AN ACT

RELATING TO HEALTH; AMENDING THE NEW MEXICO DRUG, DEVICE AND COSMETIC ACT TO PROVIDE FOR REGULATION OF BIOSIMILAR PRODUCTS.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF NEW MEXICO:

SECTION 1. Section 26-1-2 NMSA 1978 (being Laws 1967, Chapter 23, Section 2, as amended) is amended to read:

"26-1-2. DEFINITIONS.--As used in the New Mexico Drug, Device and Cosmetic Act:

A. "board" means the board of pharmacy or its duly authorized agent;

B. "person" includes an individual, partnership, corporation, association, institution or establishment;

C. "biological product" means any of the following that is applicable to the prevention, treatment or cure of a disease or condition of human beings:

(1) a virus;

(2) a therapeutic serum;

(3) a toxin;

(4) an antitoxin;

(5) a vaccine;

(6) blood;

(7) a blood component or derivative;

(8) an allergenic product;

(9) a protein, except any chemically synthesized polypeptide;

(10) a product that is analogous to any of the products listed in Paragraphs (1) through (9) of this subsection; or

(11) arsphenamine, a derivative of arsphenamine or any other trivalent organic arsenic compound;

D. "biosimilar" or "biosimilarity" means, in reference to a biological product that the federal food and drug administration has licensed, that:

(1) the biological product is highly similar to the reference product notwithstanding minor differences in clinically inactive components; and

(2) there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity and potency of the product;

E. "controlled substance" means a drug, substance or immediate precursor enumerated in Schedules I through V of the Controlled Substances Act;

F. "drug" means articles:

(1) recognized in an official compendium;

(2) intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in humans or other animals and includes the domestic animal biological

products regulated under the federal Virus-Serum-Toxin Act, 37 Stat 832-833, 21 U.S.C. 151-158, and the biological products applicable to humans regulated under Federal 58 Stat 690, as amended, 42 U.S.C. 216, Section 351, 58 Stat 702, as amended, and 42 U.S.C. 262;

(3) other than food, that affect the structure or any function of the human body or the bodies of other animals; and

(4) intended for use as a component of Paragraph (1), (2) or (3) of this subsection, but "drug" does not include devices or their component parts or accessories;

G. "dangerous drug" means a drug, other than a controlled substance enumerated in Schedule I of the Controlled Substances Act, that because of a potentiality for harmful effect or the method of its use or the collateral measures necessary to its use is not safe except under the supervision of a practitioner licensed by law to direct the use of such drug and hence for which adequate directions for use cannot be prepared. "Adequate directions for use" means directions under which the layperson can use a drug or device safely and for the purposes for which it is intended. A drug shall be dispensed only upon the prescription or drug order of a practitioner licensed by law to administer or prescribe the drug if it:

(1) is a habit-forming drug and contains any

quantity of a narcotic or hypnotic substance or a chemical derivative of such substance that has been found under the federal act and the board to be habit forming;

(2) because of its toxicity or other potential for harmful effect or the method of its use or the collateral measures necessary to its use is not safe for use except under the supervision of a practitioner licensed by law to administer or prescribe the drug;

(3) is limited by an approved application by Section 505 of the federal act to the use under the professional supervision of a practitioner licensed by law to administer or prescribe the drug;

(4) bears the legend: "Caution: federal law prohibits dispensing without prescription.";

(5) bears the legend: "Caution: federal law restricts this drug to use by or on the order of a licensed veterinarian."; or

(6) bears the legend "RX only";

H. "counterfeit drug" means a drug that is deliberately and fraudulently mislabeled with respect to its identity, ingredients or sources. Types of such pharmaceutical counterfeits may include:

(1) "identical copies", which are counterfeits made with the same ingredients, formulas and packaging as the originals but not made by the original

manufacturer;

(2) "look-alikes", which are products that feature high-quality packaging and convincing appearances but contain little or no active ingredients and may contain harmful substances;

(3) "rejects", which are drugs that have been rejected by the manufacturer for not meeting quality standards; and

(4) "relabels", which are drugs that have passed their expiration dates or have been distributed by unauthorized foreign sources and may include placebos created for late-phase clinical trials;

I. "device", except when used in Subsection R of this section and in Subsection G of Section 26-1-3, Subsection L and Paragraph (4) of Subsection A of Section 26-1-11 and Subsection C of Section 26-1-24 NMSA 1978, means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent or other similar or related article, including any component, part or accessory, that is:

(1) recognized in an official compendium;

(2) intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment or prevention of disease in humans or other animals; or

(3) intended to affect the structure or a function of the human body or the bodies of other animals and that does not achieve any of its principal intended purposes through chemical action within or on the human body or the bodies of other animals and that is not dependent on being metabolized for achievement of any of its principal intended purposes;

J. "prescription" means an order given individually for the person for whom prescribed, either directly from a licensed practitioner or the practitioner's agent to the pharmacist, including by means of electronic transmission, or indirectly by means of a written order signed by the prescriber, and bearing the name and address of the prescriber, the prescriber's license classification, the name and address of the patient, the name and quantity of the drug prescribed, directions for use and the date of issue;

K. "practitioner" means a certified advanced practice chiropractic physician, physician, doctor of oriental medicine, dentist, veterinarian, euthanasia technician, certified nurse practitioner, clinical nurse specialist, pharmacist, pharmacist clinician, certified nurse-midwife, physician assistant, prescribing psychologist, dental hygienist, optometrist or other person licensed or certified to prescribe and administer drugs that are subject to the New Mexico Drug, Device and Cosmetic Act;

L. "cosmetic" means:

(1) articles intended to be rubbed, poured, sprinkled or sprayed on, introduced into or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness or altering the appearance; and

(2) articles intended for use as a component of any articles enumerated in Paragraph (1) of this subsection, except that the term shall not include soap;

M. "interchangeable biological product" means a biological product that the federal food and drug administration has licensed and:

(1) has determined that the biological product is biosimilar to the reference product and can be expected to produce the same clinical result as the reference product in any given patient;

(2) for a biological product that is administered more than once to an individual and:

(a) has determined to have been administered more than once to the individual; or

(b) for which the risk in terms of safety or diminished efficacy of alternating or switching between use of the biological product and the reference product is not greater than the risk of using the reference product without alternation or switching; or

(3) has determined to be therapeutically equivalent as set forth in the latest edition or supplement to the federal food and drug administration's approved drug products with therapeutic equivalence evaluations;

N. "official compendium" means the official United States pharmacopoeia national formulary or the official homeopathic pharmacopoeia of the United States or any supplement to either of them;

O. "label" means a display of written, printed or graphic matter upon the immediate container of an article. A requirement made by or under the authority of the New Mexico Drug, Device and Cosmetic Act that any word, statement or other information appear on the label shall not be considered to be complied with unless the word, statement or other information also appears on the outside container or wrapper, if any, of the retail package of the article or is easily legible through the outside container or wrapper;

P. "immediate container" does not include package liners;

Q. "labeling" means all labels and other written, printed or graphic matter:

(1) on an article or its containers or wrappers; or

(2) accompanying an article;

R. "misbranded" means a label to an article that

is misleading. In determining whether the label is misleading, there shall be taken into account, among other things, not only representations made or suggested by statement, word, design, device or any combination of the foregoing, but also the extent to which the label fails to reveal facts material in the light of such representations or material with respect to consequences that may result from the use of the article to which the label relates under the conditions of use prescribed in the label or under such conditions of use as are customary or usual;

S. "advertisement" means all representations disseminated in any manner or by any means, other than by labeling, for the purpose of inducing, or that are likely to induce, directly or indirectly, the purchase of drugs, devices or cosmetics;

T. "antiseptic", when used in the labeling or advertisement of an antiseptic, shall be considered to be a representation that it is a germicide, except in the case of a drug purporting to be or represented as an antiseptic for inhibitory use as a wet dressing, ointment, dusting powder or such other use as involves prolonged contact with the body;

U. "new drug" means a drug:

(1) the composition of which is such that the drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety

and efficacy of drugs, as safe and effective for use under the conditions prescribed, recommended or suggested in the labeling thereof; or

(2) the composition of which is such that the drug, as a result of investigation to determine its safety and efficacy for use under such conditions, has become so recognized, but that has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions;

V. "contaminated with filth" applies to a drug, device or cosmetic not securely protected from dirt, dust and, as far as may be necessary by all reasonable means, from all foreign or injurious contaminations, or a drug, device or cosmetic found to contain dirt, dust, foreign or injurious contamination or infestation;

W. "selling of drugs, devices or cosmetics" shall be considered to include the manufacture, production, processing, packing, exposure, offer, possession and holding of any such article for sale and the sale and the supplying or applying of any such article in the conduct of a drug or cosmetic establishment;

X. "color additive" means a material that:

(1) is a dye, pigment or other substance made by a process of synthesis or similar artifice or extracted, isolated or otherwise derived, with or without

intermediate or final change of identity, from a vegetable, mineral, animal or other source; or

(2) when added or applied to a drug or cosmetic or to the human body or a part thereof, is capable, alone or through reaction with other substances, of imparting color thereto; except that such term does not include any material that has been or hereafter is exempted under the federal act;

Y. "federal act" means the Federal Food, Drug, and Cosmetic Act;

Z. "restricted device" means a device for which the sale, distribution or use is lawful only upon the written or oral authorization of a practitioner licensed by law to administer, prescribe or use the device and for which the federal food and drug administration requires special training or skills of the practitioner to use or prescribe. This definition does not include custom devices defined in the federal act and exempt from performance standards or premarket approval requirements under Section 520(b) of the federal act;

AA. "prescription device" means a device that, because of its potential for harm, the method of its use or the collateral measures necessary to its use, is not safe except under the supervision of a practitioner licensed in this state to direct the use of such device and for which

"adequate directions for use" cannot be prepared, but that bears the label: "Caution: federal law restricts this device to sale by or on the order of a _____", the blank to be filled with the word "physician", "physician assistant", "certified advanced practice chiropractic physician", "doctor of oriental medicine", "dentist", "veterinarian", "euthanasia technician", "certified nurse practitioner", "clinical nurse specialist", "pharmacist", "pharmacist clinician", "certified nurse-midwife", "dental hygienist" or "optometrist" or with the descriptive designation of any other practitioner licensed in this state to use or order the use of the device;

BB. "valid practitioner-patient relationship" means a professional relationship, as defined by the practitioner's licensing board, between the practitioner and the patient;

CC. "pedigree" means the recorded history of a drug;

DD. "drug order" means an order either directly from a licensed practitioner or the practitioner's agent to the pharmacist, including by means of electronic transmission or indirectly by means of a written order signed by the licensed practitioner or the practitioner's agent, and bearing the name and address of the practitioner and the practitioner's license classification and the name and

quantity of the drug or device ordered for use at an inpatient or outpatient facility; and

EE. "reference product" means the single biological product against which a biosimilar was evaluated in its marketing application to the federal food and drug administration."

SECTION 2. Section 26-3-3 NMSA 1978 (being Laws 1976, Chapter 60, Section 4, as amended) is amended to read:

"26-3-3. DRUG AND BIOLOGICAL PRODUCT SELECTION PERMITTED--CONDITIONS--EXCEPTION FOR PROHIBITION--LABELING.--

A. Upon receipt of a prescription written by a licensed practitioner who may prescribe drugs or biological products for a drug or biological product for which one or more multiple-source drugs or interchangeable biological products are recognized, listed as final determinations and published in the federal register by the federal department of health and human services, a pharmacist may dispense any one of the drugs or interchangeable biological products that satisfies the final determinations so recognized and listed by the federal department of health and human services and is sold at a lower cost than the drug or biological product listed in the prescription.

B. Upon receipt of a prescription written by a licensed practitioner for a drug or biological product that appears on the federal food and drug administration's

approved prescription drug products with therapeutic equivalence evaluation list as supplemented, or for a biological product that is listed as interchangeable on the lists of the federal food and drug administration's lists of licensed biological products with reference product exclusivity and biosimilarity or interchangeability evaluations, as supplemented, a pharmacist may dispense any of the listed therapeutically equivalent drugs or interchangeable biological products that is lower in cost than the prescribed drug or biological product.

C. Drug and biological product selection shall be permitted only under circumstances and conditions set forth in Subsections A and B of this section unless the licensed practitioner prescribing prohibits drug or biological product selection. A licensed practitioner shall prohibit drug or biological product selection by making an entry that is electronically accessible that includes the words "no substitution" or the diminution "no sub" on a prescription.

D. If drug or biological product selection occurs as permitted in Subsections A and B of this section, the pharmacist shall indicate on the label of the dispensed container the brand of drug or the specific biological product prescribed and the name of the drug or interchangeable biological product dispensed.

E. A pharmacist who selects an interchangeable

biological product shall inform the patient or the patient's representative.

F. A pharmacist shall not select a therapeutically equivalent drug or interchangeable biological product unless the substitution is in accordance with the provisions of Subsection A of this section.

G. Within five business days following the dispensing of a biological product, the dispensing pharmacist or the pharmacist's designee shall make an entry of the specific product provided to the patient, including the name of the product and the manufacturer. The communication shall be conveyed by making an entry that is electronically accessible to the prescriber through:

(1) an interoperable electronic medical records system;

(2) an electronic prescribing technology;

(3) a pharmacy benefit management system; or

(4) a pharmacy record.

H. Entry into an electronic medical records system pursuant to Subsection G of this section is presumed to provide notice to the prescriber. Otherwise, the pharmacist shall communicate to the prescriber what biological product was dispensed, using facsimile, telephone, electronic transmission or other prevailing means; provided that communication shall not be required when:

(1) there is no interchangeable biological product that has been approved by the federal food and drug administration for the product prescribed; or

(2) a refill prescription is not changed from the product dispensed on the prior filling of the prescription.

I. The board shall maintain a link on its website to the current lists of all biological products that the federal food and drug administration has determined to be interchangeable biological products.

J. For purposes of this section:

(1) "multiple-source drug" means a drug marketed or sold by two or more manufacturers, formulators or labelers; and

(2) "therapeutically equivalent" means drug products that have the same amount of the active drug in the same dosage form that when administered can be expected to provide the same therapeutic effect."