REQUEST LETTER

08-004

January 21, 2008

NAME
COMPANY
ADDRESS

Re: Request for Private Letter Ruling on Sales Tax Exemption from the State Tax Commission from Utah, regarding the taxability of PRODUCT NAME product, manufactured by COMPANY.

To Whom It May Concern:

My name is NAME and I am the Corporate Controller of COMPANY (Tax ID #####, State filing# Pending), a medical device manufacturer, located in CITY, STATE. The intent of this correspondence is to respectfully request a ruling from your State Tax Commission regarding whether PRODUCT NAME, (the product manufactured by COMPANY) can be deemed exempt from sales & use tax in Utah.

PRODUCT NAME is an implant that contains 20% non-resorbable polymethylmethacrylate (PMMA) microspheres, 30 to 50 microns in diameter, and 80% purified bovine collagen gel, with 0.3% lidociane hydrochloride, an anesthetic. Please note that lidocaine hydrochloride is a drug and is listed in the United States Pharmacopeia (USP). PRODUCT NAME is currently indicated for the correction of nasolabial folds (smile lines) and we are investigating its use in other indications. PRODUCT NAME replaces the collagen that is missing in the nasolabial folds and provides a permanent support structure for such area.

PRODUCT NAME has been approved by the United States FDA. Our product is considered to be a medical device. The Food and Drug Administration defines a medical device as such:

"an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:

- Recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them.
- Intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, and which does not achieve any of it's 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."

Each medical device that is to be distributed commercially in the United States requires either prior 510(k) clearance or a PMA approval from the FDA. Medical devices are classified into one of three classes – Class I, Class II, Class III – depending on the degree of risk associated with each medical device and the extent of control needed to ensure safety and effectiveness. PRODUCT NAME is considered to be a Class III device, which requires PMA approval. The PMA application process is much more demanding than the 510(k) pre-market notification process. A PMA application must be supported by extensive data, including but not limited to technical information, pre-clinical data, clinical trials, manufacturing information and labeling to demonstrate to the FDA's satisfaction the safety and effectiveness of the device.

PRODUCT NAME is only obtained via prescription and is injected as an outpatient procedure by only Company trained physicians such as dermatologists, plastic surgeons, or cosmetics surgeons.

We have been informed by our physician customers (who use both our product and our competitor's products) that our competitors have received exemption from your state for dermal fillers, such as PRODUCT NAME`. For the purposes of helping to streamline your research, the product brand names for some of our competitor's products are PRODUCT 1 (Manufactured by COMPETITOR 1), PRODUCT 2 (Manufactured by COMPETITOR 2), PRODUCT 3 (Manufactured by COMPETITOR 3), PRODUCT 4 (Manufactured by COMPETITOR 4), and PRODUCT 5 (Manufactured by COMPETITOR 5).

For the purposes of streamlining your research I have attached some promotional materials, information that COMPANY sends to the physicians and label information.

COMPANY is anxious to receive your final determination as to whether the product is deemed exempt from sales and use tax in your state. If we are granted exemption status, please advise us as to the steps we need to take to appropriately reflect such status.

If the state deems the product taxable, we would appreciate knowing of any other exemption possibilities that our physician clients may be worthy of receiving but may not be aware of.

Please feel free to contact me at any time to discuss any questions you may have pursuant to this request for determination. I can be reached directly at ###-###-#### or via email at EMAIL ADDRESS.

Thank you again for your prompt response to the important issue.

NAME
ADDRESS

Cc: 2ND NAME, 2ND COMPANY
3RD NAME 3RD COMPANY

RESPONSE LETTER

NAME
ADDRESS

Re: Private Letter Ruling 08-004

Dear NAME,

This letter is in response to your request for tax guidance. This letter ruling is not intended as a statement of broad Tax Commission policy. It is an interpretation and application of the tax law as it relates to the facts presented in your request letter and the assumptions stated in the Analysis portion of this ruling letter. If the facts or assumptions are not correctly described in this letter ruling, please let me know so we can assure a more accurate response to your circumstances.

Facts

The Commission understands that COMPANY is a medical device manufacturer located in San Diego, California that manufactures a product called PRODUCT NAME. As COMPANY has explained its product, PRODUCT NAME is an implant that contains 20% non-resorbable polymethylmethacrylate (PMMA) microspheres, 30 to 50 microns in diameter, and 80% purified bovine collagen gel, with 0.3% lidociane hydrochloride, an anesthetic. COMPANY indicates that lidocaine hydrochloride is a drug that is listed in the United States Pharmacopeia (USP). COMPANY represents that PRODUCT NAME is currently indicated for the correction of nasolabial folds (smile lines) and that it is investigating other uses. As the product is currently used, PRODUCT NAME replaces the collagen that is missing in the nasolabial folds and provides a permanent support structure for such area.

COMPANY represents that the U.S. Food & Drug Administration ("FDA") has approved PRODUCT NAME for its current indicated uses. COMPANY likewise indicates that the FDA considers PRODUCT NAME to be a medical device under FDA definitions. COMPANY indicates that PRODUCT NAME requires a prescription and is

injected as an outpatient procedure by only by physicians such as dermatologists, plastic surgeons, or cosmetics surgeons.

COMPANY indicates that its understanding is that others providing products similar to PRODUCT NAME have already received indication from Utah officials that their products are not subject to sales tax. COMPANY has inquired whether it should collect sales tax on the Utah sales of its PRODUCT NAME product.

Relevant Authority

Utah Code §59-12-103(1)(a) imposes sales tax on amounts paid or charged for "retail sales of tangible personal property made within the state."

Utah Code § 59-12-104(55) provides exemption from sales tax for prosthetic devices purchased by a hospital or other medical facility or for which a prescription is required.

Utah Code § 59-12-102(69) defines "prosthetic device" as follows:

(a) "Prosthetic device" means a device that is worn on or in the body to:
(i) artificially replace a missing portion of the body;
(ii) prevent or correct a physical deformity or physical malfunction; or
(iii) support a weak or deformed portion of the body.
(b) "Prosthetic device" includes:
(i) parts used in the repairs or renovation of a prosthetic device;
(ii) replacement parts for a prosthetic device; or
(iii) dental prostheses.
(c) "Prosthetic device" does not include:
(i) corrective eyeglasses;
(ii) contact lenses; or
(iii) hearing aids.

Utah Code § 59-12-104(10) provides exemption from sales tax for a drug, if the drug meets two requirements. First, the drug must be "for use on or in a human." Second, it must either be purchased by a hospital or medical facility or issued under a prescription.

Utah Code § 59-12-102(29) defines "drug" as follows:

(a) "Drug" means a compound, substance, or preparation, or a component of a compound, substance, or preparation that is:
(i) recognized in:
(A) the official United States Pharmacopoeia;
(B) the official Homeopathic Pharmacopoeia of the United States;

(C) the official National Formulary; or
(D) a supplement to a publication listed in Subsections (29)
(a)(i)(A) through (C);
(ii) intended for use in the:
(A) diagnosis of disease;
(B) cure of disease;
(C) mitigation of disease;
(D) treatment of disease; or
(E) prevention of disease; or
(iii) intended to affect:
(A) the structure of the body; or
(B) any function of the body.
(b) "Drug" does not include:
(i) food and food ingredients;
(ii) a dietary supplement;
(iii) an alcoholic beverage; or
(iv) a prosthetic device.

Analysis and Ruling

As COMPANY has described the current use of its PRODUCRT NAME product, it will qualify for a sales tax exemption if it fits within the Utah statutory definitions for a "prosthetic device." A device comes within the statutory definition for "prosthetic device" if it is a device that is worn on or in the body to: (i) artificially replace a missing portion of the body; (ii) prevent or correct a physical deformity or physical malfunction; or (iii) support a weak or deformed portion of the body.

Applying the definition for "prosthetic device," it appears that the PRODUCT NAME product, as COMPANY has described it, would be a prosthetic device. In making this determination, the Commission relies on the facts as presented by COMPANY. The PRODUCT NAME product has already been determined by the FDA to be a device. It is worn in the body of the patient. It provides physical support for skin and related tissues that have a deformation in the form of a wrinkle or fold. Considering these facts as presented by COMPANY, the Commission finds that PRODUCT NAME can be sold without sales tax in Utah because it is exempt as a prosthetic device.

If the PRODUCT NAME product did not fit Utah's definition of a prosthetic device, it would likely qualify for exemption as a "drug." Utah Code § 59-12-102(29) defines "drug" in three broad categories. Each of those broad categories has a separately numbered subsection in section 102(29). Subsection (i) refers to listings in official drug publications; subsection (ii) makes reference to the intended use of the product; and subsection (iii) discusses the effect of the product on the body of the user. It is important to note that these three subsections are connected by an "or" rather than an "and" connector.

The disjunctive "or" connector used to join the three subsections of Utah Code § 59-12-102(29) indicates that if a product meets any one of the three subsections, it is a "drug" under Section 102(29). Thus, if a product is listed in official publications as described in subsection (i), qualifies under use descriptions under subsection (ii), ***or*** has the required effect on the body of the user under subsection (iii), it is a "drug" for purposes of Utah Code § 59-12-102(29).

Under the facts as described by COMPANY for its PRODUCT NAME product, if the product was not a prosthetic device, it would be a drug under Utah Code § 59-12-102(29) because it is a "compound, substance, or preparation, or a component of a compound, substance, or preparation . . . intended to affect . . . the structure of the body." As a drug, the PRODUCT NAME product also meets the requirements for exemption in Utah Code § 59-12-104(10). The drug requires a prescription and is "intended for human use."

Conclusion

Under Utah law, sales of PRODUCT are transactions for the sale of tax-exempt prosthetic devices. Sales of this product by a medical facility are thus not subject to Utah sales or use tax under the product's current use as described by COMPANY. Should COMPANY contemplate other uses of its PRODUCT NAME product, it should seek advice whether those different uses would trigger sales or use tax under Utah law.

For the Commission,

Marc B. Johnson
Commissioner

MBJ/CDJ
08-004