STATE OF CALIFORNIA

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July 25, 2008

To Interested Parties:

Notice of Proposed Regulatory Action
by the
State Board of Equalization

Proposed to Adopt Regulation 1591, *Medicines and Medical Devices*, and Regulation 1602, *Food Products*

NOTICE IS HEREBY GIVEN

The State Board of Equalization (Board), pursuant to the authority vested in it by section 15606, subdivision (a), of the Government Code, proposes to amend sections 1602., *Food Products*, and 1591, *Medicines and Medical Devices*, in Title 18, Division 2, Chapter 4, Articles 19 and 20 of the California Code of Regulations, relating to regulatory changes to the processes for clarifying the manner in which tax applies to sales of dietary supplement and adjunct products that are furnished by a physician as part of a medically supervised weight loss program to treat obesity. A public hearing on the proposed regulations will be held in Room 121, 450 N Street, Sacramento, at 9:30 a.m., or as soon thereafter as the matter may be heard, on Wednesday, September 17, 2008. At the hearing, any person interested may present statements or arguments orally or in writing relevant to the proposed regulatory action. The Board will consider written statements or arguments if received by September 17, 2008.

INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

Sales and Use Tax Regulation 1602, *Food Products*, specifies that tax does not apply to products which either are otherwise exempted respecting prescription medicines or are complete dietary foods providing the user in the recommended daily dosage with substantial amounts of vitamins, proteins, minerals and foods providing adequate caloric intake. Sales and Use Tax Regulation 1591, Medicines and Medical Devises, specifies that when vitamins, minerals, herbs, and other such supplements are used in the cure, mitigation, treatment or prevention of disease, and are commonly recognized as a substance or preparation intended for such use, they will qualify as medicines for the purposes of Revenue and Taxation Code section 6369. Consequently, their sale or use is not subject to tax when sold or furnished under specified conditions.

The proposed amendments would amend regulation 1602 to clarify that when dietary supplement and adjunct products do not meet the definition of food under 1602(a)(4), and are furnished by a physician to his or her own patient as part of a medically supervised weight loss program to treat obesity, such products are regarded as "medicine". The proposed change to Regulation 1591 would add new subdivision (e)(7) to explain that when a dietary supplement or adjunct product does not qualify as food product, it qualifies as a medicine under certain conditions.

COST TO LOCAL AGENCIES AND SCHOOL DISTRICTS

The State Board of Equalization has determined that the proposed amendments do not impose a mandate on local agencies or school districts. Further, the Board has determined that the amendments and regulations will result in no direct or indirect cost or savings to any State agency, any costs to local agencies or school districts that are required to be reimbursed under Part 7 (commencing with section 17500) of Division 4 of Title 2 of the Government Code or other non-discretionary costs or savings imposed on local agencies, or cost or savings in federal funding to the State of California.

EFFECT ON BUSINESS

Pursuant to Government Code section 11346.5, subdivision (a)(8), the Board of Equalization makes an initial determination that the adoption of the amendments to Regulations 1602 and 1591 will have no significant statewide adverse economic impact directly affecting business.

The adoption of the proposed amendments to these regulations will neither create nor eliminate jobs in the State of California nor result in the elimination of existing businesses nor create or expand business in the State of California.

The amendments to the regulations as proposed will not be detrimental to California businesses in competing with businesses in other states.

The proposed regulations may affect small business.

COST IMPACT ON PRIVATE PERSON OR BUSINESSES

The Board is not aware of any cost impacts that a representative private person or business would necessarily incur in reasonable compliance with the proposed action.

SIGNIFICANT EFFECT ON HOUSING COSTS

No significant effect.

FEDERAL REGULATIONS

Regulations 1602 and 1591 and the proposed changes have no comparable federal regulations.

AUTHORITY

Section 7051, Revenue and Taxation Code.

REFERENCE

Section 6091, 6343 and 6359, Revenue and Taxation Code; Section 6006 and 6359, Revenue and Taxation Code, and sections 1200, 1200.1, 1204.1 and 2250 Health and Safety Code.

CONTACT

Questions regarding the substance of the proposed regulation should be directed to Mr. Tim Treichelt (916) 324-2640, at 450 N Street, Sacramento, CA 95814, e-mail Tim.Treichelt @boe.ca.gov or MIC:85, P.O. Box 942879, 450 N Street, Sacramento, CA 94279-0082.

Written comments for the Board's consideration, notice of intent to present testimony or witnesses at the public hearing, and inquiries concerning the proposed administrative action should be directed to Mr. Rick Bennion, Regulations Coordinator, telephone (916) 445-2130, fax (916) 324-3984 , e-mail Richard.Bennion@boe.ca.gov or by mail at State Board of Equalization, Attn: Rick Bennion MIC:81, P.O. Box 942879, 450 N Street, Sacramento, CA 94279-0080.

ALTERNATIVES CONSIDERED

The Board determined that no reasonable alternative considered by it or that has otherwise been identified and brought to its attention would be more effective in carrying out the purpose for which this action is proposed or would be as effective as and less burdensome to affected private persons than the proposed action.

AVAILABILITY OF INITIAL STATEMENT OF REASONS AND TEXT OF PROPOSED REGULATION

The Board has prepared an initial statement of reasons and an underscored and strikeout version (express terms) of the proposed regulation. Both of these documents and all information on which the proposal is based are available to the public upon request. The Rulemaking file is available for public inspection at 450 N Street, Sacramento, California. The express terms of the proposed regulation are available on the Internet at the Board's Web site http://www.boe.ca.gov.

AVAILABILITY OF FINAL STATEMENT OF REASONS

The final statement of reasons will be made available on the Internet at the Board's Web site following its public hearing of the proposed regulation. It will also be available for public inspection at 450 N Street, Sacramento, California.

ADDITIONAL COMMENTS

Following the hearing, the State Board of Equalization may, in accordance with the law, adopt the proposed regulations if the text remains substantially the same as described in the text

originally made available to the public. If the State Board of Equalization makes modifications which are substantially related to the originally proposed text, the Board will make the modified text, with the changes clearly indicated, available to the public for fifteen days before adoption of the regulation. The text of any modified regulation will be mailed to those interested parties who commented on the proposed regulatory action orally or in writing or who asked to be informed of such changes. The modified regulation will be available to the public from Mr. Bennion. The State Board of Equalization will consider written comments on the modified regulation for fifteen days after the date on which the modified regulation is made available to the public.

Sincerely,

Diane G. Olson

Diane G. Olson, Chief
Board Proceedings Division

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Enclosures

INITIAL STATEMENT OF REASONS
NON-CONTROLLING SUMMARY

Sales and Use Tax Regulations 1602, Food Products, and 1591, Medicines and Medical Devices

Specific Purpose

The purpose of the proposed amendments to California Code of Regulations, title 18, sections 1602, *Food Products* and 1591, *Medicines and Medical Devices*, respectively, is to clarify that when dietary supplement and adjunct products do not meet the definition of food under subdivision (a)(4) and are furnished by a physician to his or her own patient as part of a medically supervised weight loss program to treat obesity, such products are regarded as "medicine." A new subdivision (e)(7) is added to Regulation 1591 to explain that when a dietary supplement or adjunct product does not qualify as a food product, it qualifies as a medicine under certain conditions.

Necessity

This regulation is necessary to provide clarification to taxpayers and staff regarding whether sales of dietary supplement and adjunct products that are furnished by a physician as part of a medically supervised weight loss program to treat obesity may qualify for exemption from tax as food products or as medicines.

Factual Basis

In the audit of a weight loss clinic, Board of Equalization (BOE) staff questioned how tax applied to sales of very low calorie meal replacement products. The products were in liquid or powdered form, provided 800 calories or less per day, and were furnished by a physician operating a weight loss clinic. At issue was whether sales of the products qualified as exempt sales of food or medicines.

In general, sales of food products for human consumption are exempt from tax pursuant to Revenue and Taxation Code (RTC) section 6359 unless otherwise excluded from the exemption by statute. As relevant to this issue, subdivision (c) of RTC section 6359 provides:

"For purposes of this section, "food products" do not include medicines and preparations in liquid, powdered, granular, tablet, capsule, lozenge, and pill form sold as dietary supplements or adjuncts."

Regulation 1602(a)(4) provides an example of a complete dietary food, as contrasted with a dietary supplement or adjunct, as a product that provides the user daily with at least 900 calories, 70 grams of high quality protein, and minimum daily requirements as established by the Federal Food and Drug Administration of specified vitamins and minerals. Board staff has historically used the example in 1602(a)(4) to determine the minimum number of calories, grams of protein, and other vitamins per day that a meal replacement product must provide in order to be regarded as a complete dietary food rather than a dietary supplement or adjunct. Accordingly, a sale of a meal replacement product which provides fewer than 900 calories per day by itself would not qualify for exemption from tax as a sale of a food product, but would be subject to tax as a sale of a dietary supplement or adjunct in the absence of another exemption.

RTC section 6369, subdivision (a)(2) provides that the sale or use of medicines furnished by a licensed physician to his or her own patient for treatment of the patient is exempt from taxation. The term "medicines" includes any substance or preparation intended for use by "internal application to the human body in the diagnosis, cure, mitigation, treatment, or prevention of disease and commonly recognized as a substance or preparation intended for that use." Very low calorie meal replacement products meet the definition of a "medicine" because they are intended for use by internal application to the human body in the treatment of obesity, which commonly is recognized as a disease. Therefore, when these products are furnished by a physician to his or her own patient as part of a medically supervised weight loss program to treat obesity, although the sales of these products do not qualify as exempt sales of food products, the sales qualify for exemption as exempt sales of medicines.

No mandate Regarding Use of Specific Technologies

The proposed amendments do not mandate the use of specific technologies or equipment.

Initial Determination Regarding Alternatives

The Board does not believe that the proposed amendments will have any adverse impact on small business, and has made an initial determination that there are no reasonable alternatives to the proposed amendments, which would lessen any adverse impact on small business.

Regulation 1591. MEDICINES AND MEDICAL DEVICES.

Reference: Sections 6006 and 6369 Revenue and Taxation Code, and sections 1200, 1200.1, 1204.1, and 1250 Health and Safety Code.

(a) DEFINITIONS.

(1) ADMINISTER. "Administer" means the direct application of a drug or device to the body of a patient or research subject by injection, inhalation, ingestion, or other means.

(2) DISPENSE. "Dispense" means the furnishing of drugs or devices upon a prescription from a physician, dentist, optometrist, or podiatrist. Dispense also means and refers to the furnishing of drugs or devices directly to a patient by a physician, dentist, optometrist, or podiatrist acting within the scope of his or her practice.

(3) FURNISH. "Furnish" means to supply by any means, by sale or otherwise.

(4) HEALTH FACILITY. "Health Facility" as used herein has the meaning ascribed to the term in section 1250 of the Health and Safety Code, and also includes "clinic" as defined in sections 1200 and 1200.1 of the Health and Safety Code.

(A) Section 1250 of the Health and Safety Code provides that "health facility" means any facility, place or building that is organized, maintained, and operated for the diagnosis, care, prevention, and treatment of human illness, physical or mental, including convalescence and rehabilitation and including care during and after pregnancy, or for any one or more of these purposes, for one or more persons, to which the persons are admitted for a 24-hour stay or longer.

(B) Section 1200 of the Health and Safety Code provides that "clinic" means an organized outpatient health facility which provides direct medical, surgical, dental, optometric, or podiatric advice, services, or treatment to patients who remain less than 24 hours, and which may also provide diagnostic or therapeutic services to patients in the home as an incident to care provided at the clinic facility. A place, establishment, or institution which solely provides advice, counseling, information, or referrals on the maintenance of health or on the means and measures to prevent or avoid sickness, disease, or injury, where such advice, counseling, information, or referrals does not constitute the practice of medicine, surgery, dentistry, optometry, or podiatry, shall not be deemed a clinic for purposes of this subdivision.

(C) Section 1200.1 of the Health and Safety Code provides that "clinic" also means an organized outpatient health facility which provides direct psychological advice, services, or treatment to patients who remain less than 24 hours. As provided in section 1204.1 of the Health and Safety Code, such clinics serve patients under the direction of a clinical psychologist as defined in section 1316.5 of the Health and Safety Code, and are operated by a nonprofit corporation, which is exempt from federal taxation under paragraph (3), subsection (c) of section 501 of the Internal Revenue Code of 1954, as amended, or a statutory successor thereof, and which is supported and maintained in whole or in part by donations, bequests, gifts, grants, government funds, or contributions which may be in the form of money, goods, or services. In such clinics, any charges to the patient shall be based on the patient's ability to pay, utilizing a sliding fee scale. Such clinics may also provide diagnostic or therapeutic services authorized under Chapter 6.6 (commencing with section 2900) of Division 2 of the Business and Professions Code to patients in the home as an incident to care provided at the clinic facility.

(5) PHARMACIST. "Pharmacist" means a person to whom a license has been issued by the California State Board of Pharmacy, under the provisions of section 4200 of the Business and Professions Code, except as specifically provided otherwise in Chapter 9 of the Pharmacy Law.

(6) PHARMACY. "Pharmacy" means an area, place, or premises licensed by the California State Board of Pharmacy in which the profession of pharmacy is practiced and where prescriptions are compounded. Pharmacy includes, but is not limited to, any area, place, or premises described in a license issued by the California State Board of Pharmacy wherein controlled substances, dangerous drugs, or dangerous devices are stored, possessed, prepared, manufactured, derived, compounded, or repackaged, and from which the controlled substances, dangerous drugs, or dangerous devices are furnished, sold, or dispensed at retail. Pharmacy shall not include any area specifically excluded by paragraph (b) of section 4037 of the Business and Professions Code.

(7) PRESCRIPTION. "Prescription" means an oral, written, or electronic transmission order that is issued by a physician, dentist, optometrist, or podiatrist licensed in this state *and* given individually for the person or persons for whom ordered. The order must include all of the following:

(A) The name or names and address of the patient or patients.

(B) The name and quantity of the drug or device prescribed and the directions for use.

(C) The date of issue.

(D) Either rubber stamped, typed, or printed by hand or typeset, the name, address, and telephone number of the prescriber, his or her license classification, and his or her federal registry number, if a controlled substance is prescribed.

(E) A legible, clear notice of the conditions for which the drug is being prescribed, if requested by the patient or patients.

(F) If in writing, signed by the prescriber issuing the order.

(8) PHYSICIANS, DENTISTS, OPTOMETRISTS, AND PODIATRISTS. "Physicians," "dentists," "optometrists," and "podiatrists" are persons authorized by a currently valid and unrevoked license to practice their respective professions in this state. "Physician" means and includes any person holding a valid and unrevoked physician's and surgeon's certificate or certificate to practice medicine and surgery, issued by the Medical Board of California or the Osteopathic Medical Board of California and includes an unlicensed person lawfully practicing medicine pursuant to section 2065 of the Business and Professions Code, when acting within the scope of that section.

(9) MEDICINES. "Medicines" means:

(A) Except where taxable for all uses as provided in subdivision (c), any product fully implanted or injected in the human body, or any drug or any biologic, when such are approved by the U.S. Food and Drug Administration to diagnose, cure, mitigate, treat or prevent any disease, illness or medical condition regardless of ultimate use, or

(B) Any substance or preparation intended for use by external or internal application to the human body in the diagnosis, cure, mitigation, treatment or prevention of disease and which is commonly recognized as a substance or preparation intended for that use. The term medicines also includes certain articles, devices, and appliances as described in subdivision (b) of this regulation.

(b) "MEDICINES." In addition to the definition set forth in subdivision (a)(9) of this section, the term "medicines" means and includes the following items:

(1) PREPARATIONS AND SIMILAR SUBSTANCES. Preparations and similar substances intended for use by external or internal application to the human body in the diagnosis, cure, mitigation, treatment or prevention of disease and which are commonly recognized as a substance or preparation intended for such use qualify as medicines. Tax does not apply to the sale or use of such medicines sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6).

"Preparations and similar substances" include, but are not limited to, drugs such as penicillin, and other antibiotics, "dangerous drugs" (drugs that require dispensing only on prescription); alcohol (70% solution) and isopropyl; aspirin; baby lotion, oil, and powder; enema preparations; hydrogen peroxide; lubricating jelly; medicated skin creams; oral contraceptives; measles and other types of vaccines; topical creams and ointments; and sterile nonpyrogenic distilled water. Preparations and similar substances applied to the human body in the diagnosis, cure, mitigation, treatment, or prevention of disease qualify as medicines. "Preparations and similar substances" also include Total Parenteral Nutrition (also called TPN), Intradialytic Parenteral Nutrition (also called IDPN), and food provided by way of enteral feeding, except when the TPN, IDPN, or food provided by enteral feeding qualifies as a meal under Regulation 1503. For purposes of this regulation, TPN, IDPN, and enteral feeding are means of providing complete nutrition to the patient; TPN and IDPN are provided in the form of a collection of glucose, amino acids, vitamins, minerals, and lipids, TPN being administered intravenously to a patient who is unable to digest food through the gastrointestinal tract and IDPN being administered to hemodialysis patients as an integral part of the hemodialysis treatment; enteral feeding is the feeding of the patient directly into the gastrointestinal tract.

(2) PERMANENTLY IMPLANTED ARTICLES. Articles permanently implanted in the human body to assist the functioning of, as distinguished from replacing all or any part of, any natural organ, artery, vein or limb and which remain or dissolve in the body qualify as medicines. An article is considered to be permanently implanted if its removal is not otherwise anticipated. Tax does not apply to the sale or use of articles permanently implanted in the human body to assist the functioning of any natural organ, artery, vein or limb and which remain or dissolve in the body when such articles are sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6).

Permanently implanted articles include, but are not limited to, permanently implanted artificial sphincters; bone screws and bone pins, dental implant systems including dental bone screws and abutments; permanently implanted

catheters; permanently implanted hydrocephalus devices and their implanted pressure regulating components; implanted defibrillators and implanted leads; pacemakers; tendon implants; testicular gel implants; and ear implants. Sutures are also included whether or not they are permanently implanted. A non-returnable, nonreusable needle fused or prethreaded to a suture is regarded as part of the suture.

Implantable articles that do not qualify as "permanently" implanted medicines include, but are not limited to, Chemoport implantable fluid systems; Port-a-Cath systems used for drug infusion purposes; disposable urethral catheters; temporary myocardial pacing leads used during surgery and recovery; and defibrillator programmer and high voltage stimulator used with an implanted defibrillator. The sale or use of these items is subject to tax.

(3) ARTIFICIAL LIMBS AND EYES. Artificial limbs and eyes, or their replacement parts, including stump socks and stockings worn with artificial legs and intraocular lenses for human beings, qualify as medicines as provided by Revenue and Taxation Code section 6369 (c)(5). Tax does not apply to the sale or use of these items when sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6).

(4) ORTHOTIC DEVICES. Orthotic devices and their replacement parts, other than orthodontic devices, designed to be worn on the person of the user as a brace, support or correction for the body structure are medicines as provided under Revenue and Taxation Code section 6369(c)(3). The sale or use of orthotic devices and their replacement parts is not subject to tax when sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6). Orthotic devices and their replacement parts do not need to be furnished by a pharmacist, within the meaning of subdivision (d)(1), to be considered dispensed on prescription provided the devices are furnished pursuant to a written order of a physician or podiatrist. For the purposes of this regulation, orthotic devices furnished pursuant to a written order of a physician or podiatrist by, but not limited to, medical device retailers, clinics, physical therapists, device suppliers, intermediate care facilities, or other such persons, are deemed to be dispensed on prescription within the meaning of subdivision (d)(1).

Orthotic devices worn on the body of the person include, but are not limited to, abdominal binders and supports, ace bandages, ankle braces, anti-embolism stockings, athletic supporters (only for patients recovering from rectal or genital surgery), casts and cast components, cervical supports, neck collars, cervical traction devices, clavicular splints, post-surgical corsets, elbow supports, head halters, pelvic traction devices, post-operative knee immobilizers and braces, legging orthoses, rib belts and immobilizers, rupture holders, sacral belts, sacro-lumbar back braces, shoulder immobilizers, slings, stump shrinkers, sternum supports, support hose (and garter belts used to hold them in place), thumb and finger splints, trusses, and wrist and arm braces. All of the above must be worn on the body of the person and act as a brace, support or correction for body structure to qualify as a medicine. If any part of the orthotic device is not worn on the person, the device is not a medicine for the purposes of this regulation.

Orthopedic shoes and supportive devices for the foot do not qualify as medicines unless they are an integral part of a leg brace or artificial leg or are custom-made biomechanical foot orthoses. "Custom-made biomechanical foot orthosis" means a device that is made on a positive model of the individual patient's foot. The model may be individually constructed from suitable model material such as plaster of paris, stone, or wax, and may be manually constructed or fabricated using electronic technology.

"Custom-made biomechanical foot orthosis" do not include:

(A) any pre-made or pre-molded foot orthosis or shoe insert even if it has been modified or customized for an individual patient by the practitioner regardless of the method of modification;

(B) any foot orthosis fabricated directly on the patient's foot regardless of the method and materials used and regardless of its individual character; or

(C) any foot orthosis fabricated inside of the patient's shoe regardless of the method of manufacture and materials used and regardless of its individual character.

(5) PROSTHETIC DEVICES. Prosthetic devices and their replacements parts designed to be worn on or in the patient to replace or assist the functioning of a natural part of the human body are medicines as provided under Revenue and Taxation Code section 6369(c)(4). The sale or use of prosthetic devices and their replacement parts is not subject to tax when sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6). Prosthetic devices and their replacement parts do not need to be furnished by a pharmacist, within the meaning of subdivision (d)(1), to be considered dispensed on prescription provided the devices are furnished pursuant to a written order of a physician or podiatrist. For the purposes of this regulation, prosthetic devices furnished pursuant to a written order of a physician or podiatrist by, but not limited to, medical device retailers, clinics, physical therapists, device suppliers, intermediate care facilities, or other such persons are deemed to be dispensed on prescription within the meaning of subdivision (d)(1). For purposes of this regulation only, prosthetic devices include bags and tubing, as well as filters, locks, tape, clamps, and connectors which are integral to the tubing, each of which is used to

dispense enteral feeding to the patient, including: gastrostomy tubes (also called G tubes) which are used to deliver the nutrition directly into the stomach; jejunostomy tubes (also called J tubes) which are used to deliver the nutrition directly into the intestinal tract; and nasogastric tubes (also called NG tubes) which are used to deliver the nutrition directly through the nasal passage to the stomach. For purposes of this regulation only, prosthetic devices also include needles, syringes, cannulas, bags, and tubing, as well as filters, locks, tape, clamps, and connectors which are integral to the tubing, each of which is used to dispense TPN or IDPN to the patient, provided each of these items is used primarily to dispense the TPN or IDPN.

Prosthetic devices that are considered medicines when worn on or in the patient include, but are not limited to, acetabular cups, atrial valves, breast tissue expanders and tissue expanders, cervical cuff, dacron grafts, heart valves, orbital implant, nerve cups, rhinoplasty prosthesis, neuromuscular electrical stimulators, transcutaneous nerve stimulators, urinary incontinent devices, and wigs and hairpieces prescribed by a physician or podiatrist.

Prosthetic devices that do not qualify as "medicines," include, but are not limited to, air compression pumps and pneumatic garments; noninvasive, temporary pace makers; and vacuum/constriction devices used to treat male impotency; auditory, ophthalmic and ocular devices or appliances; and dental prosthetic devices and materials such as dentures, removable or fixed bridges, crowns, caps, inlays, artificial teeth, and other dental prosthetic materials and devices. Sales of such items are subject to tax in the same manner as any other sale of tangible personal property.

(6) DRUG INFUSION DEVICES. Programmable drug infusion devices worn on or implanted in the human body which automatically cause the infusion of measured quantities of a drug on an intermittent or continuous basis at variable dose rates and at high or low fluid volume into the body of the wearer of the device qualify as medicines under Revenue and Taxation Code section 6369(c)(6). The sale or use of the qualifying infusion device is not subject to tax when the device is sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6).

(c) EXCLUSIONS FROM THE DEFINITION OF "MEDICINES." Except as otherwise provided in subdivision (b), the following items are specifically excluded from the definition of medicines. Sales of these items are subject to tax in the same manner as any other sale of tangible personal property.

(1) Orthodontic, prosthetic (except as described in subdivision (b)(5)), auditory, ophthalmic or ocular devices orappliances.

(2) Articles which are in the nature of splints, bandages, pads, compresses, supports, dressings, instruments, apparatus, contrivances, appliances, devices or other mechanical, electronic, optical or physical equipment or article or the component parts and accessories thereof. "Medicines" does not include arch supports, cervical pillows, exercise weights (boots or belts), hospital beds, orthopedic shoes and supportive devices (unless an integral part of a leg brace or artificial leg), plastazote inserts, plastazote shoes, plastic shoes (custom or ready-made), sacro-ease seats, shoe modifications, spenco inserts, traction units (other than those fully worn on the patient), thermophore pads, or foot orthoses.

(3) Any alcoholic beverage the manufacture, sale, purchase, possession or transportation of which is licensed and regulated by the Alcoholic Beverage Control Act (Division 9, commencing with section 23000, of the Business and Professions Code).

(d) APPLICATION OF TAX—IN GENERAL. Tax applies to retail sales, including over-the-counter sales of drugs and medicines, and other tangible personal property by pharmacists and others. However, tax does not apply to the sale or use of medicines when sold or furnished under one of the following conditions:

(1) prescribed for the treatment of a human being by a person authorized to prescribe the medicines, and dispensed on prescription filled by a pharmacist in accordance with law, or

(2) furnished by a licensed physician, dentist or podiatrist to his or her own patient for treatment of the patient, or

(3) furnished by a health facility for treatment of any person pursuant to the order of a licensed physician, dentist or podiatrist, or

(4) sold to a licensed physician, dentist, podiatrist or health facility for the treatment of a human being, or

(5) sold to this state or any political subdivision or municipal corporation thereof, for use in the treatment of a human being; or furnished for the treatment of a human being by a medical facility or clinic maintained by this state or any political subdivision or municipal corporation thereof, or

(6) effective January 1, 1995, furnished by a pharmaceutical manufacturer or distributor without charge to a licensed physician, surgeon, dentist, podiatrist, or health facility for the treatment of a human being, or to an institution of higher education for instruction or research. Such medicine must be of a type that can be dispensed only: (a) for the treatment of a human being, and (b) pursuant to prescriptions issued by persons authorized to prescribe medicines. The exemption provided by this subdivision applies to the constituent elements and ingredients used to produce the medicines and to the tangible personal property used to package such medicines.

(e) SPECIFIC TAX APPLICATIONS.

(1) PRESCRIPTIONS. No person other than a licensed physician, dentist, optometrist or podiatrist is authorized to prescribe or write a prescription for the treatment of a human being. Tax does not apply to the sale or use of medicines prescribed by a licensed physician, dentist, optometrist, or podiatrist for the treatment of a human being and dispensed on prescription filled by a pharmacist.

(2) LICENSED PHYSICIAN, DENTIST OR PODIATRIST. Tax does not apply to a specific charge made by a licensed physician, dentist or podiatrist to his or her own patient for medicines furnished for the treatment of the patient. Tax also does not apply to sales of medicines to licensed physicians, dentists or podiatrists for the treatment of a human being regardless of whether the licensed physician, dentist or podiatrist makes a specific charge-to his or her patient for the medicines furnished.

(3) HEALTH FACILITY. Tax does not apply to sales of medicines by a health facility (as defined in suddivision (a)(4)) for the treatment of any person pursuant to the order of a licensed physician, dentist or podiatrist. Tax does not apply to sales of medicines to a health facility for the treatment of a human being regardless of whether or not a specific charge is made for the medicines.

(4) PHARMACEUTICAL MANUFACTURER OR DISTRIBUTOR. Tax does not apply to the storage, use or consumption of medicines furnished by a pharmaceutical manufacturer or distributor without charge to a licensed physician, surgeon, dentist, podiatrist, or health facility for the treatment of a human being or furnished without charge to an institution of higher education for instruction or research provided the medicines furnished are of a type that can be dispensed only (1) on prescription by persons authorized to prescribe and (2) for the treatment of a human being. The exemption from tax includes the costs of the materials used to package the "sample" medicines, such as bottles, boxes, blister packs, patches impregnated with medicines, or pre-filled syringes, and the elements and ingredients used to produce the "samples" whether or not such items are purchased under a resale certificate in this state or outside this state. When a pre-filled syringe or other such delivery device is used to package and contain a sample medicine (i.e., pre-filled with the medicine) as well as to inject or otherwise administer the medicine to the patient, the exemption from tax will not be lost due to the fact that the device is used for a dual purpose. However, the use of empty syringes or other such delivery devices, furnished to the licensed physician separately or included in the packages with the medicines, is subject to tax.

This exemption applies in the same manner to the use of clinical trial medicines during the United States Food and Drug Administration's drug development and approval process. "Clinical trial medicines" are substances or preparations approved as "Investigational New Drugs" by the United States Food and Drug Administration intended for treatment of, and application to, the human body, which are furnished by a pharmaceutical developer, manufacturer, or distributor to a licensed physician and subsequently dispensed, furnished, or administered pursuant to the order of the licensed physician. "Clinical trial medicines" do not include placebos. Placebos are not used for the treatment of a human being and, as such, do not qualify for the exemption provided under this subdivision. Thus, the use of placebos is subject to tax.

(5) ANTIMICROBIAL AGENTS USED BY HOSPITAL PERSONNEL. Tax does not apply to the sale or use of substances or preparations, such as antiseptic cleansers or scrubs, when such substances or preparations qualify as medicines and are used by hospital personnel on the patient or by hospital personnel on their own bodies to benefit the patient, and which constitute a critical component of the patient's treatment. Qualifying medicines used on the bodies of hospital personnel include antimicrobial agents used for preoperative scrubbing or hand cleansing prior to any patient contact such as Accent Plus Skin Cleanser; Accent Plus Perinal Cleanser; Bacti-Stat; Betadine; and Medi-Scrub. However, antimicrobial agents such as Accent Plus 1 Skin Lotion; Accent Plus 2 Body Massage; Accent Plus 2 Skin Crème; and Accent Plus Total Body Shampoo applied to the body of hospital personnel are not considered used in the treatment of the patient and the sale or use of these products is subject to tax.

(6) VITAMINS, MINERALS, HERBS, AND OTHER SUCH SUPPLEMENTS. In general, sales of vitamins, minerals, herbs and other such supplements are subject to tax. However, when vitamins, minerals, herbs and other such supplements are used in the cure, mitigation, treatment or prevention of disease, and are commonly recognized as a substance or preparation intended for such use, they will qualify as medicines for the purposes of Revenue and Taxation Code section 6369. As such, their sale or use is not subject to tax when sold or furnished under one of the conditions in subdivision (d)(1) through (d)(6).

(7) DIETARY SUPPLEMENTS AND ADJUNCTS. Dietary supplements and adjuncts furnished to a patient as part of a medically supervised weight loss program to treat obesity qualify as medicines for the purposes of Revenue and Taxation Code section 6369 when the product does not otherwise qualify as a food product under Regulation 1602. The sale or use of such products is not subject to tax when sold or furnished under one of the conditions in subdivision (d)(1) through (d)(6) of Regulation 1591.

(~~7~~8) DIAGNOSTIC SUBSTANCES, TEST KITS, AND EQUIPMENT. Tax applies to the sale or use of diagnostic substances applied to samples of cells, tissues, organs, or bodily fluids and waste after such samples have been removed, withdrawn, or eliminated from the human body. Diagnostic substances are applied to the samples outside the living body ("in vitro") in an artificial environment. They are not administered in the living body ("in vivo"). As the substances are not applied internally or externally to the body of the patient, they do not qualify as medicines under Revenue and Taxation Code section 6369.

Except as provided in Regulation 1591.1(b)(4), tax applies to the sale or use of test kits and equipment used to analyze, monitor, or test samples of cells, tissues, organs and blood, saliva, or other bodily fluids. Such items do not qualify as medicines regardless of whether they are prescribed for an individual by a person authorized to prescribe and dispensed pursuant to a prescription.

(f) INSURANCE PAYMENTS

(1) MEDICAL INSURANCE AND MEDI-CAL. The exemption of retail sales of medicines is not affected by the fact that charges to the person for whom the medicine is furnished may be paid, in whole or in part, by an insurer. This is so even though a joint billing may be made by the retailer in the name of both the person and the insurer.

(2) MEDICARE

(A) Medicare Part A. Tax does not apply to the sale of items to a person insured pursuant to Part A of the Medicare Act as such sales are considered exempt sales to the United States Government. Under Part A, the healthcare provider has a contract with the United States Government to provide certain services. Therefore, sales of medicines, devices, appliances, and supplies in which payment is made under Part A qualify as exempt sales to the United States Government.

(B) Medicare Part B. Tax applies to sales of items to a person in which payment is made pursuant to Part B of the Medicare Act. Sales made under Part B do not qualify as exempt sales to the United States Government even though the patient may assign the claim for reimbursement to the seller and payment is made by a carrier administering Medicare claims under contract with the United States Government. Under Part B, the seller does not have a contract with the United States Government. The contract is between the patient and the United States Government. Unless the sale is otherwise exempt (such as a sale of a medicine under subdivision (d)), the sale is subject to tax.

(3) EMPLOYER MEDICAL CONTRACTS. Certain employers have contracted with their employees to provide the latter with medical, surgical, and hospital benefits in a hospital operated by or under contract with the employer for a fixed charge. Usually the charge is by payroll deduction. These contracts are not insurance plans; rather, they are agreements to furnish specified benefits under stated conditions, one of which may be that no charge is to be made to the employee for prescribed medicines. The agreements may provide for making a charge for medicines furnished to out-patients but not to in-patients. This in no way affects the exemption of sales of medicines.

(g) RECORDS. Any pharmacy whether in a health facility or not must keep records in support of all deductions claimed on account of medicines. Section 4081 of the Business and Professions Code requires that all prescriptions filled shall be kept on file and open for inspection by duly constituted authorities.

Pursuant to section 4081 of the Business and Professions Code, physicians and surgeons and podiatrists must keep accurate records of drugs furnished by them. Any deduction on account of sales of medicines shall be supported by appropriate records.

(1) The following written information constitutes acceptable documentation for retailers in those cases where sales are made of supplies which are "deemed to be dispensed on prescription" within the meaning of Revenue and Taxation Code section 6369:

Name of purchaser

Name of doctor

Date of sale

Item sold

The sale price

(2) "DOUBLE DEDUCTION" UNAUTHORIZED. The law does not, of course, permit a double deduction for sales of exempt medicines. For example, if an exemption is claimed on account of a sale of a prescription medicine, no additional deduction for the same sale may be taken as a sale to the United States Government under the Medicare Program.

(3) Persons making purchases of items in which their sale or use is exempt under this regulation should give their suppliers an exemption certificate pursuant to Regulation 1667.

Regulation 1602. FOOD PRODUCTS

Reference: Sections 6091, 6353 and 6359, Revenue and Taxation Code; California Constitution, Article XIII, Section 34.

(a) IN GENERAL. Tax does not apply to sales of food products for human consumption except as provided in Regulations 1503, 1574, and 1603. (Grocers, in particular, should note that tax applies to sales of "hot prepared food products" as provided in Regulation 1603(e).)

(1) "Food products" include cereal and cereal products, including malt and malt extracts, milk and milk products, including ice cream, ice milk and ice cream and ice milk novelties, sherberts, imitation ice cream and imitation ice milk, dried milk products, sugar of milk, milk shakes, malted milks, and any other similar type beverages composed at least in part of milk or a milk product and requiring the use of milk or a milk product in their preparation, oleomargarine, meat and meat products, fish and fish products, eggs and egg products, vegetables and vegetable products, including dehydrated vegetables, fruit and fruit products, spices and salt, coffee and coffee substitutes, tea, cocoa and cocoa products, sugar and sugar products, baby foods, bakery products, marshmallows, baking powder, baking soda, cream of tartar, coconut, flavoring extracts, flour, gelatin, jelly powders, mustard, nuts, peanut butter, sauces, soups, syrups (for use as an ingredient of, or upon, food products as defined herein), yeast cakes, olive oil, bouillon cubes, meat extracts, popcorn, honey, jams, jellies, certo, mayonnaise, and flavored ice products, including popsicles and snow cones. "Food products" include candy, confectionery, and chewing gum.

(2) "Food products" include all fruit juices, vegetable juices, and other beverages, whether liquid or frozen, including all beverages composed in part of fruit or vegetable juice and concentrates, powders, or other bases for such beverages, and noncarbonated and noneffervescent bottled water intended for human consumption regardless of the method of delivery. "Food products" does not include carbonated or effervescent bottled waters, spirituous, malt or vinous liquors, or carbonated beverages.

Sales of purified drinking water through vending machines or outlets in retail stores where the water enters the machine or outlet through local supply lines and is dispensed into the customer's own containers are exempt under Revenue and Taxation Code section 6353.

Tax does not apply to sales of water in bulk quantities of 50 gallons or more to an individual for use in a residence when that residence is not serviced by lines, mains or pipes.

(3) "Food products" do not include medicines, cough drops, mineral oils, cigarettes, cigars, tobacco, coloring extract, ice, and dog, cat, bird and other animal foods.

(4) "Food products" do not include any product for human consumption in liquid, powdered, granular, tablet, capsule, lozenge, or pill form (A) which is described on its package or label as a food supplement, food adjunct, dietary supplement, or dietary adjunct, and to any such product (B) which is prescribed or designed to remedy specific dietary deficiencies or to increase or decrease generally one or more of the following areas of human nutrition:

1. Vitamins
2. Proteins
3. Minerals
4. Caloric intake

In determining whether a product falls within category (B), it is important whether the manufacturer has specially mixed or compounded ingredients for the purpose of providing a high nutritional source. For example, protein supplements and vitamin pills are taxable as food supplements.

Other items, such as cod liver oil, halibut liver oil, and wheat germ oil, are considered dietary supplements and thus subject to tax even though not specially compounded.

However, unusual foods such as brewer's yeast, wheat germ and seaweed are not subject to tax except when their label states they are a food supplement or the equivalent. Finally, the compounding of nutritional elements in items traditionally accepted as food does not make them taxable, e.g., vitamin-enriched milk and high protein flour.

Tax, however, does not apply to any such products which either are exempted by Revenue and Taxation Code section 6369, respecting prescription medicines, or are complete dietary foods providing the user in the recommended daily dosage with substantial amounts of vitamins, proteins, minerals and foods providing adequate caloric intake. ~~An example of t~~The latter is a food ~~daily providing~~if it provides the user with the following daily minimums:

1. 70 grams of high quality protein
2. 900 calories
3. Minimum daily requirements as established by the regulations of the Federal Food and Drug Administration of the following vitamins: A, B1, C, D, Riboflavin, and Niacin or Niacinamide; and the following minerals: Calcium, Phosphorus, Iron and Iodine.

When supplement or adjunct products that do not meet the definition of food under this subdivision are furnished by a physician to his or her own patient as part of a medically supervised weight loss program to treat obesity, such products are regarded as "medicine." The sale and use of such products are exempt from tax pursuant to subdivision (e)(7) of Regulation 1591 which interprets and explains Revenue and Taxation Code section 6369.

(b) SALES OF COMBINATION PACKAGES. When a package contains both food products (e.g., dried fruit) and nonfood products (e.g., wine or toys), the application of tax depends upon the essential character of the complete package. If more than 10 percent of the retail value of the complete package, exclusive of the container, represents the value of the nonfood products, a segregation must be made if the retailer has documentation that would establish the cost of the individual component parts of the package, with the tax measured by the retail selling price of such nonfood products.

When the retailer does not have documentation that would establish the cost of the individual component parts of the package, and the package consists of nonfood products whose retail selling price would exceed 10 percent of the retail selling price for the entire package, exclusive of the container, the tax may be measured by the retail selling price of the entire package.

If the retail value of the nonfood products is 10 percent or less, exclusive of the container, and the retail value of the container is 50 percent or less of the retail value of the entire package, the selling price of the entire package is not subject to tax.

(c) SALES OF NON-EDIBLE DECORATIONS. When the sale of a cake or other bakery good for a single price includes non-edible decorations, the application of tax depends upon the value of the non-edible merchandise versus the value of the cake or bakery good. If more than 50 percent of the total retail value of the cake or bakery good represents the value of non-edible decorations, a segregation must be made and the tax measured by the retail selling price of such non-edible decorations. If the price of the non-edible decoration is separately stated, then tax applies to such charge.

(d) FOOD PRODUCTS PROCESSED BY THE CONSUMER. A commodity included in the term "food products" under Revenue and Taxation Code section 6359 may be sold to a consumer to be processed and incorporated into a product which is for human consumption but which is excluded from the term "food products." For example, grapes may be sold to be used in making wine for consumption and not for resale. If the commodity sold to the consumer is included in the term "food products" and if the product into which it is incorporated is for human consumption, the sale of the commodity is within the exemption provided by this section.

Regulation History

Type of Regulation: Sales and Use Tax

Regulation: 1591 & 1602

Title: 1591, Medicines and Medical Devices, and 1602, Food Products .

Preparation: Lynn Whitaker
Legal Contact: Windie Scott

Regulations, 1591, *Medicines and Medical Devices*, and 1602., *Food Products* are proposed regulatory changes to the processes for clarifying the manner in which tax applies to sales of dietary supplement and adjunct products that are furnished by a physician as part of a medically supervised weight loss program to treat obesity.

History of Proposed Regulation:

September 17, 2008	Public hearing
September 8, 2008	45-day public comment period ends
July 25, 2008	OAL publication date; 45-day public comment period begins; IP mailing
July 14, 2008	Notice to OAL
June 24, 2008	BTC Board Authorized Publication (vote 5-0)
May 2, 2008	Last day for IP to respond to Initial Discussion Paper
April 15, 2008	First Interested Parties (IP) meeting

Sponsor:	NA
Support:	NA
Oppose:	NA