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Executive Director

October 21, 2009

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Re: Tax Opinion Request 09-161

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Dear ---:

This is in response to your letter dated May 7, 2009, in which you request guidance as to the proper application of California's Sales and Use Tax Law to the sale of "medical foods" by your company, --- (taxpayer).

Taxpayer is engaged in business in California as a retailer of various fitness and healthcare-related products. Your letter requests advice concerning taxpayer's retail sales of products that fall within the definition of a "medical food" under section 5(b) of the federal Orphan Drug Act. (See 21 U.S.C. § 360ee(b)(3).) You specifically request advice concerning whether a "medical food" falls within the definition of a "food product" (Rev. & Tax. Code, § 6359) or a "medicine" (Rev. & Tax. Code, § 6369) provided under California's Sales and Use Tax Law. As examples, you attached photocopies of the pill boxes for two "medical foods" sold by taxpayer.<sup>1</sup> We understand that these pills are specifically formulated to be used "for the Daily Dietary Management of [a specified medical disease or condition.]" From these attachments I assume that you are requesting advice with respect to medical foods sold in pill or capsule form.

In your follow-up letter, dated May 22, 2009, you further clarify the purpose of your request:

The advisory opinion was requested to provide guidance on products that are being brought into the store for sales to the ultimate consumer. I do not believe current California regulations specifically address products [qualifying] as "Medical Foods."

<sup>1</sup> You provided sample pill boxes for "

" brand "medical foods" manufactured by

Based on your follow-up letter, I understand that the medical foods for which you request advice are sold as over-the-counter products at one of taxpayer’s California retail locations. I also understand that none of the transactions in question involve products sold to this state or any political subdivision or municipal corporation thereof. Consistent with these assumptions, I note that the two medical foods identified in your letter, along with other “ ” brand medical foods, may be purchased directly via the manufacturer’s website where they are advertised as “over-the-counter, drug-free medical foods” that are “[a]vailable at over 40,000 retailers nationwide including Rite Aid, Walgreen’s, Wal-Mart, CVS/Pharmacies, Albertsons, K-Mart, Kroger, Safeway and online at Amazon.com, Drugstore.com, Rofay.com and DoctorVicks.com.”<sup>2</sup>

Before discussing your questions in more detail below, I note that the facts you provided are not sufficiently complete. Therefore, I have made assumptions throughout this opinion letter to answer your questions. If the actual facts differ from the facts summarized in this letter, or if any of the assumptions I have made are incorrect, the opinions expressed in this letter may not be reliable. Provided that the facts in this letter (both summarized and assumed) are accurate and verifiable by audit, the taxpayer may rely on this response for purposes of Revenue and Taxation Code section (Section) 6596. (See Cal. Code Regs., tit. 18, § (Regulation or Reg.) 1705, subd. (b) [describing the circumstances under which relief from liability is available for reasonable reliance on written advice given by the Board].)

**DISCUSSION**

As a starting point, California imposes sales tax on a retailer’s gross receipts from the retail sale of tangible personal property in California unless the sale is specifically exempt from taxation by statute. (Rev. & Tax. Code, §§ 6012, 6051.) A “sale” includes any transfer of title or possession, in any manner or by any means whatsoever, of tangible personal property for a consideration. (Rev. & Tax. Code, § 6006, subd. (a).) The sales tax is imposed on the retailer, who may then collect reimbursement from its customer if the contract of sale so provides. (Civ. Code, § 1656.1; Reg. 1700.)

**I. Medicines**

Certain transactions involving medicines are exempt from tax under Section 6369, which provides in pertinent part:

(a) There are exempted from the taxes imposed by this part the gross receipts from the sale in this state of, and the storage, use, or other consumption in this state of, medicines:

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

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<sup>2</sup> See

(Rev. & Tax. Code, § 6369, subd. (a).)

Regulation 1591 explains the exemption for medicines and, in pertinent part, interprets the definition of a “medicine”<sup>3</sup> provided under subdivision (b) of Section 6369:

(a)(9) **Medicines.** “Medicines” means:

[¶] . . . [¶]

(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.

[¶] . . . [¶]

(d) Tax applies to retail sales, including over-the-counter sales of drugs and medicines, and other tangible personal property by pharmacists and others.

(Reg. 1591, subd. (a)(9), (d) [interpreting subdivision (b) of Section 6369].)

II. Food Products

Section 6359, which exempts certain transactions involving food products from tax, provides in pertinent part:

(a) There are exempted from the taxes imposed by this part the gross receipts from the sale of, and the storage, use, or other consumption in this state of, food products for human consumption.

Subdivisions (a)(3) and (4) of Regulation 1602 further interpret and explain the definition of “food products” provided under Section 6359:

(3) “Food products” do not include medicines . . . .

(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 . . . .

Tax, however, does not apply to any such products which either [(1)] are exempted by Revenue and Taxation Code Section 6369, respecting prescription medicines, or [(2)] are complete dietary foods providing the user in the recommended daily dosage with substantial amounts of vitamins, proteins,

<sup>3</sup> There are certain exclusions from the definition of “medicine” that are not relevant for purposes of this opinion letter. (See generally Rev. & Tax. Code, § 6369, subd. (b); Reg. 1591, subd. (c).)

minerals and foods providing adequate caloric intake. The latter is a food if it provides the user with [all three of] 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.

(Reg. 1602, subd. (a)(3), (4) [interpreting subdivisions (b) and (c) of Section 6359].) I assume that none of the medical foods sold by taxpayer is designed for the daily dietary management of obesity.<sup>4</sup>

III. Medical Foods

You ask whether medical foods are properly categorized as “food products” or as “medicines.” The Orphan Drug Act defines a “medical food” as:

[A] food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation.

(21 U.S.C. § 360ee(b)(3).) I assume that all of the products at issue qualify as “medical foods” as defined in the Orphan Drug Act.<sup>5</sup>

Page 3 of the Food and Drug Administration’s (FDA) February 2, 2009, consumer update, available for download from the Consumer Health Information section of the FDA’s Web site,<sup>6</sup> further explains:

**FDA does not approve medical foods.**

A medical food is used for the dietary management of a disease or health condition that requires special nutrient needs. An example of a medical food is a food for use by persons with phenylketonuria, a genetic disorder. A person with this disorder may need medical foods that are formulated to be free of the amino acid phenylalanine. A medical food is intended for use under the supervision of a physician. [¶] Medical foods do not have to undergo premarket approval by FDA . . . .

<sup>4</sup> Please note that tax may apply differently to sales of certain medical foods designed for the daily dietary management of obesity. (See Regs. 1591, subd. (e)(7); 1602, subd. (a)(4).)

<sup>5</sup> To qualify as a “medical food” under the federal Orphan Drug Act definition, the product must be labeled for the dietary management of a specific medical disorder, disease, or condition. (Food and Drug Administration, Compliance Program Guidance Manual, Chapter 21, Program No. 7321.002 (1988-1991); see, e.g., 56 Fed.Reg. 60366 (Nov. 27, 1991).) We note that for sales and use tax purposes the fact that a product is labeled as a medicine or otherwise makes medicinal claims has no bearing on the determination of whether or not the product is a “medicine” as defined under Section 6369. (See Reg. 1591, subd. (a)(9); see also, e.g., Sales and Use Tax Annotation 245.0724 (11/17/08).) Therefore, any medicinal claims made on the boxes of medical foods are wholly irrelevant to the analysis of whether medical foods are “medicines” as defined in Regulation 1591.

<sup>6</sup> Available at: <http://www.fda.gov/consumer/updates/approvals093008.pdf>.

#### A. Treatment of Medical Foods under Regulation 1591 (Medicines)

As indicated above, the terms “food product” and “medicine” are mutually exclusive for Sales and Use Tax Law purposes because, if a product is a medicine, it cannot qualify as a food product. (Reg. 1602, subd. (a)(3); see, e.g., Sales and Use Tax Annotation (Annot.) 245.0724 (11/17/08).)<sup>7</sup> Based on information provided on the FDA’s Web site,<sup>8</sup> we understand that products qualifying as medical foods are not approved by the FDA to diagnose, cure, mitigate, treat or prevent disease. (See Reg. 1591, subd. (a)(9)(A).) As explained above, however, the term “medicine” also includes substances or preparations: (1) intended for use by external or internal application to the human body (2) in the diagnosis, cure, mitigation, treatment or prevention of disease (3) if it is commonly recognized as a substance or preparation intended for that use. (Reg. 1591, subd. (a)(9)(B).)

First, we understand that medical foods are intended for consumption under the supervision of a physician for the dietary management of a disease or condition. (21 U.S.C. § 360ee(b)(3).) Thus, we understand that the medical foods sold by taxpayer are substances or preparations intended for internal application to the human body via ingestion.

Second, we understand that medical foods must be intended for the dietary management of a disease or condition of a patient who, because of therapeutic or chronic medical needs, has limited or impaired capacity to ingest, digest, absorb, or metabolize ordinary foodstuffs or certain nutrients, or who has other special medically determined nutrient requirements, the dietary management of which cannot be achieved by the modification of the normal diet alone. (21 C.F.R. § 101.9(j)(8)(ii) (2009).) The products at issue are specially formulated for the daily dietary management of lactose intolerance and irritable-bowel-syndrome-related symptoms, respectively. Adults suffering from these medical conditions are instructed to take one capsule daily with water. The manufacturer’s Web site advertises that, with respect to both products, “[o]ur advantage is our beneficial bacteria, or ‘probiotics’ – ” which we understand is a primary ingredient in the pills.<sup>9</sup> For example, the box for e explains that it is “[t]he only product that uses specially isolated live cultures ( to help break down lactose and the complex sugars found in dairy products and other foods.” Therefore, we understand that medical foods are intended for use in the mitigation, treatment or prevention of a medical disease or condition. (See Reg. 1591, subd. (a)(9)(B).)

The third requirement is that the product at issue must be commonly recognized as a medicine for use in the diagnosis, cure, mitigation, treatment or prevention of the disease for which it is intended to be used. (Reg. 1591, subd. (a)(9)(B).) The term “commonly recognized” means broad-based acceptance by either the state’s scientific or legal community. (See Reg. 1591, subd. (a)(9)(B); see also, e.g., Annot. 245.0724 (11/17/08).) This would mean and

<sup>7</sup> Annotations do not have the force or effect of law but are intended to provide guidance regarding the interpretation of the Sales and Use Tax Law with respect to specific factual situations. (Reg. 5700, subds. (a)(1), (c)(2).)

<sup>8</sup> See the February 2, 2009, consumer update cited in footnote 4; see also “Guidance for Industry: Frequently Asked Questions About Medical Foods,” available at: <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/MedicalFoods/ucm054048.htm>.

<sup>9</sup> Medical foods are exempt from labeling requirements for nutrient content claims. (21 U.S.C. § 343(q)(5)(A)(iv).) We note that nutritional information is not provided for the products at issue and based on the ingredient list the products do not appear to be of any nutritional value (e.g., there is no indication that they contain calories, vitamins, and only contain “trace amounts” of milk protein).

include 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 (i.e., the established medical community); or (2) constitutional, statutory, or controlling case law authorities establishing that the substance in question is a medicine as a matter of law. (*Ibid.*) As discussed, the Orphan Drug Act defines “medical food” to mean a product intended for the “management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation.” (21 U.S.C. § 360ee(b)(3).) Thus, unlike food products which may make medicinal claims or may actually be consumed for medicinal purposes (such as some herbal teas),<sup>10</sup> “medical foods” must be formulated<sup>11</sup> based on recognized scientific principles to manage a specific medical disease or condition and the disease or condition must be identified based on a medical evaluation. Further, a physician should be providing ongoing medical supervision for use of the medical food. Therefore, we understand that in order to qualify as a medical food a product must be commonly recognized by the established medical community as a product used for managing the medical disorder, disease or condition for which they are specifically formulated. (See Reg. 1591, subd. (a)(9)(B).)

Based on these facts and the assumptions stated herein, a product qualifying as a “medical food” falls under the definition of a “medicine” for Sales and Use Tax Law purposes. (See Reg. 1591, subd. (a)(9)(B).) In order to qualify for exemption, taxpayer’s sales of medical foods must meet the requirements for exemption as specified in Regulation 1591 for the sale of certain prescription medicines. (See Reg. 1591, subds. (d)(1)-(6), (e).) Therefore, tax applies to taxpayer’s sales of the two medical foods identified in your letter because these medicines are sold at retail over the counter.

In summary, based on our understanding that the medical foods offered for sale by taxpayer are medicines that are sold at retail over the counter, tax applies to taxpayer’s retail sales of medical foods unless the transaction is otherwise exempted or excluded under a different provision. (See Reg. 1591, subd. (d).) As relevant to your inquiry, the sale of these products would not qualify for the Section 6359 exemption for food products because medicines are statutorily excluded from the definition of a “food product.” (Rev. & Tax. Code, § 6359, subd. (c); see Reg. 1602, subd. (a)(3); see also, e.g., Annot. 245.2100 (2/24/1997).) This opinion does not address whether the sale of medical foods over the counter is regulated in any way under federal or state law.

I trust that I have fully addressed your concerns. If you have any further questions, please write again.

Sincerely,

Andrew J. Kwee

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<sup>10</sup> Again, medicinal claims per se (on labels or otherwise) are irrelevant to whether the products in question are “medicines” under the Sales and Use Tax Law. (See footnote 5, *supra*.)

<sup>11</sup> As relevant to your inquiry, we understand that the requirement that the product be formulated based on recognized scientific principles would mean that the term “medical food” would not include naturally occurring foodstuffs used in their natural state such as herbs sold in dried and cut leaf form or dried and ground leaf form.

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- 7 -

October 21, 2009

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Tax Counsel

AJK/yg

cc: --- District Administrator (--)