RULES AND REGULATIONS

PERTAINING TO

DRUG PRODUCT SELECTION

(R21-31-DPS)

STATE OF RHODE ISLAND AND PROVIDENCE PLANTATIONS

Department of Health

October 1981

As amended:
January 2002 (re-filing in accordance with the provisions of section 42-35-4.1 of the Rhode Island General Laws, as amended)

These rules and regulations are promulgated pursuant to the authority conferred under section 21-31-20 of the General Laws of Rhode Island, 1956, as amended, for the purpose of establishing the criteria for the determination of drug product selection.

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Section 1.0 DEFINITIONS

Wherever used in these rules and regulations the following terms shall be construed as follows:

1.1 "Act" shall refer to Chapter 21-31 of the General Laws of Rhode Island, 1956, as amended, entitled "Rhode Island Food, Drugs and Cosmetics Act".

1.2 "Director" means the Director of Health of the State of Rhode Island.

1.3 "Dosage form" means the form of the completed drug product (such as tablet, syrup or suppository).

1.4 "Drug product" means a dosage form containing one or more active therapeutic ingredients along with other substances included during the manufacturing process.

1.5 "Equivalent and interchangeable" means having the same generic name, dosage form and labeled potency, meeting standards of the United States Pharmacopoeia or National Formulary, or their successors, if applicable, and not found in violation of the requirements of the United States Food and Drug Administration, or its successor agency, or the Rhode Island Department of Health.

1.6 "Generic" means the chemical or established name of such drug or drug product.

1.7 "List" refers to the prescription drug product(s) that the Director deems, after evaluation, not to be therapeutically equivalent and interchangeable.

1.8 "Person" includes individual, partnership, corporation and association.

Section 2.0 GENERAL PROVISIONS

2.1 Pursuant to section 21-31-16.1 of the Act, the Director, on his own initiative, may deem prescription drugs not to be therapeutically equivalent and interchangeable, as determined in accordance with the provisions of section 3.1 herein.

2.1.1 In addition, any person may request the inclusion, addition or deletion of any drug product to the list, provided such requests meets the criteria established in section 3.0 herein.

Section 3.0 CRITERIA TO DETERMINE THE INCLUSION, ADDITION OR DELETION OF A DRUG PRODUCT TO THE LIST

3.1 Any person requesting the inclusion, addition or deletion of any drug product to the list, must submit in duplicate forms to the Director the following:

a) evidence of adequate and well controlled investigations, including clinical investigations, by experts qualified by scientific training and experience, on the basis of which it could be fairly and responsibly determined by the Director that a drug product demonstrates or does not demonstrate, clinically significant biological or therapeutic inequivalence and which, if substituted for another drug product under the provisions of section 21-31-16.1 of the Act, would pose a threat to the health and safety of the patient receiving the prescription medication;

b) adequate identification of all drug products involved by name of manufacturer, lot number(s), dosage form(s), generic name, stated labeled potency, applicable standards of the United States Pharmacopeia or National Formulary, requirements of the United States Food and Drug Administration, requirements of the Rhode Island Department of Health pursuant to the Act and the rules and regulations herein, and indication of the condition(s) of use (e.g. duration, frequency, etc.) of any such drug product where substitution poses a threat to the health and safety of the patient; and

c) such other information as the Director may deem appropriate.

3.2 After evaluation of all evidence and information as required in section 3.1 herein, the Director shall make a determination that a drug product is or is not therapeutically equivalent and interchangeable.

3.3 Whenever action is proposed by the Director to deny addition, deletion or inclusion of a drug product to the list as may be requested by any person, the Director shall notify said person by certified mail setting forth the reasons for the proposed action, and said person shall be given an opportunity for a prompt and fair hearing in accordance with the provisions of section 4.0 herein.

3.3.1 Whenever action is proposed in accordance

with section 3.3 above, the Director shall notify by certified mail the manufacturer of the drug product, and shall set forth the reasons for the proposed action. Pursuant to section 42-35-1 (b) of the General Laws of Rhode Island, 1956, as amended, said manufacturer shall be entitled to an administrative hearing, if so requested, to be conducted in accordance with the requirements of section 4.0 herein.

3.3.2 If a hearing is not requested within ten (10) days by the person and/or the manufacturer, the Director will proceed to carry out such action as has been determined pertaining to the drug product and shall distribute the list to all physicians and pharmacists, to other appropriate persons and shall supply a copy to any person upon request pursuant to section 21-31-16.1 of the Act.

Section 4.0 RULES GOVERNING PRACTICES AND PROCEDURES

4.1 All hearings and reviews hereunder shall be held in accordance with he provisions of Chapter 42-35 of the General Laws of Rhode Island, 1956, as amended, and the rules and regulations promulgated by the Rhode Island Department of Health entitled "Rules and Regulations Governing Practices and Procedures before the Rhode Island Department of Health" (R42-35-PP).

Section 5.0 SEVERABILITY

5.1 If any provision of these rules and regulations or the application thereof to any person or circumstance shall be held invalid, such invalidity shall not affect the provisions or application of the rules and regulations which can be given effect, and to this end the provisions of the rules and regulations are declared to be severable.