penalty.

1. Except as provided in subsection 2, the pharmacist filling prescription orders for drug products prescribed by trade or brand name may select another drug product with the same active chemical ingredients of the same strength, quantity and dosage form, and of the same generic drug type, as determined by the United States Adopted Names and accepted by the Federal Food and Drug Administration. Selection pursuant to this section is within the discretion of the pharmacist, except as provided in subsection 2. The pharmacist who selects the drug product to be dispensed pursuant to this section shall assume the same responsibility for selecting the dispensed drug product as would be incurred in filling a prescription for a drug product prescribed by generic name. The pharmacist shall not select a drug product pursuant to this section unless the product selected costs the patient less than the prescribed product.
2. A pharmacist who receives a prescription for a brand name drug may, unless requested otherwise by the purchaser, select a less expensive generically equivalent product under the following circumstances:
   (1) If a written prescription is involved, the prescription form used shall have two signature lines at opposite ends at the bottom of the form. Under the line at the right shall be clearly printed the words: "Dispense as Written". Under the line at the left side shall be clearly printed the words "Substitution Permitted". The prescriber shall communicate the instructions to the pharmacist by signing the appropriate line. No prescription shall be valid without the signature of the prescriber on one of these lines.
   (2) If an oral prescription is involved, the practitioner or the practitioner's agent, communicating the instructions to the pharmacist shall instruct the pharmacist as to whether or not a therapeutically equivalent generic drug may be substituted. The pharmacist shall note the instruction on the file copy of the prescription.

3. All prescriptions written in the state of Missouri by practitioners authorized to write prescriptions shall be on forms which comply with the section 2 hereof.
4. Notwithstanding the provisions of subsection 2 of this section to the contrary, a pharmacist may fill a prescription written by a practitioner licensed in a state other than Missouri according to the laws regarding generic substitution in such other state.
5. Violations of this section are infractions.

338.057. List of nonacceptable substitutions-preparation-publication. The department of economic development shall publish a list of drug products for which substitution as provided in section 338.056 shall not be permitted. The list of drug products to be included on this list shall be based upon a joint determination made by the department of health, the state board of registration for healing arts, and the state board of pharmacy. The Department of Economic Development shall publish the list no less often then semiannually, and shall publish amendments to the list as required.

338.196. Prescription by practitioner licensed in another state, may be filled, requirement. Notwithstanding the provisions of section 338.056 to the contrary, a pharmacist may fill a prescription
written by a practitioner licensed in a state other than Missouri according to the practitioner's direction as to generic substitution

SAMPLE PRESCRIPTION FORM

Date_____

For_____

Address_____

.....

SIG:

_____ _____

SUBSTITUTION PERMITTED **DISPENSE AS WRITTEN**

CODE OF STATE REGULATIONS

20 CSR 2220-3.011 GENERIC DRUG FORMULARY

PURPOSE: *The purpose of this rule is to comply with section 338.057 RSMo which directs the Department of Economic Development to publish a list of drug products*

for which substitution, by a pharmacist, shall not be permitted. Noting that there are a number of drug products within a specific drug product category that have been proved bioequivalent and bio-available to the Federal Food and Drug Administration, the Department of Economic Development has delineated within a particular drug product category those drugs that may be substituted. The list is dual in nature. There are certain drugs where substitution will not be permitted and there are certain drug products where qualified substitution will be allowed, again only if the drug manufacturer is specifically designated in the list.

(1) If a written prescription is involved, the prescription form used shall have two (2) signature lines at opposite ends at the bottom of the form. Under the line at the right side shall be clearly printed the words "Dispense as Written". Under the line at the left side shall be clearly printed the words "Substitution Permitted". The prescriber shall communicate the instructions to the pharmacist by signing the appropriate line. No prescription shall be valid without the signature of the prescriber on one of these lines.

(2) All pharmacists and dispensing physicians should be warned that any drug product not holding an approved New Drug Application or Abbreviated New Drug Application may not be used as a substitute in the state of Missouri without the dispenser assuming some personal liability.

(3) A pharmacist shall not substitute drug products that are rated as therapeutically inequivalent to other pharmaceutically equivalent products as listed in the latest edition or cumulative supplement of the "Approved Drug products with Therapeutic Equivalence Evaluations" published by the United States government, Department of Health and Human Services.

(4) Any drug that is manufactured by an innovator company under a supplement to their New Drug Application (NDA) for that specific drug may apply to the Missouri Board of Pharmacy for consideration as a drug that is generically equivalent to the innovator product. A written request for such consideration must be accompanied by an affidavit or other acceptable documentation from the Food and Drug Administration (FDA) attesting to the equivalency of the generic product to the innovator product. Once the Missouri Board of Pharmacy determines that the two (2) products are considered generically equivalent under state law, an appropriate notation will be made in the next revision of the Generic Drug Formulary.

Auth. Chapter 338.057, RSMo (Supp. 1986). For history of amendment, see Code of State Regulations. Amended: Filed April 17, 1989, effective September 1, 1990. Amended: Filed August 25, 1995, effective April 30, 1996. Moved to 20 CSR 2220-3.011, effective Aug. 28, 2006.

Any portions of the list that appear with a ~~strike-through~~ are considered deleted from the list.

Any portions of the list that appear in **bold type** are considered new editions to the list.

PRESCRIPTION DRUG PRODUCT LIST

ALBUTEROL SULFATE AEROSOL

BENZOYL PEROXIDE; CLINDAMYCIN PHOSPHATE; GEL TOPICAL 5%/EQ 1%

BUPROPRION HCL; TABLET, EXTENDED RELEASE 100MG; 150MG; 200MG (Group 1)
- Actavis
- GlaxoSmithKline (Wellbutrin SR)
- Impax
- Sandoz
- **Watson**

BUPROPRION HCL; TABLET, EXTENDED RELEASE 150MG (Group 2)
- Actavis
- GlaxoSmithKline (Zyban)
- Impax
- Sandoz
- **Watson**

BUPROPRION HCL; TABLET, EXTENDED RELEASE 150MG; **300mg** (Group 3)
- Actavis
- Anchen Pharms
- Impax Labs
- SmithKline Beecham (Wellbutrin XL)
- Watson Labs

~~BUPROPRION HCL; TABLET, EXTENDED RELEASE 300MG (Group 3)~~
- ~~Actavis~~
- ~~Anchen Pharms~~
- ~~Impax Pharms~~
- ~~SmithKline Beecham (Wellbutrin XL)~~
- ~~Watson Labs~~

~~CARBIDOPA; LEVODOPA, TABLET, EXTENDED RELEASE; 50MG; 200MG~~
- ~~Bristol Meyers Squibb~~
- ~~Impax~~
- ~~Mylan~~
- ~~Sun Pharm~~
- ~~Torpharm~~

CHLORPROMAZINE HCL; TABLET

CIPROFLOXACIN HCL; TALBET
Apotex
Aurobindo Pharma
Bayer Hlthcare
Carlsbad
Cobalt
Dr. Reddys Labs LTD
Genpharm
Hikma
Ivax Pharms
Mylan
Ranbaxy
Sandoz
Taro
~~Teva~~
~~Torpharm~~
Unique Pharm Labs

CLINDAMYCIN PHOSPHATE GEL; TOPICAL
Altana
Pharmacia and Upjohn

CLOBETASOLE PROPIONATE CREAM (Group 1)
Acatavis Mid Atlantic
Altana (Temovate)
Fougera
Healthpoint (Cormax)
Taro
Teva

CLOBETASOLE PROPIONATE CREAM (Group 2)
Altana (Temovate E)
Healthpoint (Embeline E)
Taro

COLCHICINE; PROBENECID
Concord
Watson

CYCLOSPORINE CAPSULE 25MG; 100MG (Group 1)
Abbott
Ivax
Novartis (Neoral)
Pliva
Sandoz

CYCLOSPORINE CAPSULE 25MG; 100MG (Group 2)
Novartis (Sandimmune)
Torpharm

CYCLOSPORINE CAPSULE 50MG
Abbott
Ivax

CYCLOSPORINE ORAL SOLUTION 100MG/ML (Group 1)
Abbott
Ivax
Novartis (Neoral)
Novex
Pliva

CYCLOSPORINE ORAL SOLUTION 100MG/ML (Group 2)
Morton Grove
Novartis (Sandimmune)

~~DEXAMETHASONE TABLET, 0.5 MG, 0.75 MG, 1.5 MG, 4 MG, 6 MG~~

DIFLORASONE DIACETATE CREAM; TOPICAL (Group 1)
Altana
Sanofi Aventis (Psorcon)
Taro

DIFLORASONE DIACETATE CREAM; TOPICAL (Group 2)

DILTIAZEM HCL CAPSULE, EXTENDED RELEASE (Group 2)
Andrx (does not include Cartia XT or Taztia XT)
Mylan
Torpharm (does not included DIlt-CD)
Watson (Dilacor XR)

DILTIAZEM HCL CAPSULE, EXTENDED RELEASE (Group 3)
Actavis Elizabeth
Andrx (Cartia XT) (does not include Taztia XT)
Apotex (Dilt-CD)
Biovail (Cardizem CD) (Brand name Tiazac not included as equivalent) (Cardizem CD 360mg not included as equivalent)
~~Torpharm (Dilt-CD)~~

DILTIAZEM HCL CAPSULE, EXTENDED RELEASE (Group 4)
Andrx (Taztia XT) (does not include Cartia XT)
Apotex (Diltzac)
Biovail (Tiazac) (Brand name Cardizem CD not included as equivalent)
KV Pharm

ESTRADIOL FILM, EXTENDED RELEASE, TRANSDERMAL 0.05MG and 0.1MG/24 HR (Group 1)
Novartis (Vivelle-Dot and Vivelle only)

ESTRADIOL FILM, EXTENDED RELEASE, TRANSDERMAL 0.025MG; 0.05 MG; 0.075MG AND 0.1MG/24 HR (Group 2)
Berlex (Climara)
Mylan

ETHINYL ESTRADIOL; LEVONORGESTREL, TABLET, 0.02mg; 0.1mg; ORAL-28 (Group 1)
- Duramed Pharm Barr (Aviane 28)
- Watson

ETHINYL ESTRADIOL; LEVONORGESTREL, TABLET, 0.02mg; 0.1mg; ORAL-28 (Group 2)
- Barr (Lessina 28)
- Bayer (Levlite)
- Watson

FENOFIBRATE, TABLET 160MG
- Impax
- Ranbaxy
- Teva

FLUCONAZOLE; TABLET
- Aurobindo Pharm
- Genpharm
- Glenmark Generics
- Ivax Pharms
- Mylan
- Pfizer
- Pliva
- Ranbaxy
- Sandoz
- Taro
- Teva
- Torpharm
- Unique Pharms Labs

FLUOCINONIDE CREAM; TOPICAL (Group 1)
- Actavis Mid Atlantic
- Fougera
- Medicis (Lidex)
- Taro
- Teva

FLUOCINONIDE CREAM TOPICAL (Group 2)
- Altana
- Medicis (Lidex E)
- Taro
- Teva

FLUOXETINE HCL CAPSULE 10MG; 20MG (Group 1)
Alembic
Alpharma
Aurobindo
Barr
Beijing Double Crane
Carlsbad
Dr Reddys
IVAX
Lilly (Prozac)
Mallinckrodt
Mylan
Pliva
~~Ranbaxy~~
Rx Elite
Sandoz
Teva
Wockhardt

FLUOXETINE HCL CAPSULE 10MG; 20MG (Group 2)
Lilly (Sarafem)
Mylan
Sandoz
Teva

GALLIUM CITRATE (GA-67)

GLYBURIDE TABLET 1.25MG; 2.5MG; 5MG
Aurobindo
Corepharma
~~Pharmacia and Upjohn~~
Teva

HYDROCORTISONE, TABLET, 20MG
Pharmacia and Upjohn
Stiefel
Vintage

HYDROCORTISONE ACETATE; PRAMOXINE HCL, AEROSOL; TOPICAL

~~IBUPROFEN, SUSPENSION, ORAL~~
~~Actavis Mid~~
~~McNeil Cons~~
~~Perrigo R and D~~

IRON DEXTRAN, INJECTION

LEUCOVORIN CALCIUM TABLET, 5 MG
Barr
Roxane

LEVONORGESTREL, IMPLANT; IMPLANTATION

LEVOTHYROXINE SODIUM, TABLET; ORAL (Group 1)
Abbott
King
Mylan
Stevens J (Unithroid)

LEVOTHYROXINE SODIUM, TABLET; ORAL (Group 2)
Abbott (Synthroid)
Alara
~~Genpharm~~
Merck KGAA
Mylan
Stevens J

LEVOTHYROXINE SODIUM, TABLET; ORAL (Group 3)
Alara
~~Genpharm~~
King (Levoxyl)
Merck KGAA
Mylan
Stevens J

LEVOTHYROXINE SODIUM, TABLET; ORAL (Group 4)
Lloyd (Levothroid)
Mylan

MEDROXPROGESTERONE ACETATE TABLET, 10 MG
Barr
Pharmacia and Upjohn

METFORMIN HCL , EXTENDED RELEASE 500MG
Actavis Elizabeth
Amneal Pharms NY
Apotex
Bristol Meyers
Cobalt
Impax
Ivax
Mylan
Neurosci
Nostrum
Ranbaxy
Sandoz
Sun Pharms (IN)
Teva
Watson
Zydus

METFORMIN HCL, EXTENDED RELEASE 1GM.

METHYLPHENIDATE HCL CAPSULE, EXTENDED RELEASE

METHYLTESTOSTERONE CAPSULE

METHYLTESTOSTERONE TABLET

METRONIDAZOLE GEL, VAGINAL
- Graceway
- Tolmar

MORPHINE SULFATE CAPSULE, EXTENDED RELEASE

MORPHINE SULFATE TABLET, EXTENDED RELEASE
- ~~AB Generics~~
- Endo Pharm
- KV Pharm
- Mallinckrodt
- Purdue Pharma
- Watson (100mg)

MUPIROCIN OINTMENT; TOPICAL
- Altana
- GlaxoSmithKline
- Perrigo New York (not Centany)
- Taro
- Teva

NEFAZODONE HCL, TABLET
- Ivax Pharms
- Ranbaxy
- Sandoz
- Teva

NIFEDIPINE, TABLET, EXTENDED RELEASE 30 MG (GROUP 1)
- Abrika
- Bayer (Adalat CC)
- Biovail
- Watson

NIFEDIPINE, TABLET, EXTENDED RELEASE 30 MG (GROUP 2)
- Biovail
- Mylan
- Osmotica
- Pfizer (Procardia XL)

NIFEDIPINE, TABLET, EXTENDED RELEASE 60MG (GROUP 1)
- Abrika
- Bayer (Adalat CC)
- Biovail
- Watson

NIFEDIPINE, TABLET, EXTENDED RELEASE 60MG (GROUP 2)
Biovail
Mylan
Osmotica
Pfizer (Procardia XL)

NIFEDIPINE, TABLET, EXTENDED RELEASE 90MG (GROUP 1)
Bayer (Adalat CC)
Biovail

NIFEDIPINE, TABLET, EXTENDED RELEASE 90MG (GROUP 2)
Mylan
Osmotica
Pfizer (Procardia XL)

NITROGLYCERIN FILM, EXTENDED RELEASE; TRANSDERMAL, 0.1mg; 0.2mg; 0.4mg; 0.6mg (Group I)
Graceway (Minitran)
Key (Nitro-Dur)
Kremers Urban
~~Mylan Technologies~~

NITROGLYCERIN FILM, EXTENDED RELEASE; TRANSDERMAL, 0.2mg; 0.4mg; 0.6mg (Group 2)
Hercon
Mylan Technologies

NORETHINDRONE TABLET; ORAL 28 (Group 1)
Barr (Camila)
Watson Labs (Nor-QD)

NORETHINDRONE TABLET; ORAL 28 (Group 2)
Barr (Errin)
Ortho McNeil Janssen (Micronor)

PENICILLIN G BENZATHINE, INJECTION

PHENDIMETRAZINE TARTRATE, CAPSULE, EXTENDED RELEASE

~~PHENYTOIN SODIUM CAPSULE, ORAL, PROMPT~~

PHYTONADIONE, INJECTABLE, INJECTION, 1MG/0.5ML

POTASSIUM CHLORIDE, TABLET, CONTROLLED RELEASE, 8MEQ
Alra
Copley Pharm
Upsher Smith

POTASSIUM CHLORIDE, TABLET, CONTROLLED RELEASE, 10 mEq
~~Andrx~~
~~Key~~
Schering
Upsher-Smith (Klor-Con M10 Only)
Watson

PROMETHAZINE HYDROCHLORIDE, - SUPPOSITORY, RECTAL, 25mg
G and W Labs
Paddock
Perrigo New York
Taro

PROPRANOLOL HYDROCHLORIDE, CAPSULE, EXTENDED RELEASE
Actavis
Mylan
Par
Upsher Smith
Wyeth

PROPYLTHIOURACIL

QUINIDINE GLUCONATE, TABLET, EXTENDED RELEASE, 324 MG

RESERPINE, TABLET

SILVER SULFADIAZINE CREAM, - TOPICAL
Dr Reddys (SSD only)
Kendall LP
King Pharms

SOMATROPIN RECOMBINANT INJECTION, 4mg/VIAL, 5mg/VIAL, 5.8mg/VIAL, 6mg/VIAL, 5mg/1.5ml, 10mg/1.5ml

SOTALOL HYDROCHLORIDE, TABLET, ALL STRENGTHS (GROUP 1)
Apotex
Berlex (Betapace only)
GenPharm
Impax
Mylan
Sandoz
Teva
Upsher Smith
Vintage

SOTALOL HYDROCHLORIDE, TABLET, 80MG; 120MG; 160MG (GROUP 2)
Amneal
Bayer (Betapace AF only)
Mylan
Teva
Torpharm

TECHNETIUM, TC-99M, ALBUMIN AGGREGATED KIT, - INJECTION

TERCONAZOL CREAM, VAGINAL, 0.8%
Ortho McNeil Janssen
Taro

TESTOSTERONE GEL; TRANSDERMAL
~~Unimed~~
~~Watson~~

THEOPHYLLINE CAPSULE, CONTROLLED RELEASE

TIMOLOL MALEATE OPTHALMIC DROPS, 0.5%
Akorn
Bausch and Lomb
Falcon
FDC
Hi Tech
Merck (Timoptic Only)
Novex
Pacific Pharma

TRAMADOL HCL TABLET, EXTENDED RELEASE

TRETINOIN CREAM; TOPICAL, 0.05% (Group 1)
Johnson/Johnson (Retin-A)
Triax

TRETINOIN CREAM; TOPICAL, 0.05% (Group 2)
Johnson/Johnson (Renova)
Spear

TRETINOIN GEL; TOPICAL, 0.025%
Johnson and Johnson
Spear

VERAPAMIL HYDROCHLORIDE TABLET, EXTENDED RELEASE, 180 MG
Ivax
Mylan
Ranbaxy

VERAPAMIL HYDROCHLORIDE TABLET, EXTENDED RELEASE, 240 MG
Ivax
Kali
Mylan
Ranbaxy

END.