

**STATE BOARD OF EQUALIZATION**

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October 8, 1991

Mr. K. J. K---
Corporate Controller, V--- Corp.
XXXX --- Drive
--- ---, California XXXXX

RE: SR – XX-XXXXXX

Dear Mr. K---:

I have been asked to respond to your letter dated September 20, 1991, to Tax Counsel of the State Board of Equalization. You have requested advice as to whether sales or use tax applies to V---'s sales of certain products.

I. FACTUAL BACKGROUND

You attached to your letter a brochure which describes V---'s operations, in part, as follows:

“By utilizing a variety of novel polymer technologies, V--- has developed materials which provide controlled presentation of bioactive agents. With the localized delivery of antimicrobial agents, V--- and its corporate partners are addressing infection control concerns associated with medical devices in vascular access and urology. With the tissue presentation of collagen polypeptides, V--- and its corporated partners are propelling advances in ophthalmic and surgical wound care products.”

You state that V---'s products are not available over the counter but by physician's prescription.

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 P.2d 201.) “The taxpayer has the burden of showing that he clearly comes within the exemption.” Standard Oil Co. v. State Bd. of Equalization (1974) 29 Cal.App.3d 765, 769 [114 Cal.Rptr. 571].)

B. Prescription Medicines.

Section 6369 interpreted and implemented by Title 28, California Code of Regulation, Regulation 1591 provides that sales of medicines, 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) of Regulation 1591 defines “medicines” to “mean and include any substances 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.” (Regulations are Board promulgations that have the force and effect of law). As a general 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”. Regulation 1591(b)(4) includes orthotic devices, or their replacement parts, designed to be worn on the person of the user as a brace, support, or other correction for the body structure. Regulation 1591(b)(5) includes prosthetic devices and their replacement parts designed to be worn on or in the person of the user to replace or assist in the functioning of a natural part of the human body. Each of the above categories is subject to certain exceptions.

C. Tax Consequences to V---

1. V---C---. You attached to your letter a brochure which describes this product, in part, as follows:

“THE ONLY COLLEGEN-SILVER CUFF THAT PROTECTS YOUR PATIENTS AGAINST CVC INFECTIONS.

“Just place V---c--- around your catheter and position it under the skin. The collagen-silver cuff protects against CVC infections for up to six weeks.

* * *

“Silver provides broad spectrum prophylaxis against: [three kinds of bacteria].

“Implanted cuff creates mechanical barrier:

Collagen immediately swells upon contact with blood and fills the site.

Subsequent (2-3 days) tissue ingrowth reinforces the barrier.”

This product appears to be designed to prevent infection and stop bleeding resulting from the insertion of a catheter into the body of a patient. As a result it acts much like a dressing. Although Regulation 1591(c)(2) excludes “dressings” from the definition of “medicine,” we have previously concluded that dressings impregnated with a “medicine,” as defined above, do qualify for the exemption. In this case, however, we conclude that the collagen-silver ingredient of the V---C--- is not a “medicine” because it is not intended for application to the human body in the prevention of disease. Rather, the material seems intended only to impart certain characteristics to the V---C--- itself. Accordingly, tax applies to the sale of this product.

2. Collastat. The flyer you enclosed with your letter describes this product in part, as follows:

“Collastat absorbable collagen hemostat is a soft, white, pliable, absorbent sponge. Because of its non-friable, coherent structure, the application to the site where hemostatic (arrest of bleeding) is desired is easily controlled and unwanted dispersal over the operative site does not occur.

“The basic material from which the hemostatic sponge is fabricated is collagen obtained from bovine deep flexor tendon (achilles tendon), known to be one of the purest sources of collagen that can be readily processed.

“... Collastat should be used in surgical procedures ... as an adjunct to hemostatic when control of bleeding by ligature or conventional procedures is ineffective or impractical.

The flyer further states that Collastat absorbs over 40 times its weight providing a greater surface area for platelet activation. Its sponge-like structure provides a framework for stable clot formation.

As noted above, bandages and dressings are excluded from the term “medicines” under the regulation. The medical profession is continually developing newer and better products which perform the same functions performed by older products, perhaps under different names. Collastat appears to perform the same functions – stopping bleeding and promoting clot formation – as do traditional dressing or bandages made out of gauze and so is in the nature of a temporary biological dressing. Therefore, we conclude that this product is not a “medicine,” as defined above. Sales of Collastat are thus subject to tax.

3. Collagen Corneal Shield. You enclosed a flyer for this product which describes it, in part, as follows:

“P--- Collagen Corneal Shields are the latest advancement from A--- to help reduce post surgical corneal trauma and stress in patients with compromised corneas or acute epithelial defects, e.g. corneal transplantation, radial keratotomy, and epikeratophakia. The shield is a transparent, thin, pliable film of bovine collagen.

“P--- keeps the cornea hydrated, giving you an immediate means of postoperative care when hydrated with the solution of your choice. ...

* * *

“P--- protect the corneal tissue compromised by surgery, corneal ulcer or post surgical and acute epithelial defects, recurrent erosions and contact lens-induced trauma. The barrier film temporarily separates the compromised ocular surface from eyelid movements.”

We consider that this product is also a temporary biological dressing whose function it is to protect the cornea while it is healing. As a result, its sales are subject to tax.

For your information, I have enclosed a copy of Board of Equalization Pamphlet No. 45, “Hospitals”, which includes 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

JLW:es
4102I
Enclosure: Pamphlet No. 45