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June 13, 1994

Mr. V--- O---  
Manager, E--- & Y---  
xx --- Boulevard  
--- ---, California XXXXX

Re: [No Permit Number]  
Drug Manufacturers

Dear Mr. O---:

I am responding to your letter to Assistant Chief Counsel Gary J. Jugum dated March 31, 1994. You ask for an opinion regarding the application of sales and use tax to the drug manufacturing operations of your client. Since you did not identify the taxpayer, this letter does not constitute specific written advice to the taxpayer under Revenue and Taxation Code Section 6596. Rather, it constitutes general comments regarding the applicability of California Sales and Use Tax Law to a set of hypothetical facts.

The facts contained in your letter are too lengthy for me to repeat in full here. I have therefore attached a copy of your letter for ease of reference. In sum, your client "is involved in developing drug-delivery technology [and] has developed a therapeutic delivery technology to improve the effectiveness and reduce the toxicity of established chemotherapeutic agents for the treatment of cancer and serious skin diseases." The product consists of two (sometimes three) separate elements (you call them Drugs X, Y, and Z, sometimes collectively termed hereinafter as "the raw materials") that your client purchases from separate suppliers and then combines to make its product. Each element could be purchased as a prescription drug in its own right.

Your client purchases Drug X in bulk quantities and syringes from vendors located both within and without the state. (We assume that your client purchases the drugs tax-paid and not for resale.) It then ships them to an independent laboratory located in Maryland which combines Drugs X and Y into one syringe to form Drug XY and Drug Z into a separate syringe. The lab then returns the drugs to your client in California which then "packages the syringes into clinical trial kits, and distributes the kits at no charge to various clinical trial sites located in and out of state. [We assume that the syringes are packed into the kits in a filled state.] Drugs SY and Z are combined into a single injection to be administered to the patient by the doctor who is running the clinical trial. Furthermore, [your client] pays the doctors (who practice at various healthcare facilities (e.g., clinics, hospitals, or in their own private practices) to participate in this human clinical trial stage of the [FDA]'s drug approval process."

As part of the clinical trials phase, your client uses placebo injections which contain the same ingredients as the other injections with one of those ingredients being inactive. These clinical trials are double-blind.

#### OPINION

You ask several questions regarding the application of tax to this scenario. The general rule is that for the sale or transfer of a medicine to be exempt from tax, the transaction must satisfy two elements: (1) the product must be a "medicine" as defined in Regulation 1591; and (2) unless otherwise provided, the sale or transfer of the product must satisfy the conditions set forth in sub-division (a). We note at the outset that, while no provision exempts the sale or transfer of medicines by manufacturers or distributors, sales by such entities are usually not subject to tax as being sales for resale. With that exception, transfers of medicines not in conformance with the requirements of sub-division (a) are subject to tax.

For the above reasons, when a medicine manufacturer conveys its product to a licensed physician gratuitously, such transfers are generally subject to use tax. However, where it is paying the physician to participate in a study of a medicine, we have concluded that the transfer is not subject to tax as follows:

"An experimental drug dispensed by doctors who are being paid by a drug company to participate in the study of an experimental drug is 'prescribed for the treatment of a human being...' and 'furnished by a licensed physician and surgeon... to his own patient for treatment of the patient.' When the experimental drug is sold by a manufacturer to a drug company which pays doctors to participate in the experiment, an exempt sale of medicine occurs since the sale is in the manner prescribed in Regulation 1591(a)(1) and (2) and tax will not apply to such sales. The use of the drug made by the doctors is attributable to the drug company, for whom the doctors act as agents."

(Annot. 425.0050.)

First of all, your client's purchases of the raw materials and the placebos are properly subject to tax. A placebo is an inactive substance or preparation formerly given to gratify or please a patient (hence the name), but now also used, as here, in controlled studies to determine the efficacy of experimental medicines. (Dorland's Illustrated Medical Dictionary, 24th ed., (1959).) It is not sold or used for treatment of the patient but rather to test the effectiveness of another drug in treating a human being. These placebos, then, do not qualify as "medicines" under Regulation 1591(b)(1). You indicate there may be some reaction to the placebo because of its pharmaceutical properties, but this is apparently not a desired result. The raw materials themselves are also not purchased for the treatment of a human being, but for incorporation into another product, and it is that product which is used to treat human beings. The raw materials cannot be purchased for resale at this time since they are not being resold but are being consumed by the company through the agency of the physician.

Second, we are also of the opinion that, under the facts you give, Drug XY and Drug Z are not "medicines" under Regulation 1591(b)(1). Although their experimental nature does not, in the abstract, prevent them from being termed "medicines," they are still being developed and tested for effectiveness as part of the FDA approval process. Thus, they cannot be said at this stage to be "commonly recognized as [substances or preparations] intended for the [diagnosis, etc., of disease]."

Third, Company C's "services" are part of the manufacturing process and so ordinarily subject to tax. (Reg. 1526(a).) Since it operates in Maryland, however, its gross receipts are not subject to tax. (§§ 6010.5, 6017.) However, your client cannot deduct its charges for Company C's services from its own gross receipts.

Finally, we conclude that the above annotation does not apply to this situation for two reasons. First, as we have previously noted, Drug XY and Drug Z do not qualify as medicines. The drugs at issue in the annotation were considered to be "medicines" under Regulation 1591(b)(1). Second, in the fact situation supporting the annotation, the drug company had bought the medicines ex-tax for resale, as they had previously-approved uses, and withdrew a portion from resale inventory for testing for a new use. Here, the facts you give indicate that the raw materials are being purchased specifically to develop a new drug, and they are not being withdrawn from previously-acquired resale inventory. In that case, the annotation protects the withdrawal of medicines from resale inventory from use tax by considering the use of the medicine by the doctor (exempt from tax under Regulation 1591(a)(2)) pursuant to a paid-agency relationship to be that of the entity also, thus exempting the transfer from use tax under Regulation 1591(a)(1) and (2).

As noted above, you do not identify the client. As you can see from this letter, we have also had to assume a large number of facts in order to give you a coherent opinion. For this further reason, this letter does not constitute written advice to the taxpayer under Section 6596.

Mr. V--- O---

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June 13, 1994  
425.0028

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

JLW:es

Attach.