24:6E-4

LEGISLATIVE HISTORY CHECKLIST
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("Dosage in Prescription Drug" price law)

NJSA: 24:6E-4

LAWS OF: 1993 **CHAPTER:** 256

BILL NO: A2625

SPONSOR(S) Colburn and Doria

DATE INTRODUCED: May 24, 1993

COMMITTEE: **ASSEMBLY:** Health & Human Services

SENATE: Health & Human Services

AMENDED DURING PASSAGE: Yes Amendments during passage denoted by superscript numbers
First reprint enacted

DATE OF PASSAGE: **ASSEMBLY:** June 17, 1993

SENATE: June 28, 1993

DATE OF APPROVAL: August 13, 1993

FOLLOWING STATEMENTS ARE ATTACHED IF AVAILABLE:

SPONSOR STATEMENT: Yes

COMMITTEE STATEMENT: **ASSEMBLY:** Yes

SENATE: Yes

FISCAL NOTE: No

VETO MESSAGE: No

MESSAGE ON SIGNING: No

FOLLOWING WERE PRINTED:

REPORTS: No

HEARINGS: No

KBG:pp

[FIRST REPRINT]

ASSEMBLY, No. 2625

STATE OF NEW JERSEY

INTRODUCED MAY 24, 1993

By Assemblymen COLBURN and DORIA

AN ACT concerning prescription drug substitutions and amending P.L.1977, c.240.

BE IT ENACTED *by the Senate and General Assembly of the State of New Jersey:*

1. Section 5 of P.L.1977, c.240 (C.24:6E-4) is amended to read as follows:

5. As used in this act unless the context clearly indicates otherwise:

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

b. "Brand name" means the proprietary name assigned to a drug by the manufacturer thereof.

c. "Established name" with respect to a drug or ingredient thereof, means (1) the applicable official name designated pursuant to the Federal Food, Drug and Cosmetic Act (Title 21, USC 301 et seq.), or (2) if there is no such official name and such drug or ingredient is recognized in an official compendium, then the official title thereof in such compendium, except that where a drug or ingredient is recognized in the United States Pharmacopoeia and in the Homeopathic Pharmacopoeia under different official titles, the official title used in the United States Pharmacopoeia shall apply unless it is labeled and offered for sale as a homeopathic drug, in which case the official title used in the Homeopathic Pharmacopoeia shall apply, or (3) if neither (1) nor (2) is applicable, then the common or usual name, if any, of such drug or ingredient.

d. "Prescription" means an order for drugs or combinations or mixtures thereof, written or signed by a duly licensed physician, dentist, veterinarian or other medical practitioner licensed to write prescriptions intended for the treatment or prevention of disease in man or animals, and includes orders for drugs or medicines or combinations or mixtures thereof transmitted to pharmacists through word of mouth, telephone, telegraph or other means of communication by a duly licensed physician, dentist, veterinarian or other medical practitioner licensed to write prescriptions intended for the treatment or prevention of disease in man or animals.

e. "Council" means the Drug Utilization Review Council.

f. "Chemical equivalents' means those drug products that contain the same amounts of the same therapeutically active

EXPLANATION--Matter enclosed in bold-faced brackets [thus] in the above bill is not enacted and is intended to be omitted in the law.

Matter underlined thus is new matter.
Matter enclosed in superscript numerals has been adopted as follows:
1 Assembly AHH committee amendments adopted June 3, 1993.

ingredients in the same dosage forms and that meet present compendial standards.

g. "Reference drug product" means the product which is adopted by the council as the standard for other chemically equivalent drugs in terms of testing for the therapeutic equivalence. In all cases, the reference drug product shall be a currently marketed drug which is the subject of a full (not abbreviated) new drug application approved by the Federal Food and Drug Administration.

h. "Therapeutic equivalents" means chemical equivalents which, when administered to the same individuals in the same dosage regimen, will provide essentially the same efficacy or toxicity as their respective reference drug products.

i. "Bioavailability" means the extent and rate of absorption from a dosage form as reflected by the time-concentration curve of the administered drug in the systemic circulation.

j. "Bioequivalents" means chemical equivalents which, when administered to the same individuals in the same dosage regimen, will result in comparable bioavailability.

k. "Pharmaceutical equivalents" means those drug products that contain the same amounts of the same therapeutically active ingredients in the same dosage form and that meet established standards.

l. "Interchangeable drug products" means pharmaceutical equivalents or bioequivalents that are determined to be therapeutic equivalents by the council.

m. "Present compendial standards" means the official standards for drug excipients and drug products listed in the latest revision of the United States Pharmacopoeia (USP) and the National Formulary (NF).

n. "Dosage form" means the physical formulation or medium in which the product is intended, manufactured and made available for use, including, but not limited to: tablets, capsules, oral solutions, aerosols, inhalers, [1][jells] gels[1], lotions, creams, ointments, transdermals and suppositories, and the particular form of the above which utilizes a specific technology or mechanism to control, enhance or direct the release, targeting, systemic absorption or other delivery of a dosage regimen in the body.

(cf: P.L.1977, c.240, s.5)

2. This act shall take effect immediately.

Defines "dosage form" in "Prescription Drug Price and Quality Stabilization Act."

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(cf: P.L.1977, c.240, s.5)

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STATEMENT

This bill amends the "Prescription Drug Price and Quality Stabilization Act" to include the definition of "dosage form." The bill provides that "dosage form" means the physical formulation or medium in which the product is intended, manufactured and made available for use, including, but not limited to: tablets, capsules, oral solutions, aerosols, inhalers, jells, lotions, creams, ointments, transdermals and suppositories, and the particular form of the above which utilizes a specific technology or mechanism to control, enhance or direct the

release, targeting, systemic absorption or other delivery of a dosage regimen in the body. It is the sponsor's belief that this clarification will ensure patient care in that the physician who prescribes a drug can be sure that its full therapeutic value is delivered to the patient.

Defines "dosage form" in "Prescription Drug Price and Quality Stabilization Act."

ASSEMBLY HEALTH AND HUMAN SERVICES COMMITTEE

STATEMENT TO

ASSEMBLY, No. 2625

with committee amendments

STATE OF NEW JERSEY

DATED: JUNE 3, 1993

The Assembly Health and Human Services Committee favorably reports Assembly Bill No. 2625 with committee amendments.

As amended by the committee, this bill amends the "Prescription Drug Price and Quality Stabilization Act," P.L.1977, c.240 (C.24:6E-1 et seq.) to include the definition of "dosage form." The amended bill provides that "dosage form" means the physical formulation or medium in which the product is intended, manufactured and made available for use, including, but not limited to: tablets, capsules, oral solutions, aerosols, inhalers, gels, lotions, creams, ointments, transdermals and suppositories, and the particular form of the above which utilizes a specific technology or mechanism to control, enhance or direct the release, targeting, systemic absorption or other delivery of a dosage regimen in the body. This bill is intended to promote high quality patient care by assuring the physician who prescribes a drug that its full therapeutic value is delivered to the patient.

The committee adopted a technical amendment to correct the spelling of the term "gel."

SENATE HEALTH AND HUMAN SERVICES COMMITTEE

STATEMENT TO

[FIRST REPRINT]

ASSEMBLY, No. 2625

STATE OF NEW JERSEY

DATED: JUNE 21, 1993

The Senate Health and Human Services Committee favorably reports Assembly Bill No. 2625 (1R).

This bill amends the "Prescription Drug Price and Quality Stabilization Act," P.L.1977, c.240 (C.24:6E-1 et seq.) to include the definition of "dosage form." The bill provides that "dosage form" means the physical formulation or medium in which the product is intended, manufactured and made available for use, including, but not limited to: tablets, capsules, oral solutions, aerosols, inhalers, gels, lotions, creams, ointments, transdermals and suppositories, and the particular form of the above which utilizes a specific technology or mechanism to control, enhance or direct the release, targeting, systemic absorption or other delivery of a dosage regimen in the body. This bill is intended to promote high quality patient care by assuring the physician who prescribes a drug that its full therapeutic value is delivered to the patient.

This bill is identical to Senate Bill No. 1935 (Bassano/Sinagra) which was also favorably reported by the committee on this date.