STATE OF CALIFORNIA

425.0237

STATE BOARD OF EQUALIZATION
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October 28, 1996

Dear X----------,

I am responding to your letter to the Legal Division dated September 11, 1996. X---------- is in the process of obtaining approval to sell the CEPRATE SC Cell Concentration System ("the CEPRATE System") in the United States. You aver that sales of the CEPRATE System would be exempt from sales and use tax in California under the provisions of Revenue and Taxation Code Section 6369.1, which exempts from tax the sale of hemodialysis systems under certain conditions. You ask if we agree.

You describe the operation of the CEPRATE System as follows:

> "The CEPRATE SC System is used in a process called immunoadsorption which removes specific cells from the bone marrow or blood of human beings. The initial use to the product will be for the removal of stern cells from patients prior to their under going myeloablative (extremely high dose) chemotherapy. After the chemotherapy, the stern cells are returned to the patient. This is referred to as an autologous (patient's own) stern cell transplantation. This procedure is performed to prevent important healthy cells (stern cells) from being destroyed during the chemotherapy. Stern cells are unique in their ability to divide into additional stern cells, as well as into progenitor cells which replicate to replenish all the cells of the body's blood and immune systems. The CEPRATE SC System has been shown to significantly deplete tumor cells from blood prior to stern cell transplantation. Also, other impurities are removed from the patient's extracted blood as a result of this immunoadsorption procedure.
>
> "The CEPRATE SC System will be used by hospitals that perform transplant procedures and may only be used pursuant to the prescription of a licensed physician .... "

A check of our files shows that X---------- has not obtained a California seller's permit nor has it registered to collect California use tax. You do not describe X----------'s operations as to whether or not X---------- has a physical presence here. We will assume for the sake of discussion, however, that it does and so is required to collect California use tax.

OPINION

A. Use Tax on Tangible Personal Property

In California, except where specifically exempted by statute, Revenue and Taxation Code section 6051 imposes an excise tax, computed as a percentage of gross receipts, upon all retailers for the privilege of selling tangible personal property at retail in this state. (Unless otherwise stated, all statutory references are to the Revenue and Taxation Code.) Likewise, section 6201 imposes a use tax on the storage, use, or other consumption in this state of tangible personal property purchased from any retailer for use, storage, or other consumption in this state, unless otherwise exempted from taxation by statute, purchased for use in this state in a transaction not subject to sales tax.

Please note that the sales tax is imposed upon the retailer for the privilege of selling tangible personal property in this state while the use tax is upon the purchaser who uses, stores, or otherwise consumes such property here. Pursuant to agreement, the purchaser may reimburse the retailer for its sales taxes paid (Civ. Code § 1656.1), but the retailer must collect the use tax from the purchaser if engaged in business in this state. (Bank of America v. St. Bd. of Equalization (1962) 209 Cal.App.2d 780, 792-793 [26 Cal.Rptr. 348] .); § 6303.)

B. Exemption Burden.

"[I]t shall be presumed that all gross receipts are subject to tax until the contrary is established. The burden of proving that a sale of tangible personal property is not a sale at retail is upon the person who makes the sale ... " (§ 6091.) "Exemptions from taxation must be found in the statute." (Market St. Ry. Co. v. Cal. St. Bd. of Equal. (1953) 137 Cal.App.2d 87, 96 [290 P.2d 201.]) "The taxpayer has the burden of showing that he clearly comes within the exemption." (Standard Oil Co. v. St. Bd. of Equalization (1974) 39 Cal.App.3d 765, 769 [114 Cal.Rptr. 571].)

C. Prescription Medicines.

Section 6369, interpreted and implemented by Title 18, California Code of Regulations, section 1591, provides that sales of medicine, when prescribed and sold or furnished under certain conditions for the treatment of a human being, are exempt from sales or use tax. (Reg. 1591(a).) Subdivision (b) (1) defines "medicine" to "mean and include 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 such use." However, Regulation 1591(c) (2) adds that "medicines" do not include "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." (Sales and Use Tax Regulations are Board promulgations which have the force and effect of law.) As a rule, then, items used to diagnose a condition or to apply medicine or treatment to the patient are not considered to be medicines.

Regulation 1591(b) does provide that certain items which might otherwise be considered as being devices, etc., are defined as "medicines." Subdivision (j), which interprets and implements section 6369(g), provides that tax does not apply to sales of any appliances and related supplies necessary as the result of any surgical procedure by which an artificial opening is created in the human body for the elimination of natural waste. The term "appliances" and "related supplies" includes kidney dialysis machines, and the tubing, pumps, blood sets, fistula sets, and shunts used in conjunction with such machines.

You cite section 6369.1 in your letter. This statute is interpreted and implemented by Regulation 1591 as follows:

> **"(a) GENERAL**. Tax applies to retail sales of drugs, medicines, and other tangible personal property by pharmacists and others except as follows:
>
> Tax does not apply to sales of medicines for the treatment of a human being which medicines are:
>
> * * *
>
> (b) hemodialysis products supplied on order of a licensed physician to a patient by a registered pharmacist or by a manufacturer, wholesaler, or other supplier authorized by Section 4050.7 or 4227 of the Business and Professions Code to distribute such products directly to hemodialysis patients."

It is critical to recognize that section 6369.1 does not enlarge the class of items which may be exempt from tax. To qualify for exemption under section 6369.1, a particular item must be a "medicine" within the meaning of section 6369. The change which section 6369.1 made in the law was to enable hemodialysis patients to acquire such medicines free of tax from manufacturers and distributors rather than having to get them from a pharmacy.

D. Tax Consequences.

We do not agree that the CEPRATE System is a hemodialysis system within the meaning of Regulation 1591(j). As you describe it, the primary purpose of the system is to remove stem cells from the body of the patient prior to chemotherapy and to return those cells to the patient. We have previously examined similar systems and have concluded that they are not used in conjunction with artificial openings surgically created in the human body for the elimination of natural waste. Rather, they are an instrument for administering treatment to a patient excluded from the definition of ~medicine" under Regulation 1591(c) (2). As a result, sales of this item will be subject to tax when it is sold for use in California.

As noted above, our files indicate that X---------- is not registered with the Board to pay sales tax or collect use tax. If X---------- is (or will be at such time as the systems are sold here) engaged in business in California, it will be, as also noted above, required to collect California use tax from its customers. It will be "engaged in business" in California if it has an office or an agent here. (§ 6203(a) & (b).) It will be "engaged in business" here if it leases the CEPRATE System here as well.

For your information, I have included a copy of Regulation 1591. I hope the above discussion has answered your question. If you need anything further, please do not hesitate to write again

Sincerely,

John L. Waid
Senior Tax Counsel

JLW:sr
Enclosure: Reg. 1591