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March 14, 1994

BURTON W. OLIVER
Executive Director

Mr. C--- S. W---
Director of Tax, M--- M---, Inc.
XXX --- Boulevard
P.O. Box XXXX
--- ---, Missouri XXXXX

Re: SZ --- XX-XXXXXX
Ultra-TechneKow Generators

Dear Mr. Wiley

I am answering your letter to me dated January 24, 1994. You ask for an opinion regarding the application of sales and use tax to M---'s sales of Ultra-TechneKow FM Technetium-99m Generators ("Generators").

I. FACTUAL BACKGROUND.

Your letter describes the function of the Generator, in pertinent part, as follows:

"... A generator [as that term is used in the field of Nuclear Medicine] is a transportable and renewable source of short-lived radionuclides. Although generators were originally classified as a medical device, they were reclassified by the United States Board of Pharmacology as a legend (prescription) drug.

* * *

"Generators are constructed on the principle of the growth relationship between a long-lived parent radionuclide (in this case, Molybdenum-99) and its short-lived daughter radionuclide (Technetium-99m). The long-lived parent radionuclide is irreversibly attached to an exchange column which decays to a short-lived

daughter radionuclide. The short-lived daughter radionuclide can then be chemically separated from the parent. Solvent is pulled through the generator by vacuum in an evacuated collecting vial, removing the daughter radionuclide from the column into the solution contained in the collecting vial. The system must be sterile and pyrogen-free.

* * *

“The radioactive daughter nuclide in the vial solution is Technetium-99m in the form of pertechnetate, a radioactive drug (called a radiopharmaceutical), which can be dispensed only by properly licensed physicians. The radiopharmaceutical, Technetium-99m pertechnetate, is ingested by or injected into the patient (by the physician), as agents in brain imaging, thyroid imaging, salivary gland imaging, placental localization, blood pool imaging, urinary bladder imaging for detection of vesico-ureteral reflux and nasolacrimal drainage system imaging. Technetium-99m pertechnetate can also be attached chemically to certain molecules which carry the radionuclide to a specific organ for imaging....”

II. OPINION

A. Sales and Use Tax Generally.

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.) “[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 PO.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].)

B. Prescription Medicines.

Section 6369, interpreted and implemented by Title 28, California Code of Regulations, Regulation 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.

C. Tax Consequences.

Your description indicates that the Generator is, basically, a device for producing a radionuclide which may be injected into or ingested by the patient for the purposes of imaging. Sold to facilities that use it to produce the Technetium-99m which they use in diagnostic imaging, this item is not a medicine itself but instead produces a medicine. (Annot. 425.0580. Sales and Use Tax Annotations are excerpts from previous Legal staff opinion letters and serve as a guide to staff positions.) We have previously determined that such radioactive application equipment do not constitute medicines in themselves but rather are devices or physical equipment excluded from the definition of “medicines” under Regulation 1591(c)(2). (Annot. 425.0765.) As a result, sales of the Generator are subject to tax.

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
Tax Counsel

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Enclosure: Reg. 1591