

425.0053.100

Memorandum**To:** Mr. Jeffrey L. McGuire, Chief
Tax Policy Division, MIC:92**Date:** November 17, 2008**From:** Cary Huxsoll
Tax Counsel, MIC:82**Telephone:** (916) 324-2641**Subject:** Legal Opinion Request – Medicinal Claims
Assignment No. 08-385

This is in response to your October 9, 2008 memorandum in which you request a legal opinion clarifying when food products such as herbal teas should be classified as food, medicines, or supplements under California Code of Regulations, title 18, section (hereafter Regulation or Reg.) 1602. In your memo, you state, in relevant part:

“When an item qualifies as medicine under subdivision (a)(3) of [Regulation 1602], it does not qualify as a food product. To date, we relied on the guidance provided in annotations and looked for written claims of medicinal use to determine if the sale of a food product including an herb or herbal tea, or other similar product is exempt as a sale of a food product or taxable as a sale of medicine under Revenue and Taxation Code . . . section 6359(c), and Regulation 1602 (a)(3). However, due to recurring questions from taxpayers and our staff regarding these products, the guidance provided in some of the annotations is unclear and confusing, causing inconsistencies in the application of tax. For example, while some of the annotated opinions require that the . . . medicinal claim be specific, other opinions conclude that a generalized claim is sufficient to qualify a product as medicine ([Sales and Use Tax] Annotations 245.0499.200, 245.0499.300, 245.0722, 245.1369).

“The confusion in the classification of products as either a food, medicine, or supplement also makes it difficult to maintain uniformity in applying the tax to separate sales of the same product, especially herbal teas. For example, in the course of recent audit activities, our staff found medicinal claims included in the packaging of Ginseng Root Tea, Herbal Laxative Tea, and Slimming Special Tea, and, based on their interpretation of the specificity of the claim, staff in different district offices reached different conclusions. One opinion was that the products qualify as food because the medicinal claims do not rise to the level of ‘medicine’ as defined in Regulation 1591 (a)(9) and (b), or ‘supplements’ as defined in 1602(a)(4)(B) and 1591(e)(6). The other opinion was that the items qualify as medicine due to the specificity of the medicinal claim in the package and the fact that it indicates the product is intended to be used as medicine, or as a product

prescribed or designed to remedy specific dietary deficiencies under 1602(a)(4)(B). The fact that the packaging included an ingredient commonly known as a laxative, and warnings that the products are not suitable for children, the elderly, and pregnant women, and that the use of the products should be discontinued when excessive bowel movements occur, contributed to staff's conclusion that the products fail to qualify as food.

"In addition, Annotation 245.0518 states that sales of honey that make no medicinal or weight-loss claims are exempt from tax. The implication is that a known food product such as honey could fail to qualify as food if it were to make a medicinal claim. Although it is our opinion that oatmeal is a well-established food product, a test relying on specific medicinal claims could support an argument that certain brands of oatmeal are medicine, since the package indicates that the fiber level in oatmeal works to remove cholesterol from the body and lower high cholesterol levels. The concern is that as well-established food products are increasingly marketed as having medicinal benefits, the inconsistency and confusion in the classification of products as food or medicine, based on a written medical claim, will increase.

"Based on the above, we ask that you review the 'medicinal claim' test that is included in a number of annotations, and that you provide specific guidance regarding the following:

"1. What constitutes 'medicine' rather than food pursuant to subdivision (a)(3) of Regulation 1602;

"2. How the term 'medicine' in Regulation 1602 relates to the definition of medicine in Regulation 1591.

"In addition, in regard to supplements, we ask for clarification regarding:

"3. Whether a dried herb sold in a ground/crushed form such as in tea bags, as opposed to cut leaf form, is considered to be in powder form for purposes of subdivision (a)(4) of Regulation 1602."

You ask several questions concerning the application of tax to sales of food products. I will first provide a discussion of relevant portions of the Sales and Use Tax Law and their corresponding regulations and then address your specific questions.

DISCUSSION

General Provisions of the Sales and Use Tax Law

California imposes a sales tax measured by a retailer's gross receipts from the retail sale of tangible personal property inside this state, unless the sale is specifically exempted from taxation by statute. (Rev. & Tax. Code, §§ 6051, 6091.) The sales tax is imposed on the retailer who may collect reimbursement from its customer if the contract of sale so provides. (Civ. Code, § 1656.1;

Reg. 1700.) When sales tax does not apply, use tax is imposed, measured by the sales price of property purchased from a retailer for the storage, use, or other consumption of the property in California, unless specifically exempted or excluded from taxation by statute. (Rev. & Tax. Code, §§ 6201, 6401.) The use tax is imposed on the person actually storing, using, or otherwise consuming the property. (Rev. & Tax. Code, § 6202.) Taxable gross receipts or sales price includes all amounts received with respect to the sale, with no deduction for the cost of the materials, service, or expense of the retailer passed on to the purchaser, unless there is a specific statutory exclusion. (Rev. & Tax. Code, §§ 6011, 6012.)

Application of Tax to the Sales of Food Products

Revenue and Taxation Code section 6359 provides an exemption from sales and use taxes for sales of food products for human consumption under certain circumstances. Regulation 1602 interprets and applies Revenue and Taxation Code section 6359, and relevant to your inquiry, subdivisions (a)(1) and (a)(2) of Regulation 1602 addresses what items are considered “food products” under the Sales and Use Tax Law. Relevant to your inquiry, tea is a food product. (Rev. & Tax. Code, § 6359, subd. (b)(1); Reg. 1602, subd. (a)(1).)

“Food products” do not include “medicines and preparations in liquid, powdered, granular, tablet, capsule, lozenge, and pill form sold as dietary supplement or adjuncts.” (Rev. & Tax. Code § 6359, subd. (c).) Even if a product would otherwise qualify as a food product for the purposes of the exemption described in Revenue and Taxation Code section 6359 (hereafter the food products exemption), it does not qualify as a food product if it is a medicine or if it is sold as a supplement or adjunct. (Rev. & Tax. Code, § 6359, subd. (c); Reg. 1602, subd. (a)(3), (a)(4).) A product is either a food, medicine, or a supplement or adjunct; these classifications are mutually exclusive.

“Medicines” are defined in subdivision (b) of Revenue and Taxation Code section 6369. It states, in relevant part:

“‘Medicines,’ as used in this section, means 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 commonly recognized as a substance or preparation intended for that use.”

Revenue and Taxation Code section 6369 excludes certain items from the definition of medicines; however, these exclusions are not relevant to your inquiry.¹ Regulation 1591 interprets and applies Revenue and Taxation Code section 6369. Subdivision (a)(9)(B) of Regulation 1591 provides an identical definition of medicine to the definition found in subdivision (b) of Revenue and Taxation Code section 6369.² Regulation 1591, subdivision (a)(9)(A) further defines medicine and states, in relevant part:

¹ Subdivision (b)(3) of Revenue and Taxation Code section 6369 states that alcoholic beverages licensed and regulated by the Alcoholic Beverages Control Act are not medicines. Such beverages are also not food products. (Rev. & Tax. Code, § 6359, subd. (b)(3); Reg. 1602, subd. (a)(2).)

² Regulation 1591 also contains similar exclusions to the definition of medicines to those found in Revenue and Taxation Code section 6369. (See Regulation 1591, subd. (c).)

“‘Medicines’ means . . . 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[.]”

Subdivision (a)(4) of Regulation 1602 provides further detail on how food products do not include preparations sold as supplements or adjuncts. It states, in relevant part:

“‘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.”

Food products do not include products described in either category (A) or category (B) of this subdivision. In other words, even if a product is not described on its package or label as a food supplement, food adjunct, dietary supplement, or dietary adjunct, it still will not qualify as a food product if it falls within the description of category (B).

Inconsistent Application of Sales and Use Tax Annotations

As you discuss in your memorandum, there has been a great deal of confusion for both taxpayers and Board staff in applying these rules. Many letters written by the Board’s Legal Department on this topic have been the subject of annotations. These annotations have provided confusing and sometimes conflicting advice to taxpayers and Board staff. As discussed below, by way of nonexhaustive example, certain annotations concerning herbs sold by acupuncturists are in

direct conflict. This confusion and conflict is illustrated on the one hand by Sales and Use Tax Annotation (hereafter Annotation or Annot.) 245.0501 (12/31/91), which states that herbs sold by a licensed acupuncturist are sold for medicinal purposes and the sales do not qualify for the food products exemption. Specifically, this annotation provides:

“A licensed acupuncturist in the state of California, with a doctorate in oriental medicine, is considered a primary health care practitioner in the state of California. The acupuncturist dispenses herbs and supplements to patients.

“The Legislature, in adopting the language in section 6369(a)(1) Revenue and Taxation Code chose to adopt the limiting definition of ‘prescription’ found in section 4036 of the Business and Professional Code rather than the broader interpretation implicit in section 4937 Business and Professional Code. The reference in Revenue and Taxation Code section 6369(a)(1) to ‘person authorized to prescribe medicine’ means that person must be a physician, dentist, or podiatrist. Unless the acupuncturist is also licensed as one of these entities, his/her prescriptions are not exempted from the sales and use taxes as being within the prescription medicine exemption. In addition, the prescription must be filled by ‘a registered pharmacist in accordance with the law.’

“Since the sales are made for medicinal purposes, the herb and supplement sales also do not qualify under the food product exemption.”

On the other hand, Annotation 245.0506 (8/26/96) states that herbs sold by acupuncturist with remedial intent are exempt from tax as a sale of food products for human consumption if medicinal claims are made orally and not in writing.

“Herbs are sold to clients in brown paper bags by an acupuncturist. Many of the bulk herbs are listed as food products, but they are given with remedial intent. Sales of those herbs which are ordinarily food products in unlabeled brown paper bags are exempt from tax under section 6359 provided that the only instructions regarding the herbs are oral.”

Thus, taxpayers and Board staff who have attempted to follow the guidance provided in such annotations, which are focused on the significance of medicinal claims, have reached different conclusions as to the proper application of tax to the same sales depending on which annotations they rely. Because of the confusing guidance provided by these annotations, retailers who have charged customers for tax reimbursement on such transactions and have reported tax to the state and retailers who have not reported tax should both be viewed as properly following guidance provided by the Board.

Products Sold as Supplements or Adjuncts and Medicines

It appears that a source of much of the confusion in determining the application of tax to these transactions results from improperly applying the rules associated with supplements and food adjuncts to medicines. For example, the back-up letter to Annotation 245.0499.250 (8/25/97)

recommends deleting numerous annotations on the basis that the annotations confuse various provisions of Regulation 1602, subdivision (a)(3) and Regulation 1602, subdivision (a)(4).³ Principals concerning food supplements were applied to medicines and vice versa.

As stated above, the food products exemption does not apply to medicines or to preparations in certain forms sold as dietary supplements or adjuncts. (Rev. & Tax. Code, § 6359, subd. (c).) In applying these provisions, Regulation 1602 states, among other things, that food products do not include medicines or products in certain forms labeled as supplements or adjuncts. (Reg. 1602, subd. (a)(3), (a)(4).)

Products labeled as food supplements or adjuncts are not food products because they are being sold as supplements or adjuncts. It is necessary to examine the label in order to determine if the product is being sold as a supplement. (Reg. 1602, subd. (a)(4).) At some point the Legal Department apparently began applying this analysis to subdivision (a)(3) of Regulation 1602 and looked at a product's label to determine if it is being sold as a medicine even though there is no direction in the regulation to do so. The standard that evolved was that if a product makes medicinal claims on its labels or in its brochures, it is being sold as a medicine and does not qualify for the food products exemption.

However, Revenue and Taxation Code section 6359, subd. (c) (and Regulation 1602, subdivisions (a)(3) and (a)(4)) does not support the position that a product's labeling may disqualify it from the food products exemption as a medicine. Under Regulation 1602, subdivision (a)(4), if a product states it is a supplement, its sale is not exempt from tax because it is being ***sold as*** a supplement or adjunct. (See Rev. & Tax. Code, § 6359, subd. (c).) However, products sold as medicines are not excluded from the definition of food products; actual medicines are. Simply put, for purposes of determining if sales of a product come within the purview of the food products exemption, it is irrelevant if specific medicinal claims are made regarding the product; instead, the product must actually be a medicine not to qualify for the food products exemption. In short, there is no direction in Regulation 1602, subdivision (a)(3) to examine a product's label to determine if it is a medicine.

Definition of Medicines

As stated above, medicines are defined in subdivision (a)(9) of Regulation 1591.⁴ If a product falls within this definition of medicines, then it is not a food product. (Reg. 1602, subd. (a)(3).) To repeat, medicinal claims on a product's label will not convert a food product into a medicine.

³ These annotations were deleted in response to this letter.

⁴ Again, while the statutory definition of medicines is found in Revenue and Taxation Code section 6369, subdivision (b), this definition is identical to the one found in subdivision (a)(9)(B) of Regulation 1591.

In determining if a product is a medicine, it must first be determined if the product is approved for use by the U.S. Food and Drug Administration to diagnose, cure, mitigate, treat or prevent any disease, illness or medical condition. (See Reg. 1591, subd. (a)(9)(A).) If a product is so approved, it is a medicine under Regulation 1591, subdivision (a)(9)(A) and is not a food product. (Reg. 1602, subd. (a)(3).)

To determine whether a product qualifies as a medicine under Regulation 1591, subdivision (a)(9)(B), we look to whether it is “commonly recognized” as a substance for use in the mitigation, treatment, or prevention of disease. Regulation 1591 does not define “commonly recognized.” However, it is a function of the Board to interpret its own regulations. (See *Yamaha Corp. of America v. State Board of Equalization* (1998) 19 Cal.4th 1, 10.) It is a settled rule of construction that words should be given their common meaning. (*Lungren v. Deukmejian* (1988) 45 Cal. 3d 727, 735.) We understand Regulation 1591’s reference to “commonly recognized” to pertain to broad-based acceptance by either the state’s scientific or legal community. Thus, we conclude that “commonly recognized” as a medicine means general acceptance indicated by either: (1) the greater weight of opinion in the medical community, as reflected, for example, by refereed medical journals or similarly authoritative scientific publications or pronouncements from authoritative regulatory institutions; or (2) constitutional, statutory, or controlling case law authorities establishing that the substance in question is a medicine as a matter of law.

If a product does not meet the definition of medicine, as discussed above, it may still be considered a food product for human consumption and its sales may qualify for the food products exemption notwithstanding the fact that medicinal claims are made on the product’s label or product brochures.⁵

CONCLUSION

In your memorandum you ask:

“1. What constitutes ‘medicine’ rather than food pursuant to subdivision (a)(3) of Regulation 1602;

“2. How the term ‘medicine’ in Regulation 1602 relates to the definition of medicine in Regulation 1591.”

As discussed above, “medicine,” as used in subdivision (a)(3) of Regulation 1602 has the same meaning as “medicine” as defined in Regulation 1591. A product that does not meet the definition of a medicine in Regulation 1591 is not a medicine for purposes of Regulation 1602, subdivision (a)(3). A product cannot be classified as a medicine solely on the basis of medicinal claims on the product’s label.

⁵ We have previously determined that products given by doctors to patients for remedial purposes are not medicines if they do not meet the definition of medicine found in Regulation 1591. (See, e.g., Annotation 425.0820 (12/2/66).) Even if a product is given by a doctor to a patient for certain medicinal purposes, it does not qualify as a medicine under Revenue and Taxation Code section 6369 if it is not commonly recognized for use in the treatment or prevention of disease. (See Reg. 1591, subd. (a)(9)(B).)

“3. Whether a dried herb sold in a ground/crushed form such as in tea bags, as opposed to cut leaf form, is considered to be in powder form for purposes of subdivision (a)(4) of Regulation 1602.”

If an herb is sold in cut leaf form, it is not in one of the forms listed in Regulation 1602, subdivision (a)(4); therefore, the herb cannot be considered a supplement or adjunct for purposes of the food products exemption even if it is labeled as such. Only a dried herb that is ground or crushed into the form of fine particles should be considered a powder for purposes of analysis under Regulation 1602, subdivision (a)(4). In order for such an herb to be considered to be sold as a supplement or adjunct, it must be either: (1) labeled as such (i.e., a “category (A)” supplement or adjunct); or prescribed or designed to meet specific dietary deficiencies or increase or decrease vitamins, proteins, minerals, and/or caloric intake (i.e., a “category (B)” supplement or adjunct). (Reg. 1602, subd. (a)(4).)

However, we are presently not aware of any herb that could be fairly described as a category (B) supplement or adjunct. Rather, the herbs in question should be considered to be food products (whether as “teas” under subdivision (a)(1) or “unusual food products” under subdivision (a)(4)) the sales of which are not subject to tax, provided that their labels do not state they are a supplement or adjunct. (Reg. 1602, subd. (a)(1), (a)(4).) Accordingly, provided the subject herb is not described on its package or label as a food supplement, food adjunct, dietary supplement, or dietary adjunct, the herb is a product the sale of which qualifies for the food products exemption.

Again, taxpayers and Board staff who have attempted to follow the guidance provided in annotations discussing the relevance of medicinal claims to the food products exemption have reached different conclusions as to the proper application of tax to the same sales depending on which annotations they rely. Retailers who have charged customers for tax reimbursement on such transactions and have reported tax to the state and retailers who have not reported tax should both be viewed as properly following guidance provided by the Board.

Annotations

Based on the foregoing, we recommend deletion of the following annotations:

- 245.0300 Chinese Medicinal Herbs (12/2/83)
- 245.0499.200 Herbal Tea Labeled as Herbal Medicine (10/27/94)
- 245.0499.250 Herbal Teas (8/25/97)
- 245.0499.300 Herbal Teas and Herbal Tea Capsules (11/8/96)
- 245.0501 Herbs and Supplements (12/31/96)
- 245.0506 Herbs-Unlabeled (8/26/96)
- 245.0722 Medicinal Claims (10/27/94)
- 245.0726 Medicinal Herbs (2/25/97)
- 245.1369 Herbal Teas (3/30/95)
- 245.1415.225 Correctol 100% Herbal Tea Laxative (9/5/96)
- 245.1480 Herbal Medicines (Teas) (5/31/94)
- 245.1500 Medicinal Claims for Herbal Tea (11/23/94)
- 245.2010 Yu Xiao San-Herbal Medicine (2/26/97)

425.0005 Acupuncturists (8/18/92)
425.0012 Chinese Medicinal Herbs (12/2/83)

I trust that this answers your questions. If you have any further questions, please contact me at (916) 324-2641.

CH:cme

cc: Mr. Dave Rosenthal (MIC: 50)