

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.)

June 11, 2010

Dear Xxxxx:

This letter is in response to your letter dated December 9, 2008 and follow-up dated November 30, 2009, 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 dated December 9, 2008, you have stated and made inquiry as follows:

Petitioner requests a private letter ruling concerning the application of the Illinois retailers [sic] occupation tax to the sale of biological soft tissue products made from human and animal tissues. Petitioner respectfully requests this ruling based on the facts as set forth below.

Question:

Are sales of biological soft tissue products made from human and animal tissues and used as a subcutaneous implant for the replacement of soft tissue in reconstructive surgical procedures subject to the State's retailer's [sic] occupation tax pursuant to 35 ILCS 120/2?

Facts:

Petitioner is a processor and marketer of biological soft tissue products made from human ('allograft') and animal ('xenograft') tissues. Petitioner's products include AAA, which is an allograft product used in plastic reconstructive, general surgical, burn and periodontal procedures and BBB which is a xenograft product used in plastic reconstructive and general surgical procedures.

AAA is an acellular dermal matrix derived from donated human skin tissue supplied by US AATB-compliant tissue banks utilizing the standards of the American Association of Tissue Banks (AATB) and Food and Drug Administration's (FDA) requirements. AAA has been classified as banked human tissue by the FDA. AAA is prepared from human tissue that undergoes a multi-step proprietary process that removes both the epidermis and the cells that can lead to tissue rejection and graft failure. Following transplant, AAA is revascularized and repopulated with the patient's own cells becoming engrafted into the patient.

AAA is predominately used as a subcutaneous implant for the replacement of soft tissue in reconstructive surgical procedures in various areas of the body. AAA is used to repair defects resulting from trauma, previous surgery, hernia repair, infection, tumor resection, mastectomy or general failure of the musculofacial tissue. Specific applications of the AAA product would include use in abdominal wall reconstruction, hernia repair, postmastectomy breast reconstruction, ENT/Head & Neck plastic reconstruction, burn graft, wound coverage, mucosal grafts and oral resurfacing.

BBB is porcine dermis (pig skin) that has been processed by PETITIONER to form an acellular tissue matrix. BBB supports the repair of damaged tissue by allowing rapid revascularization and cell repopulation required for tissue regeneration. BBB is regulated as a medical device and received 510(k) clearance from the FDA in June 2007 for use as a soft tissue patch to reinforce tissue were [sic] weakness exists and for surgical repair of damaged or ruptured soft tissue membranes. In October 2007, additional clearance was received to use BBB for soft tissue reinforcement in surgical procedures intended to repair rotary cuff tissue.

Petitioner's products are sold to hospitals and medical service providers for use in the repair or replacement of missing or permanently malfunctioning body parts. Petitioner's products are used in the treatment of individual patients suffering from damaged soft tissues. Although Petitioner's products are incorporated into the patients [sic] existing soft tissues, they remain separately identifiable after implantation.

Statutory Authority:

35 ILCS 120/2 provides:

A tax is imposed upon persons engaged in the business of selling at retail tangible personal property, including computer software, and including photographs, negatives, and positives that are the product of photoprocessing, but not including products of photoprocessing produced for use in motion pictures for public commercial exhibition.

35 ILCS 120/1 defines the term 'sale at retail' as:

Any transfer of the ownership of or title to tangible personal property to a purchaser, for the purpose of use or consumption, and not for the purpose of resale in any form as tangible personal property to the extent not first subjected to a use for which it was purchased, for a valuable consideration.

35 ILCS 120/2-10 provides:

Unless otherwise provided in this Section, the tax imposed by this Act is at the rate of 6.25% of gross receipts from sales of tangible personal property made in the course of business. With respect to food for human consumption that is to be consumed off the premises where it is sold (other than alcoholic beverages, soft drinks, and food that has been prepared for immediate consumption) and prescription and nonprescription medicines, drugs, medical appliances, modifications to a motor vehicle for the purpose of rendering it usable by a disabled person, and insulin, urine testing materials, syringes, and needles used by diabetics, for human use, the tax is imposed at the rate of 1%.

745 ILCS 40/2 provides:

The procuring, furnishing, donating, processing, distributing or using human whole blood, plasma, blood products, blood derivatives and products, corneas, bones, or organs or other human tissue for the purpose of injecting, transfusing or transplanting any of them in the human body is declared for purposes of liability in tort or contract to be the rendition of a service by every person, firm or corporation participating therein, whether or not any remuneration is paid therefor, and is declared not to be a sale of any such items and no warranties of any kind or description nor strict tort liability shall be applicable thereto, except as provided in Section 3.

745 ILCS 40/3 provides:

Every person, firm or corporation involved in the rendition of any of the services described in Section 2 warrants to the person, firm or corporation receiving the service and to the ultimate recipient that he has exercised due care and followed professional standards of care in providing the service according to current state of the medical arts, and in the case of a service involving blood or blood derivatives that he has rendered such service in accordance with 'The Blood Labeling Act', effective October 1, 1972.

III. Admin. Code 130.310 defines the term 'medical appliance' as:

An item that is intended by its manufacturer for use in directly substituting for a malfunctioning part of the human body. These items 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.

Petitioner's Contentions:

Petitioner contends that the transfer of human based or allograft soft tissue products for remuneration is specifically excluded from the definition of a sale under the provisions of 745 ILCS 40/2 and therefore would not be subject to the Illinois retailers [sic] occupation tax. Petitioner further contends that the sale of porcine based xenograft soft tissue product would constitute the sale of a medical appliance under the definitions provided in III. Admin. Code 130.310 and would be subject to the reduced rate of tax as provided in 35 ILCS 120/2-10.

Confidential Information:

Petitioner consents to the publication of the requested private letter ruling opinion upon issuance, with the knowledge that the advisory opinion may include information contained in this petition. Petitioner requests that petitioner's name, address, identifying numbers and product brand names be redacted from the published version of the advisory opinion.

Contact information:

Petitioner submits this request in accordance with rules as provided in Ill. Admin. Code 1200.110. Petitioner respectfully requests that response to this request for private letter ruling be forwarded to:

NAME/ADDRESS

Petitioner is not under audit by the Department and no litigation is pending with the Department. It is the Petitioners [sic] understanding that the Department has not previously ruled on the same or similar issue for the Petitioner or a predecessor. In addition, Petitioner has not previously submitted the same or a similar issue to the Department and withdrawn it prior to a letter ruling being issued. If you should have any questions regarding this matter or should require any additional information, please call me.

In your follow-up letter dated November 30, 2009, you have stated and made inquiry as follows:

PETITIONER's products are marketed to and distributed for reconstructive, general surgical and burn applications through our direct sales and marketing organization. Sales representatives are responsible for interacting with plastic surgeons; general surgeons; ear, nose and throat surgeons; and burn surgeons to educate them regarding the use and potential benefits of our reconstructive tissue products.

AAA is regulated by the U.S. Food and Drug Administration (The FDA or the agency) under the Code of Federal regulations Title 21 part 1271 Human Cells, Tissues, and Cellular and Tissue based products (HCT/P). Under this regulation the products are required to be:

- Minimally manipulated and homologous meaning the repair, reconstruction, replacement, or supplementation of a recipient's cells or tissues with an HCT/P that performs the same basic function or functions in the recipient as in the donor in order to be classified as a '361' HCT/P

As a '361' HCT/P, AAA does not require a 510(k) filing nor any other type of submission prior to marketing the product. However, PETITIONER does go through inspections by the FDA according to the agency's timeline that verifies the products should still be classified under the Code of Federal regulations Title 21 part 1271 Human Cells, Tissues, and Cellular and Tissue based products. We have enclosed the packaging for AAA and Human Cell and Tissue Establishment Regulation for your review (Exhibit I and II).

BBB (1, 4 and 5) or CCC (3 and 4) is distributed as a surgical mesh device. For these products BBB had the following 510(k) clearances:

Surgical mesh (Exhibit III)

Surgical mesh for rotator cuff (Exhibit IV)

Surgical mesh for tendons (also includes rotator cuff) (Exhibit V)

Surgical mesh for breast plastic surgery (Exhibit VI)

For each of these clearances we have included the following:

- The Product Classification
- The 510(k) Pre market Notification
- Letter from the Department of Health & Human Services 510(k) summary and Indication for Use Statement

We have also enclosed the packaging for BBB (Exhibit VII). Please let us know if you need any additional information.

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 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.

Although it appears that the items about which you have inquired would most often be used to directly substitute for a malfunctioning part of the human body, it appears that they might also be used for cosmetic reasons. Accordingly, the tax rate applicable to such items will depend on how they are used (substituting for a malfunctioning part of the body or for cosmetic purposes). For example, if the products referred to in your letter were used in a procedure involving reconstruction after a mastectomy, they would generally qualify for the low rate of tax. If, however, they were used merely for breast enhancement for cosmetic purposes, they would be taxed at the high rate.

Finally, you have cited the Blood and Organ Transaction Liability Act (745 ILCS 40/2) as a basis for exempting AAA from the Retailers' Occupation Tax Act. The Blood and Organ Transaction Liability Act does not apply here. The Retailers' Occupation Tax Act governs the taxability of sales of tangible personal property and the Service Occupation Tax Act governs the taxability of tangible personal property transferred incident to a sale of service. In addition, even by its own terms, the Blood and Organ Transaction Liability Act's declaration that certain transactions related to human tissue are declared to be the rendition of service is made only "for the purpose of liability in tort or contract". This declaration, by its own terms, has no bearing on the taxability of these items under the Service Occupation Tax or the Retailers' Occupation Tax.

I hope this information is helpful. If you require additional information, please visit our website at www.tax.illinois.gov or contact the Department's Taxpayer Information Division at (217) 782-3336.

Sincerely,

Samuel J. Moore
Associate Counsel

SJM:msk