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**Rules of**  
**Department of Economic**  
**Development**  
**Division 220—State Board of Pharmacy**  
**Chapter 3—Negative Generic Drug Formulary**

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**Title 4—DEPARTMENT OF  
ECONOMIC DEVELOPMENT  
Division 220—State Board of Pharmacy  
Chapter 3—Negative Generic  
Drug Formulary**

**4 CSR 220-3.010 Generic Drug Formulary**

*Emergency rule filed Dec. 28, 1978, effective Jan. 7, 1979, expired April 30, 1979.*

**4 CSR 220-3.011 Generic Drug Formulary**

*PURPOSE: The purpose of this rule is to comply with the section 338.057, RSMo (1986), 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 proven bioequivalent and bioavailable 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 and manufacturer is specifically designated in the list.*

*PUBLISHER'S NOTE: The secretary of state has determined that the publication of the entire text of the material which is incorporated by reference as a portion of this rule would be unduly cumbersome or expensive. Therefore, the material which is so incorporated is on file with the agency who filed this rule, and with the Office of the Secretary of State. Any interested person may view this material at either agency's headquarters or the same will be made available at the Office of the Secretary of State at a cost not to exceed actual cost of copy reproduction. The entire text of the rule is printed here. This note refers only to the incorporated by reference material.*

(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 (1) 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.

*AUTHORITY: sections 338.056, 338.057 and 338.140, RSMo 1994.\* Emergency rule filed April 26, 1979, effective May 6, 1979, expired Aug. 12, 1979. Original rule filed April 26, 1979, effective Aug. 13, 1979. Emergency amendment filed April 14, 1982, effective April 24, 1982, expired Aug. 22, 1982. Amended: Filed April 14, 1982, effective July 11, 1982. Emergency amendment filed June 14, 1982, effective July 15, 1982, expired Oct. 12, 1982. Amended: Filed June 14, 1982, effective Sept. 11, 1982. Emergency amendment filed Dec. 6, 1982, effective Jan. 1, 1983, expired March 10, 1983. Amended: Filed Dec. 6, 1982, effective March 11, 1983. Emergency amendment filed June 14, 1983, effective July 15, 1983, expired Sept. 15, 1983. Amended: Filed June 14, 1983, effective Sept. 11, 1983. Emergency amendment filed Dec. 12, 1983, effective Jan. 1, 1984, expired March 14, 1984. Amended: Filed Dec. 12, 1983, effective May 11, 1984. Emergency amendment filed Feb.*

*3, 1984, effective Feb. 13, 1984, expired June 12, 1984. Emergency amendment filed June 20, 1984, effective June 30, 1984, expired Oct. 28, 1984. Amended: Filed July 9, 1984, effective Oct. 11, 1984. Emergency amendment filed Dec. 10, 1984, effective Dec. 20, 1984, expired April 19, 1985. Amended: Filed Dec. 11, 1984, effective March 11, 1985. Emergency amendment filed Jan. 18, 1985, effective Jan. 28, 1985, expired May 28, 1985. Emergency amendment filed June 14, 1985, effective June 24, 1985, expired Oct. 12, 1985. Amended: Filed June 14, 1985, effective Sept. 27, 1985. Emergency amendment filed Dec. 23, 1985, effective Jan. 2, 1986, expired June 2, 1986. Amended: Filed Dec. 23, 1985, effective May 11, 1986. Emergency amendment filed June 21, 1986, effective July 1, 1986, expired Oct. 28, 1986. Amended: Filed June 23, 1986, effective Sept. 26, 1986. Emergency amendment filed Dec. 10, 1986, effective Dec. 20, 1986, expired April 19, 1987. Amended: Filed Dec. 10, 1986, effective April 11, 1987. Emergency amendment filed July 5, 1987, effective July 20, 1987, expired Nov. 17, 1987. Amended: Filed July 7, 1987, effective Oct. 25, 1987. Emergency amendment filed Jan. 19, 1988, effective Feb. 1, 1988, expired May 30, 1988. Amended: Filed Jan. 19, 1988, effective April 28, 1988. Amended: Filed April 15, 1988, effective Jan. 1, 1989. Emergency amendment filed July 5, 1988, effective July 15, 1988, expired Nov. 12, 1988. Amended: Filed July 5, 1988, effective Nov. 11, 1988. Emergency amendment filed Jan. 19, 1989, effective Feb. 10, 1989, expired May 19, 1989. Amended: Filed Jan. 19, 1989, effective May 11, 1989. Amended: Filed March 31, 1989, effective Sept. 1, 1989. Amended: Filed Aug. 25, 1995, effective April 30, 1996.*

*\*Original authority: 338.056, RSMo 1978; 338.057, RSMo 1978; and 338.140, RSMo 1939, amended 1981, 1989.*

**4 CSR 220-3.040 Return and Reuse of Drugs and Devices**

*PURPOSE: This rule sets guidelines for the return and reuse of drugs and devices.*

(1) Pharmacists and pharmacies shall not accept from patients or their agents for reuse or resale any drugs, prescribed medications, chemicals, poisons or medical devices unless otherwise provided for in this regulation.

(2) A pharmacist or pharmacy may receive and reuse drugs from long-term care facilities, hospitals, and hospice facilities (as reg-



ulated by the Department of Health and Senior Services, in 19 CSR 30-35.020 Hospices Providing Direct Care in a Hospice Facility), provided that the following conditions are met:

(A) The pharmacist has assurance from a person in responsible charge of the drugs at a facility delineated in this section that the drugs being returned have been stored in accordance with the manufacturer's recommendations and meet U.S.P. standards;

(B) The drugs were originally dispensed by the pharmacist or pharmacy to the facility delineated in section (2);

(C) There is an established mechanism to trace the expiration date and the manufacturer's lot number of the drugs being returned;

(D) Only drug products dispensed by a licensed pharmacy utilizing one (1) of the following sources may be reused and no drug products for reuse shall be in any way subject to further repackaging:

1. Drug products in the original manufacturer's packaging that remains sealed in tamper-evident packaging;

2. Drug products repackaged by facilities that are federally registered as a repacker of medications and the packaging remains sealed in tamper-evident packaging;

3. Drug products that have been repackaged by a licensed pharmacy and are returned unused by the facility and remain sealed in tamper-evident packaging;

4. Drug products that have been repackaged by a licensed pharmacy and are provided in unit of use packaging whereby unused portions can be separated and reused without any further repackaging processes necessary on the returned product; and

(E) Any products that are accepted for return and can be reused based on standards provided in this rule shall be re-labeled to provide accurate information concerning patient and prescription information. Original lot numbers, expiration or beyond-use-dates assigned to a product that is reused by a pharmacy shall not be altered or in any way updated.

*AUTHORITY: section 338.280, RSMo 2000.\* Original rule filed Dec. 12, 1983, effective May 11, 1984. Amended: Filed July 5, 1988, effective Nov. 11, 1988. Amended: Filed Sept. 2, 1997, effective April 30, 1998. Amended: Filed April 5, 2002, effective Nov. 30, 2002. Amended: Filed May 17, 2004, effective Dec. 30, 2004.*

*\*Original authority: 338.280, RSMo 1951, amended 1971, 1981.*