



STATE BOARD OF EQUALIZATION

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Executive Director

June 13, 2008

Dear Interested Party:

Enclosed are the Agenda, Issue Paper, and Revenue Estimate for the June 24, 2008, Business Taxes Committee meeting. This meeting will address the proposed amendments to Regulations 1602, *Food Products*, and 1591, *Medicines and Medical Devices*.

Action 1 on the Agenda concerns whether Regulations 1602 and 1591 should be revised to clarify how 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.

If you are interested in other topics to be considered by the Business Taxes Committee, you may refer to the "Business Taxes Committee" page on the Board's Internet web site (<http://www.boe.ca.gov/meetings/btcommittee.htm>) for copies of Committee discussion or issue papers, minutes, a procedures manual, and a materials preparation and review schedule arranged according to subject matter and meeting date.

Thank you for your input on these issues and I look forward to seeing you at the Business Taxes Committee meeting at **9:30 a.m.** on **June 24, 2008** in Room 121 at the address shown above.

Sincerely,

Randie L. Henry, Deputy Director  
Sales and Use Tax Department

RLH: llw

## Enclosures

cc: (all with enclosures)

Honorable Judy Chu, Ph.D., Chair, Fourth District  
Honorable Betty T. Yee, Vice Chairwoman, First District (MIC 71)  
Honorable Bill Leonard, Member, Second District (MIC 78)  
Honorable Michelle Steel, Member, Third District  
Honorable John Chiang, State Controller, c/o Ms. Marcy Jo Mandel (via e-mail)  
Mr. Mark Ibele, Board Member's Office, Fourth District (via e-mail)  
Mr. Steve Shea, Board Member's Office (3 copies), Fourth District (via e-mail)  
Mr. Alan LoFaso, Board Member's Office, First District (via e-mail)  
Ms. Sabina Crocette, Board Member's Office, First District (via e-mail)  
Mr. Gary Qualset, Board Member's Office, First District (via e-mail)  
Mr. Mengjun He, Board Member's Office, First District (via e-mail)  
Mr. Lee Williams, Board Member's Office, Second District (via e-mail)  
Mr. Erik Caldwell, Board Member's Office, Third District (via e-mail)  
Mr. Ken Maddox, Board Member's Office, Third District (via e-mail)  
Mr. Neil Shah, Board Member's Office, Third District (via e-mail)  
Ms. Elizabeth Maeng, Board Member's Office, Third District (via e-mail)  
Ms. Christina Rueck, Board Member's Office, Third District (MIC 77)  
Ms. Melanie Darling, State Controller's Office (via e-mail)  
Mr. Ramon J. Hirsig (via e-mail)  
Ms. Kristine Cazadd (via e-mail)  
Ms. Randie L. Henry (via e-mail)  
Mr. Jeff Vest (via e-mail)  
Mr. Robert Lambert (via e-mail)  
Mr. Randy Ferris (via e-mail)  
Mr. David Levine (via e-mail)  
Ms. Windie Scott (via e-mail)  
Mr. Robert Tucker (via e-mail)  
Ms. Natasha Ralston (via e-mail)  
Mr. Todd Gilman (via e-mail)  
Mr. Dave Hayes (via e-mail)  
Ms. Laureen Simpson (via e-mail)  
Ms. Freda Orendt (via e-mail)  
Mr. Stephen Rudd (via e-mail)  
Mr. Robert Buntjer (via e-mail)  
Mr. Jeff McGuire (via e-mail)  
Mr. James Kuhl (via e-mail)  
Mr. Geoffrey E. Lyle (via e-mail)  
Ms. Leila Hellmuth (via e-mail)  
Ms. Lynn Whitaker (via e-mail)  
Ms. Lynda Cardwell (via e-mail)



**AGENDA — June 24, 2008 Business Taxes Committee Meeting**  
***Proposed regulatory changes to clarify the application of tax to sales of dietary supplement and adjunct products furnished by physicians***

<p><b>Action 1 — Proposed revisions to Regulation 1602(a)(4)</b></p>	<p><b>Regulation 1602. FOOD PRODUCTS</b></p> <p>(a) (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:</p> <ol style="list-style-type: none"><li>1. Vitamins</li><li>2. Proteins</li><li>3. Minerals</li><li>4. Caloric intake</li></ol> <p>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.</p> <p>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.</p> <p>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.</p> <p>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. <del>An example of t</del><u>The latter is a food daily providing if it provides the user with the following daily minimums:</u></p> <ol style="list-style-type: none"><li>1. 70 grams of high quality protein</li><li>2. 900 calories</li><li>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.</li></ol> <p><u>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 is exempt from tax pursuant to subdivision (e)(7) of Regulation 1591 which interprets and explains Revenue and Taxation Code section 6369.</u></p>
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**AGENDA — June 24, 2008 Business Taxes Committee Meeting**  
***Proposed regulatory changes to clarify the application of tax to sales of dietary supplement and adjunct products furnished by physicians***

<p><b>Action 1 — Proposed new subdivision Regulation 1591(e)</b></p>	<p><b>Regulation 1591, MEDICINES AND MEDICAL PRODUCTS.</b></p> <p>(e) SPECIFIC TAX APPLICATIONS.</p> <p><u>(7) DIETARY SUPPLEMENTS AND ADJUNCTS.</u> 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.</p> <p><del>(7)</del> <b>DIAGNOSTIC SUBSTANCES, TEST KITS, AND EQUIPMENT.</b> 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.</p> <p>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.</p>
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Issue Paper Number **08-002**



- Board Meeting
- Business Taxes Committee
- Customer Services and Administrative Efficiency Committee
- Legislative Committee
- Property Tax Committee
- Other

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## **Proposed regulatory changes to clarify the application of tax to sales of dietary supplement and adjunct products furnished by physicians**

### **I. Issue**

Whether Regulations 1602, *Food Products*, and 1591, *Medicines and Medical Devices*, should be revised to clarify how 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.

### **II. Alternative 1 - Staff Recommendation**

Staff recommends revising Regulation 1602 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.” Staff further recommends adding a new subdivision (e)(7) 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.

The proposed revisions are attached as Exhibits 2 and 3.

### **III. Other Alternative Considered**

Do not revise Regulations 1602 and 1591.

## IV. Background

In the audit of a weight loss clinic, 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, when analyzing products of this nature, staff first determines whether the item qualifies as a food product. If the item is not a food product, staff then determines whether the product qualifies under the more complex exemption provided for prescription medicines.

**Exemption for sales of food.** 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, *Food Products*, further explains in subdivision (a)(4):

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 the latter is a food daily providing the user with the following:

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.

This portion of subdivision (a)(4) was added to Regulation 1602 in 1973 to incorporate Business Taxes General Bulletin 62-6, dated May 7, 1962. From the available records, it appears the bulletin was published based on Board staff’s analysis of one of the first meal replacement powdered drink mixes to determine whether the product should be considered a food product or dietary supplement. The product labels stated that the powdered drink mixes provided a day’s supply of protein, fat, carbohydrates, minerals, and vitamins, and could be used as a sole source of nutrition. Based on these statements, we believe staff concluded the products met the daily requirements established by the Federal Food and Drug Administration at the time and were considered complete dietary foods.

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. As a result, a meal replacement product which provides fewer than

**FORMAL ISSUE PAPER**

Issue Paper Number 08-002

900 calories per day<sup>1</sup> by itself (i.e., excluding anything to be added to the product, such as milk) would not qualify as a complete dietary food under Regulation 1602.

As explained on page 2, the meal replacement products under consideration in the audit provided only 800 calories per day. Consequently, the products were not considered “complete dietary foods” and, thus, sales of the products did not qualify as exempt as sales of food products. The next step in staff’s analysis was to determine if the sales of the products qualified as nontaxable sales of medicines.

**Exemption for sales of medicines.** 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.”

Regulation 1591, *Medicines and Medical Devices*, further explains in subdivision (e)(6):

(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).

In determining whether the dietary supplement products qualified for exemption, staff considered (1) whether the products met the definition of a “medicine” and (2) whether the products were furnished in such a way to qualify for exemption. With regard to the first criteria, Board staff has previously concluded that obesity is a disease. Staff has also previously determined that supplement products are medicines when internally applied to the human body to treat obesity. With regard to the second criteria, the products in question were furnished by a physician to his or her own patients as part of a medically supervised weight loss program to treat obesity. Given this set of facts, staff concluded that sales of the products were exempt from tax as exempt sales of medicines.

This issue was sent to the Business Taxes Committee to determine whether Regulations 1602 and 1591 should be revised to clarify how tax applies in these situations. Staff met with interested parties on April 15, 2008 to discuss the proposed changes, and as discussed below, minor revisions to staff’s originally proposed language were made. The Business Taxes Committee is scheduled to discuss this issue at its meeting on June 24, 2008.

## V. Discussion

**Products affected by proposed revisions.** It should be noted that the proposed revisions only clarify the application of tax to supplement or adjunct products that are not considered complete dietary foods when

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<sup>1</sup> To determine whether the minimum standards established by Regulation 1602 are met, the daily nutritional content offered by the product is determined by multiplying the nutritional components of a single serving by the number of servings recommended per day on the label. When there is no such recommendation, staff bases the determination on three servings per day (based on the assumption that, unless stated to the contrary, a person consumes three meals per day).

**FORMAL ISSUE PAPER**

Issue Paper Number 08-002

such products are furnished by a physician for the treatment of obesity. Such products must be in liquid, powdered, granular, tablet, capsule, lozenge, or pill form and are

- Described on their package or label as a food supplement, food adjunct, dietary supplement, or dietary adjunct, or
- 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.

Sales of complete dietary foods and other food products are not affected by the proposed revisions.

Although staff is not proposing that the 900 calorie daily minimum requirement in 1602(a)(4) be changed, the question was raised at the interested party meeting about how the minimum compares with current FDA provisions. The FDA has currently adopted a 2,000-calorie diet as the basis for calculating Daily Reference Values and the percentages of Daily Values that appear on food product labels. However, recommended calorie intake varies depending on factors such as age, gender, and activity level. Staff believes that the 900 calories minimum requirement remains appropriate for determining if a product qualifies as a complete dietary food for sales and use tax purposes, as it is a conservative guideline that has been consistently used by taxpayers and Board staff.

**Proposed language revised to be consistent with current regulatory language.** At the April 15, 2008 meeting, interested parties commented that staff's proposed language included a new term, "meal replacement products." Interested parties were concerned that this new term would be confusing to taxpayers and Board staff. Staff intended this term to be a generic description for beverages and powdered drink mixes that people consume instead of eating a meal. However, staff agrees that the proposed revisions would be more easily understood if they were consistent with the language currently in Regulations 1602 and 1591. Accordingly, staff has replaced the previously proposed term "meal replacement products" with "dietary supplement and adjunct products" (see Exhibits 2 and 3). Staff and interested parties agree that the revised language is clearer.

**Clarified that the example in 1602(a)(4) is actually a list of requirements.** As explained in the Background section, 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. In other words, the language is a listing of requirements, rather than an example of what qualifies. In view of this interpretation, staff has deleted the phrase "for example" and made other minor revisions to clarify that the minimums listed are requirements (see Exhibit 2).

## **VI. Alternative 1 - Staff Recommendation**

### **A. Description of Alternative 1**

Staff recommends revising Regulation 1602 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." Staff further recommends adding a new subdivision (e)(7) 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.

**FORMAL ISSUE PAPER**

Issue Paper Number 08-002

**B. Pros of Alternative 1**

Proposed changes clarify the current application of tax to the sale and use of dietary supplement and adjunct products furnished by a physician for the treatment of obesity.

**C. Cons of Alternative 1**

None.

**D. Statutory or Regulatory Change for Alternative 1**

No statutory change is required. However, staff's recommendation does require the amendment of Regulations 1591 and 1602.

**E. Operational Impact of Alternative 1**

Staff would notify taxpayers of the amendments to Regulations 1591 and 1602 through an article in the Tax Information Bulletin (TIB).

**F. Administrative Impact of Alternative 1**

**1. Cost Impact**

The workload associated with publishing the regulation and TIB is considered routine. Any corresponding cost would be absorbed within the Board's existing budget.

**2. Revenue Impact**

None. See Revenue Estimate (Exhibit 1).

**G. Taxpayer/Customer Impact of Alternative 1**

Clarification in the regulations will help physicians understand the application of tax to dietary supplement and adjunct products they furnish in their obesity treatment programs. Overall taxpayer impact is minimal as the proposed revisions do not change the current application of tax to these transactions.

**H. Critical Time Frames of Alternative 1**

Implementation will take place 30 days following approval of the regulation by the State Office of Administrative Law.

**VII. Alternative 2 – No Revisions**

**A. Description of Alternative 2**

Do not revise Regulations 1591 and 1602.

**B. Pros of Alternative 2**

The proposed revisions do not change the current application of tax. Revisions to clarify how tax applies to such specific transactions could be viewed as unnecessary. In addition, not revising Regulations 1591 and 1602 will avoid the workload involved in processing and publicizing the revisions.

**FORMAL ISSUE PAPER**

Issue Paper Number 08-002

**C. Cons of Alternative 2**

Current regulations do not expressly explain how tax applies to the sale and use of dietary supplements and adjuncts furnished by physicians to their patients for the treatment of obesity. Not revising Regulations 1591 and 1602 may result in a continued lack of clarity in this area and lead to the expenditure of staff time to audit these transactions and to explain the application of tax to the public.

**D. Statutory or Regulatory Change for Alternative 2**

None.

**E. Operational Impact of Alternative 2**

None.

**F. Administrative Impact of Alternative 2**

**1. Cost Impact**

None.

**2. Revenue Impact**

None. See Revenue Estimate (Exhibit 1).

**G. Taxpayer/Customer Impact of Alternative 2**

Without clarifying language in the regulations, some taxpayers may not understand how tax applies to these transactions. Consequently, they may pay more tax than is due or have to seek advice from Board staff.

**H. Critical Time Frames of Alternative 2**

None.

**Preparer/Reviewer Information**

Prepared by: Tax Policy Division, Sales and Use Tax Department

Current as of: June 9, 2008

**REVENUE ESTIMATE**

STATE OF CALIFORNIA  
BOARD OF EQUALIZATION



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**Proposed regulatory changes to clarify the application of tax to sales of dietary supplement and adjunct products furnished by physicians**

**Alternative 1 – Staff Recommendation**

Staff recommends revising Regulation 1602 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.” Staff further recommends adding a new subdivision (e)(7) 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.

**Other Alternative Considered**

Do not revise Regulations 1602 and 1591

**Background, Methodology, and Assumptions**

**Alternative 1 – Staff Recommendation**

There is nothing in staff recommendation that would impact sales and use tax revenue. Staff recommendation clarifies existing regulatory language specific to the application of tax on dietary supplements and adjunct products when those supplements and products are furnished by a physician directly to a patient and used as part of a medically supervised weight loss program to treat obesity.

**Alternative 2 - Other**

There is nothing in the alternative 2 that would impact sales and use tax revenue.

Revenue Estimate

## **Revenue Summary**

Alternative 1 – staff recommendation does not have a revenue impact.

Alternative 2 – alternative 2 does not have a revenue impact.

## **Preparation**

Mr. Bill Benson, Jr., Research and Statistics Section, Legislative and Research Division, prepared this revenue estimate. Mr. Dave Hayes, Manager, Research and Statistics Section, Legislative and Research Division, and Mr. Jeff McGuire, Tax Policy Manager, Sales and Use Tax Department, reviewed this revenue estimate. For additional information, please contact Mr. Benson at (916) 445-0840.

Current as of June 9, 2008.

## **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~~ 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 is 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 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 replacement 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 or appliances.

(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 subdivision (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) 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.