

Medicines and medical appliances are not taxed at the general State rate of 6.25%. These items are taxed at a lower State rate of 1%. See 86 Ill. Adm. Code 130.310. (This is a GIL.)

October 30, 2009

Dear Xxxxx:

This letter is in response to your letter dated December 15, 2008, in which you request information. The Department issues two types of letter rulings. Private Letter Rulings ("PLRs") are issued by the Department in response to specific taxpayer inquiries concerning the application of a tax statute or rule to a particular fact situation. A PLR is binding on the Department, but only as to the taxpayer who is the subject of the request for ruling and only to the extent the facts recited in the PLR are correct and complete. Persons seeking PLRs must comply with the procedures for PLRs found in the Department's regulations at 2 Ill. Adm. Code 1200.110. The purpose of a General Information Letter ("GIL") is to direct taxpayers to Department regulations or other sources of information regarding the topic about which they have inquired. A GIL is not a statement of Department policy and is not binding on the Department. See 2 Ill. Adm. Code 1200.120. You may access our website at www.tax.illinois.gov to review regulations, letter rulings and other types of information relevant to your inquiry.

In your letter you have stated and made inquiry as follows:

COMPANY respectfully requests a private letter ruling by the Illinois Department of Revenue, pursuant to 2 Ill. Adm. Code 1200.110, as to the applicability of Retailers' Occupation Tax to injectable tissue implants, pharmaceutical drugs and surgical adhesives which are sold to physicians and hospitals.

GENERAL INFORMATION:

1. This Private Letter Ruling ("PLR") is not requested with regard to hypothetical or alternative proposed transactions. This PLR is requested to determine the state and local Retailers' Occupation Tax implications of the actual business practice of COMPANY
2. COMPANY is not currently under audit or engaged in litigation with the Illinois Department of Revenue ("IL DOR") with regard to this or any other tax matter. Nor is COMPANY under audit with the IL DOR.
3. The IL DOR has not previously ruled regarding this matter, nor has any similar matter been issued to the IL DOR by COMPANY
4. COMPANY requests that certain information be deleted from the PLR prior to public dissemination. Specifically, COMPANY requests that its name, address,

headquarter location, manufacturing facility location, product names (PRODUCT1, PRODUCT2, PRODUCT3, and PRODUCT4), and signature lines be deleted.

5. COMPANY knows of no authority contrary to the authorities referred to and cited below.

STATEMENT QF FACTS:

COMPANY is a medical device and pharmaceutical company, headquartered in CITY/STATE, with a manufacturing facility in CITY/STATE2. COMPANY's products are used for a range of medical conditions.

I.a. Injectable Tissue Implants

a. PRODUCT1

COMPANY's core product, PRODUCT1, is a tissue filler implant that is injected by physician or a nurse under the supervision of a physician. PRODUCT1 consists of XXXX, suspended in a water-based gel carrier.

PRODUCT1 is sold in individually packaged, single dose syringes. PRODUCT1 packaging carries the following labeling as required by the FDA:

Federal (USA) law restricts this device to sale by or on the order of a physician.

PRODUCT1 repairs defects in soft tissue of the body by initially replacing lost tissue volume and then stimulating the production of new, long-term natural collagen by the body. Collagen is a fibrous protein that is the chief constituent of the fiber of the connective tissues in soft tissues of the body, including skin.

PRODUCT1 is used in the treatment of defective, diseased, traumatized, or aging human tissue to correct a number of soft tissue defects, including moderate to severe facial wrinkles and folds (such as nasolabial folds), restoration and/or correction of the signs of facial fat loss (lipoatrophy) in people with HIV, vocal fold augmentation to treat speech impediments caused typically by stroke or neurological disorder, acne scars, oral and maxillofacial defects, and nipple reconstruction after mastectomy. The U.S. Food and Drug Administration ("FDA") has issued approvals for PRODUCT1 to be marketed for the following treatments:

- 2001 Radiographic tissue marking
- 2002 Vocal fold augmentation to treat speech impediments caused typically by stroke or neurological disorder
- 2003 Oral and maxillofacial defects
- 2006 (Dec) Facial lipoatrophy
- 2006 (Dec) Nasolabial folds and marionette lines

PRODUCT1 is currently most commonly used by doctors in the U .S. for the treatment of moderate to severe facial wrinkles and folds (such as nasolabial folds). COMPANY is working with the FDA on clinical studies covering the use of PRODUCT1 for additional soft tissue treatments as well as using PRODUCT1 combined with lidocaine, a prescription anesthetic.

b. PRODUCT2

PRODUCT2 is an injectable implant used as a peri-urethral bulking agent to treat women who have stress urinary incontinence due to poorly functioning urethral sphincter muscles. PRODUCT2 consist of XXXX suspended in a gel carrier. The PRODUCT2 implant is injected into the space around the urethra near the bladder. After injection, the PRODUCT2 implant bulks the tissue near the urethral sphincter and stimulates the production of new, long-term natural collagen by the body, enabling the sphincter to function more effectively.

The FDA has issued an approval for PRODUCT2 to be marketed for the following treatment:

- 2005 Peri-urethral bulking agent to treat women who have stress urinary incontinence due to poorly functioning urethral sphincter muscles

PRODUCT2 is sold in individually packaged, single dose syringes. PRODUCT2 packaging carries the following labeling as required by the FDA:

Federal (USA) law restricts this device to sale by or on the order of a physician.

I.b. **Pharmaceutical Drugs**

c. PRODUCT3

Veins channel oxygen-depleted blood back toward the heart through one-way valves. If the valves of the veins do not function well, blood does not flow efficiently. The veins become enlarged because they are congested with blood. These enlarged vein are commonly called spider veins or varicose veins. Spider veins are small red, blue or purple veins on the surface of the skin. Varicose veins are larger distended veins that are located somewhat deeper than spider veins. There are several adverse consequences of untreated varicose veins, and their severity will vary from person to person depending on the circumstances.

Sclerotherapy is a common treatment for small (spider) and medium size (reticular) veins. A tiny needle is used to inject the veins with a solution (called a sclerosant) that irritates the lining of the vein. In response, the veins collapse and are reabsorbed. The surface veins are no longer visible. Depending on the size and location of the veins, different types and strengths of sclerosants are used. With this procedure, veins can be dealt with at an early stage, helping to prevent further complications including surgical removal of veins.

PRODUCT3 is a well recognized worldwide standard of care for venous sclerotherapy (sold under, the trade name NAME outside the U.S.). Such treatment is typically performed by vascular surgeons, phlebologists, and dermatologists. PRODUCT3 is in a clinical trial in the United States and not yet approved by FDA for use in the U.S. as a treatment for varicose veins and will be sold by COMPANY only after such approval is received. **The product is classified as a prescription pharmaceutical by the FDA.** The trade name for this product in the United States has not been selected.

II. **Surgical Adhesives**

a. PRODUCT4

PRODUCT4 is a surgical adhesive used in conjunction with sutures and staples in open surgical repair of large vessels, including cardiovascular, vascular, pulmonary and other general surgical applications. It is a sealant made of bovine serum albumin and glutaraldehyde which can be used in facial aesthetic applications to create a durable mechanical bond with full adhesion. It is an attractive alternative to conventional fixation methods such as drilling into the skull for fixation or other suspension methods. PRODUCT4 is a Class III medical device, subject to the medical device regulatory approval pathway. As a Class III item, it must go through the most stringent of the regulatory processes for devices. Class III devices are usually those that can support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential, reasonable risk of illness or injury. (U.S. Food and Drug Administration web site -"Device Advice," updated August 4, 2004)

QUESTIONS POSED:

- I. Whether the following injectable tissue implants and pharmaceutical drugs will be subject to Retailers' Occupation Tax in Illinois at the reduced tax rate of 1%, plus applicable local taxes, or the standard rate:
 - a. PRODUCT1
 - b. PRODUCT2
 - c. PRODUCT3

- II. Whether PRODUCT4 will be subject to Retailers' Occupation Tax in Illinois at the reduced tax rate of 1%, plus applicable local taxes, or the standard rate.

STATEMENT OF AUTHORITIES:

Illinois imposes a Retailers' Occupation Tax on the gross receipts from the sale of tangible personal property unless specifically exempted.¹

Illinois provides a reduced tax rate of 1%, plus applicable local taxes, for prescription and non-prescription medicines and drugs, as well as medical appliances. A medicine or drug is defined to be any pill, powder, potion, salve, or other preparation for human use that purports on the label to have medicinal qualities. A medical device is defined as an item that is intended for use directly substituting a malfunctioning part of the body.²

A General Information Letter issued in April 2002 addressed an inquiry regarding a dermatologist who used injectable collagen to correct scars and wrinkles. The IL DOR stated a determination could not be made as to whether the injections would qualify as a medicine or drug. The reasoning was the injections were used for temporary cosmetic improvements of the skin as opposed to treating disease or infection. However, the IL DOR concluded that if the collagen injections were intended by the manufacturer for human use and are purported to have medicinal qualities, they may qualify for the reduced rate of tax at 1%, plus applicable local taxes.³

¹ 35 ILCS 120/2-10

² 86 Ill. Adm. Code 130.310

³ Ill. ST 02-0075-GIL

A General Information Letter issued in February 2003 specifically addressed the application of Retailers' Occupation Tax pertaining to sutures. The IL DOR responded that sutures qualified for the reduced rate of tax.⁴

ANALYSIS:

I.a. Injectable Tissue Implants

Under 86 Ill. Adm. Code 130.310, drugs and medicines are subject to the reduced tax rate of 1%, plus applicable local taxes, if they are for human use and purport on the label to have medicinal qualities. COMPANY's injectable tissue implants have medicinal ingredients and are intended to treat defective, diseased, traumatized, or aging human tissue by initially replacing lost tissue and then stimulating the body to grow new collagen in the treated areas. COMPANY's products directly affect the structure of the tissue system in its patients by stimulating new collagen growth which provides long-term benefits to the patients.

A General Information Letter was released by the IL DOR in April 2002 which dealt with injectable collagen. A dermatologist used injectable collagen to correct scars and wrinkles. The IL DOR suggested that the collagen injections did not qualify as a medical appliance since they were not intended for use in directly substituting a malfunctioning part of the body. In addition, the IL DOR could not make a determination if the injections would qualify as a medicine or a drug. The IL DOR reasoned that the injections were used for temporary cosmetic improvements of the skin as opposed to treating any disease or infection. However, the IL DOR concluded that if the collagen injections were intended by the manufacturer for human use and are purported to have medicinal qualities, they may qualify for the reduce tax rate of 1%, plus applicable local taxes.

COMPANY's injectable tissue implants are distinguishable from that General Information Letter. COMPANY's products have medicinal ingredients, are available only upon prescription, and are sold mainly to medical clinics and doctors. PRODUCT1 is used in the treatment of defective, diseased, traumatized, or aging human tissue to correct a number of soft tissue defects. PRODUCT1 is approved by the FDA for a variety of treatments. It is most commonly used by doctors in the U.S. for the treatment of moderate to severe facial wrinkles and folds (such as nasolabial folds). PRODUCT1 is also used for the restoration and/or correction of the signs of facial fat loss (lipoatrophy) in people with HIV, vocal fold augmentation to treat speech impediments caused typically by stroke or neurological disorder, acne scars, treatment of oral and maxillofacial defects, and nipple reconstruction after mastectomy. PRODUCT2 specifically does not have any affect on the patient's appearance. It is used to bulk the tissue around the urethra to treat stress urinary incontinence due to poorly functioning sphincter muscles.

CONCLUSION	COMPANY's tissue implants (PRODUCT1 and PRODUCT2) should be considered medicines and subject to the reduced tax rate of 1%, plus applicable local taxes.
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I.b. Pharmaceutical Drugs

⁴ Ill. ST 03-0023-GIL

Under 86 Ill. Adm. Code 130.310, drugs and medicines are subject to the reduced tax rate of 1%, plus applicable local taxes, if they are for human use and purport on the label to have medicinal qualities.

PRODUCT3 (sold under the trade name NAME outside the U.S.) is classified as a prescription pharmaceutical by the FDA. If the valves of veins don't function well, blood doesn't flow efficiently. For these small and medium size red, blue or purple veins on the surface of the skin that no longer function properly, PRODUCT3 is use in sclerotherapy treatment to eliminate the veins. With this procedure, veins can be dealt with at an early stage, helping to prevent further complications including surgical removal of veins.

CONCLUSION PRODUCT3 should be considered a drug and subject to the reduced tax rate of 1%, plus applicable local taxes.

II. Surgical Adhesives

86 Ill. Adm. Code 130.310 provides a reduced tax rate of 1%, plus applicable local taxes, for medical appliances. A medical appliance is defined as an item that is intended for use directly substituting a malfunctioning part of the body.

A General Information Letter was released by the IL DOR in February 2003 which dealt with the application of Retailers' Occupation Tax to sutures. Based on the facts presented in the letter, sutures are a medical appliance and qualify for the reduced tax rate.

PRODUCT4 is a surgical adhesive currently approved by the FDA and used in conjunction with sutures and staples in cardiac surgical repair of large blood vessels. COMPANY is seeking approval by the FDA to sell it for use in aesthetic surgical procedures to create a durable mechanical bond between tissues and / or bone similar to the use of sutures and staples to hold tissues together in cardiac surgery. COMPANY will not be able to sell PRODUCT4 until it is approved by the FDA and will only be able to be sold under the direction of a physician.

CONCLUSION PRODUCT4 should be considered a medical appliance, subject to the reduced tax rate of 1%, plus applicable local taxes.

COMPANY wishes for the IL DOR to confirm these conclusions reached in the above analysis or to provide any other guidance as appropriate.

If you have any questions or concerns, please contact INDIVIDUAL.

DEPARTMENT'S RESPONSE:

The Department's regulation "Public Information, Rulemaking and Organization" provides that "[w]hether to issue a private letter ruling in response to a letter ruling request is within the discretion of the Department. The Department will respond to all requests for private letter rulings either by issuance of a ruling or by a letter explaining that the request for ruling will not be honored." 2 Ill. Adm. Code 1200.110(a)(4). The Department recently met and determined that it would decline to issue a Private Letter Ruling in response to your request. We hope, however, the following will be helpful in addressing your questions.

For useful information regarding the taxation of food, drugs, medicines and medical appliances, we refer you to the Department's regulation at 86 Ill. Adm. Code 130.310. Those products that qualify as medicines, drugs, or medical appliances are taxed at the reduced tax rate of 1% plus applicable local taxes. Those that do not qualify for the low rate are taxed at the State rate of 6.25%, plus applicable local taxes.

The Department's regulation at Section 130.310(c)(1) defines a medicine or drug as "any pill, powder, potion, salve, or other preparation intended by the manufacturer for human use and which purports on the label to have medicinal qualities." Thus, in determining whether a medicine or drug qualifies for the low rate, the Department looks at whether it has medicinal qualities.

The definition of a medical appliance is "an item which is intended by its manufacturer for use in directly substituting for a malfunctioning part of the body." Please note that 86 Ill. Adm. Code 130.310(c)(2) provides that medical appliances may be prescribed by licensed health care professionals for use by a patient, purchased by health care professionals for the use of patients, or purchased directly by individuals. Note, though, not all items prescribed by physicians or other licensed health care professionals qualify for the low rate. The Department has determined that medical appliances used for cosmetic purposes do not qualify for the low rate of tax. For example, implants that are used for cosmetic reasons and are not used to substitute for a malfunctioning part of the body do not qualify for the low rate of tax.

Health professionals and other unregistered de minimis servicemen that owe Use Tax on purchases of medical appliances that may or may not qualify for the low rate, depending upon the ultimate use of the medical appliance by the health professionals, may provide retailers with certificates that identify, based on historical use, the percentage of medical appliances being purchased that qualify for the low rate, e.g., that are purchased to be used to replace a malfunctioning part of the body. The certificate should contain the following information:

- A) the seller's name and address;
- B) the purchaser's name and address;
- C) a description of the medical appliances being purchased;
- D) the percentage of the medical appliances being purchased that qualify for the low rate;
- E) the purchaser's signature, or the signature of an authorized employee or agent of the purchaser, and date of signing; and
- F) if the purchaser is registered with the Department, the purchaser's Registration Number or Resale Number.

Without a percentage certificate, all of the products sold will be taxed at the high rate.

As you have noted, the specific items about which you have inquired may be used for different purposes. Accordingly, the tax rate applicable to those items will depend on how they are used (replacing a malfunction part of the body or for cosmetic purposes). For example, if PRODUCT1 were used in a procedure involving reconstruction after a mastectomy, it would generally qualify for the low rate of tax. If, however, it were used merely for breast enhancement for cosmetic purposes or for the treatment of facial wrinkles, it would be taxed at the high rate.

Further, please note that if PRODUCT4 were used in place of sutures or staples it may qualify for the low rate of tax. Finally, the Department declines to make a determination whether a product that has not yet been approved by the FDA for use in the United States would qualify for the low rate of tax.

I hope this information is helpful. If you have further questions related to the Illinois sales tax laws, please visit our website at www.tax.illinois.gov or contact the Department's Taxpayer Information Division at (217) 782-3336.

Very truly yours,

Debra M. Boggess
Associate Counsel

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