COLORADO
Department of Revenue
Taxation Division

Office of Tax Policy
P.O. Box 17087
Denver, CO 80217-0087

DOR_TaxPolicy@state.co.us

GIL-2008-6 amended

XXXXXXXXXXXX.
Attn: **XXXXXXXXX**
XXXXXXXXXXXX
XXXXXXXXXXXX

December 22, 2009

Dear **XXXXXXXXXX,**

The department previously provided you a general information letter (GIL-08-006) dated February 28, 2008 regarding the taxability of [Product]. The department has had an opportunity to revisit this issue and has concluded that [Product] is exempt from sales and use tax. This general information letter supersedes our February 28, 2008 general information letter.

Issue

1. Is [Product] exempt from sales and use tax?

Background

You provide the following facts. [Company] is a manufacturer of [Product]. [Product] is an implant that contains 20% non-resorbable polymethylmethacrylate microspheres (30 to 35 micros in diameter), and 80% purified bovine collagen gel, with .3% lidocaine hydrochloride, an anesthetic. Lidocaine hydrochloride is listed by the United States Pharmacopoeia (PMA) as a drug. [Product] is currently used for the correction of nasolabial folds (smile lines). The company is also investigating other uses for [Product].

[Product] is approved by the United States Food and Drug Administration (FDA) as a medical device. I assume the FDA came to this conclusion because [Product] falls within the following FDA definition: an "... implant, ... which is, ... intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes."

You further state that medical devices distributed in the United States require a 510(k) clearance or a PMA approval from the FDA. [Product] is classified as a Class III medical device, which represents a degree of risk and need of control greater than Class I or II medical devices. Approval of Class III medical devices requires extensive technical review, clinical trials, and oversight by the FDA.

[Product] is obtained only with a prescription and is injected as an outpatient procedure only by company trained physicians, such as dermatologists, surgeons, and cosmetic surgeons. You state that this "state" has previously approved exemptions for other dermal fillers, including for Radiesse (manufactured by Bioform), Sculptra (manufactured by Dermik Laboratories), Restylane (manufactured by Q-Med, Inc.), Juvederm (manufactured by Allergan), and Zyderm/Zyplast (manufactured by Allergan). You attach some promotional material which further explains [Product].

Discussion

Colorado imposes sales and use tax on the sale, use, storage, or consumption of tangible personal property. §39-26-104(1)(a), C.R.S. Certain medical devices and supplies are exempt from sales and use tax. Insofar as relevant to [Product], Colorado exempts drugs sold pursuant to a prescription, medical supplies, prosthetic devices, and therapeutic devices, appliances and accessories related to such devices. §39-26-717, C.R.S. In particular, the statute states, in pertinent part,

> (a) All sales of drugs dispensed in accordance with a prescription, ..., all sales of prosthetic devices, ... all sales of drugs or materials when furnished by a doctor as part of professional services provided to a patient ...;
>
> (b) When sold in accordance with a written recommendation from a licensed doctor, all sales of therapeutic devices, appliances, or related accessories, with a retail value of more than one hundred dollars, that are sold to correct or treat a human physical disability or surgically created abnormality; and
>
> (c) All sales of therapeutic devices, appliances, or related accessories, with a retail value of one hundred dollars or less, that are sold to correct or treat a human physical disability or surgically created abnormality.

There is considerable controversy whether collagen gel, breast implants, botox, and other similar products are exempt from sales and use tax. The debate often centers on whether these products qualify as prosthetic or therapeutic devices. For example, the Arizona department of revenue has concluded that breast augmentation implants are not prosthetic devices because they do not replace a body part or function. Arizona Private Taxpayer Ruling LR03-014, 12/11/2003. Similarly, the Illinois department of revenue concluded that breast implants, used for reconstructive surgery after a mastectomy, constitute a medical device; but breast augmentation implants, whose purpose is primarily cosmetic, are not exempt medical devices. Illinois Dept. of Rev. General Information Letter ST 07-0110-GIL, 08/07/2007. Other states have concluded that such implants are exempt because there is no specific statutory requirement that these devices have a medical purpose. Washington Tax Determination No. 91-290, 11 WTD 477, 10/02/1991; Missouri Administrative Hearing Division, *Plastic Surgery Clinic of Springfield, Inc. v. Director of Revenue,* 88-001987RS, 11/29/1989; Kansas Private Letter Ruling No. P-1998-185, 11/10/1998; Florida Technical Assistance Advisement 02A-013, 03/08/2002.

With respect to the exemption for drugs prescribed by a physician, [Product] does contain lidocaine hydrochloride, which is a drug that is available only by prescription. However, the true object of the transaction is the microspheres and collagen gel which create the desired effect of smoothing smile lines. The lidocaine hydrochloride is only temporary and incidental to the transaction. For this reason, the drug does not, in and of itself, transform the bulk of the [Product] product into an exempt transaction.

A "prosthetic device" is not defined by statute. In the absence of a specific statutory definition, the department uses the following general definition: "A prosthetic device is an artificial part which aids or replaces a bodily function and which is designed, manufactured or adjusted to fit a particular

individual." Department regulation (39-)26-717.1. Although this general definition provides some guidance, it does not directly address products that are primarily cosmetic.

Similarly, the scope of "therapeutic devices and appliances" is not well defined statutorily. The statute defines these devices and appliances as items that "correct or treat a human physical disability or surgically created abnormality."

In the absence of specific statutory guidance, courts and the department are guided by rules of statutory construction. The department is guided not only by the express terms of the statute, but also by the legislative intent as may be found by the context of the statute and other appropriate sources. However, the most specific rules of interpretation relating to taxes are the requirements that exemption itself be narrowly construed and that the exemption not be applied unless the transaction clearly falls within the exemption. *Security Life* & *Accident* Co. *v. Heckers,* 177 Colo. 455,495 P.2d 225, 226 (1972).

Prosthetic devices have traditionally included such items as an artificial arm or leg, dental implants to replace destroyed or missing teeth, and eyeglasses. Therapeutic devices encompass such items as a ventilator and muscle stimulator. See, COOR publication FYI Sales 68. Collagen gel and other implants can be prosthetic devices when used to replace body parts lost by disease or injury. For example, breast implants after mastectomy surgery and cheek implants to replace lost facial tissue destroyed by a melanoma skin cancer qualify as prosthetic devices. Common to each of these examples, however, is a use in what is traditionally and commonly understood to be a medical purpose, and not a purely cosmetic purpose.

The company states that the primary purpose of [Product] is to eliminate smile lines. In a most liberal sense, it can be argued that collagen gel smoothes (or gives structure to) skin that has lost elasticity due to aging exposure to the natural elements. In this sense, it "replaces" the elasticity the skin once had. However, under the company's view, facial creams, moisturizers, and other over-the-counter general cosmetics would qualify for this exemption if they, when applied to the face, are so infused into the skin that they alter the appearance of aging or sun damaged skin. But such a view runs counter to the principle that, when there is reasonable doubt about the scope of an exemption, it must be narrowly construed.

Moreover, exemptions are generally granted to lessen the financial burden to advance generally recognized public policy objectives (e.g., assistance to the poor, injured, and infirm). Various types of medical exemptions are granted for this reason. Thus, we view the legislative exemption for prosthetic and therapeutic devices with this objective in mind. The department has serious reservations that smoothing smile lines for only cosmetic purposes falls within what is generally understood and accepted as a prosthetic or therapeutic device.

However, [Product] falls within the exemption set forth in subsection 717(a) for "materials when furnished by a doctor as part of professional services provided to a patient." You represent that [Product] is a material furnished by physicians trained to inject the product. As such, [Product] is exempt from sales and uses taxes administered by the department.

This general information letter applies to state sales and use taxes, special district sales and use taxes administered by the department, and to local sales taxes administered by the department. He department does not administer the sales and use taxes of home-rule cities and counties. We encourage you to consult with home-rule cities and counties to determine whether their taxes apply. You can obtain a list of cities, counties and special district taxes administered by the department as well as a list of home-rule cities and counties that administer their own taxes, by visiting us on our web site at: www.taxcolorado.org > Tax Forms. Forms by Number> DRP 10002.

Pursuant to regulation 24-35-103.5, the department will publish the attached copy of a redacted version of this general information letter. You have 60 days from the date of this letter to provide the department comments, objections, or suggested changes to the redacted version in order to preserve the confidentiality of the company. Please let me know if you have any questions.

Respectfully,

Office of Tax Policy
Colorado Department of Revenue

STATE OF COLORADO

DEPARTMENT OF REVENUE
State Capitol Annex
1375 Shcnnan Street, Room 409
Denver, Colorado 80261
(303) 866-3091
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GIL-2008-6

Bill Ritter, Jr
Governor

Roxy Huber
Executive Director

XXXXXXXXXXXXX.
Attn: XXXXXXXXXX
XXXXXXXXXXXXX
XXXXXXXXXXXXX

February 28, 2008

Dear **XXXXXXXXXX,**

This letter is in response to your letter to the Colorado Department of Revenue, dated January 16, 2008, re: the taxability of medical suppliers.

Issue

1. Is [Product] exempt from sales and use tax?

Background

You provide the following facts. [Company] is a manufacturer of [Product]. [Product] is an implant that contains 20% non-resorbable polymethylmethacrylate microspheres (30 to 35 micros in diameter), and 80% purified bovine collagen gel, with .3% lidocaine hydrochloride, an anesthetic. Lidocaine hydrochloride is listed by the United States Pharmacopoeia (PMA) as a drug. [Product] is currently used for the correction of nasolabial folds (smile lines). The company is also investigating other uses for [Product].

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With respect to the exemption for drugs prescribed by a physician, [Product] does contain lidocaine hydrochloride, which is a drug that is available only by prescription. However, the true object of the transaction is the microspheres and collagen gel which create the desired effect of smoothing smile lines. The lidocaine hydrochloride is only temporary and incidental to the transaction. For this reason, the drug does not, in and of itself, transform the bulk of the [Product] product into an exempt transaction.

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Similarly, the scope of "therapeutic devices and appliances" is not well defined statutorily. The statute defines these devices and appliances as items that "correct or treat a human physical disability or surgically created abnormality."

In the absence of specific statutory guidance, courts and the department are guided by rules of statutory construction. The department is guided not only by the express terms of the statute, but also by the legislative intent as may be found by the context of the statute and other appropriate sources. However, the most specific rules of interpretation relating to taxes are the requirements that exemption itself be narrowly construed and that the exemption not be applied unless the transaction clearly falls within the exemption. *Security Life & Accident Co. v. Heckers,* 177 Colo. 455,495 P.2d 225, 226 (1972).

Prosthetic devices have traditionally included such items as an artificial arm or leg, dental implants to replace destroyed or missing teeth, and eyeglasses. Therapeutic devices encompass such items as a ventilator and muscle stimulator. See, COOR publication FYI Sales 68. Collagen gel and other implants can be prosthetic devices when used to replace body parts lost by disease or injury. For example, breast implants after mastectomy surgery and cheek implants to replace lost facial tissue destroyed by a melanoma skin cancer qualify as prosthetic devices. Common to each of these examples, however, is a use in what is traditionally and commonly understood to be a medical purpose, and not a purely cosmetic purpose.

The company states that the primary purpose of [Product] is to eliminate smile lines. In a most liberal sense, it can be argued that collagen gel smoothes (or gives structure to) skin that has lost elasticity due to aging exposure to the natural elements. In this sense, it "replaces" the elasticity the skin once had. However, under the company's view, facial creams, moisturizers, and other over-the-counter general cosmetics would qualify for this exemption if they, when applied to the face, are so infused into the skin that they alter the appearance of aging or sun damaged skin. But such a view runs counter to the principle that, when there is reasonable doubt about the scope of an exemption, it must be narrowly construed.

Moreover, exemptions are generally granted to lessen the financial burden to advance generally recognized public policy objectives (e.g., assistance to the poor, injured, and infirm). Various types of medical exemptions are granted for this reason. Thus, we view the legislative exemption for prosthetic and therapeutic devices with this objective in mind. The department has serious reservations that smoothing smile lines for only cosmetic purposes falls within what is generally understood and accepted as a prosthetic or therapeutic device.

For these reasons, I conclude that [Product] is not an exempt prosthetic device. And for these same reasons, I conclude that it does not qualify as a therapeutic device or appliance.

A similar rationale applies to [Product] as a medical supply. I note that [Product] is obtained only by a prescription and is available only through physicians trained to inject the product. It is subject to FDA approval because it is a product that is placed into a human body. For these reasons, it can be reasonably argued that, in a broad sense, this product is a medical supply. However, and as discussed above, [Product] is primarily a cosmetic product to smooth smile lines, which happens to require that a physician, rather than a cosmetologist, apply it. For the reasons discussed above, I conclude that [Product] is not a medical supply.

Finally, you state that it is your understanding that this "state" has approved similar products. I am not aware of any such approval. I assume your request for a determination has been submitted to a number of other states, some of which, as noted above, have approved competing products.

Finally, the Department makes a good faith effort to provide accurate and complete answers to questions posed to it by taxpayers. However, the information and answers provided here are not binding on the Colorado Department of Revenue, nor do they replace, alter, or supersede Colorado law and regulations. The Executive Director, who by statute is the only person having authority to bind the Department, has not formally reviewed and/or approved this response.

Respectfully,

Office of Tax Policy
Colorado Department of Revenue