

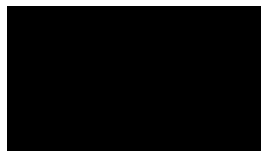


STATE OF MICHIGAN
DEPARTMENT OF TREASURY
LANSING

RICK SNYDER
GOVERNOR

NICK A. KHOURI
STATE TREASURER

January 9, 2017



Re: [REDACTED] Products

Dear [REDACTED]:

Thank you for your letter dated November 18, 2016. You have requested a technical advice letter regarding the sales and use tax treatment of certain bone grafting products sold by your client, [REDACTED] ([REDACTED]), to Michigan customers. Your request meets the requirements for issuance of a Technical Advice Letter pursuant to Revenue Administrative Bulletin 2016-20.

Facts:

[REDACTED] is a corporation engaged in the business of manufacturing and selling products and devices used in bone grafting. Each of its products is used in bone grafting by dental clinics and/or hospitals, some of which are located in Michigan. The products are surgically placed in the patient's body and are not removed. Rather, they are resorbed and/or remodeled into host tissue. The products are not used solely for research. You have specifically asked about the sales and use tax treatment of the following products:

1. [REDACTED] and [REDACTED]. These products are used in dentistry to repair or remodel patient bone (bone regeneration). Both products are surgically placed into bony defects and are incorporated to become part of a patient's bone structure. Both are considered human tissue by the Federal Drug Administration (FDA).
2. [REDACTED] made from human tissue that is [REDACTED]. This product is incorporated into a patient's bone structure. It is considered a medical device by the FDA.
3. [REDACTED] and [REDACTED]. This product is surgically placed into bony defects and become part of the patient's bone structure. This product is considered a medical device by the FDA.
4. [REDACTED] used to cover bone graft material. This product is derived from [REDACTED]; therefore, it is neither synthetic nor human. This product is surgically placed next to bony defects and is incorporated into a patient's body. This product is considered a medical device by the FDA.

5. *Medical hand instruments.*¹

You have not disclosed whether any of these products are dispensed, or are legally required to be dispensed, pursuant to a prescription.

Law and Analysis:

Michigan's General Sales Tax Act (GSTA) imposes a 6% sales tax on the gross proceeds of "all persons engaged in the business of making sales at retail, by which ownership of tangible personal property is transferred for consideration..."² Michigan's Use Tax Act (UTA) imposes a 6% tax "for the privilege of using, storing, or consuming tangible personal property in this state..."³

1. [REDACTED] and [REDACTED].

You have indicated that the FDA classifies these products as human tissue. Under Michigan's Public Health Code it is illegal to sell body parts for "valuable consideration."⁴ However, reasonable charges "for the removal, processing, preservation, quality control, storage, transportation, implantation, or disposal..." of the human tissue is permissible.⁵ The Public Health Code defines "body part" to include "tissue of a human being."⁶ "Tissue" is defined to mean "a portion of the human body other than an organ or an eye."⁷ Assuming these products constitute "tissue" for purposes of Michigan's public health code, they are not subject to Michigan sales or use tax because the charges for human tissue are related to the service of caring for and processing the human tissue; therefore, it is considered the sale of a nontaxable service, and not a taxable sale of tangible personal property.

If these products do not constitute human tissue, then the analysis in 3, below, applies.

2. [REDACTED] made from human tissue that is [REDACTED].

To the extent that this product constitutes human "tissue" the analysis in 1, above, applies. If it is not human tissue, the analysis in 3, below, applies.

3. [REDACTED] and [REDACTED] and [REDACTED] used to cover bone graft material.

The Acts exempt the sale of drugs for human use that can only be legally dispensed by a prescription.⁸ The Acts define "drug" as follows:

¹ Your letter does not provide any description of "medical hand instruments."

² MCL 205.52(1).

³ MCL 205.93(1). For purposes of this letter, "Acts" refers to both the GSTA and the UTA.

⁴ MCL 333.10116(1).

⁵ MCL 333.10116(2).

⁶ MCL 333.10102(d).

⁷ MCL 333.10102(ff).

⁸ MCL 205.54g(1)(a); MCL 205.94d(1)(a).

A “drug” is “a compound, substance, or preparation, or any component of a compound, substance, or preparation, other than food or food ingredients, dietary supplements, or alcoholic beverages, intended for human use that is 1 or more of the following:

- (i) Recognized in the official United States pharmacopoeia, official homeopathic pharmacopoeia of the United States, or official national formulary, or in any of their supplements.
- (ii) Intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease.
- (iii) Intended to affect the structure or any function of the body.⁹

Assuming these two products may only be legally dispensed pursuant to a prescription, the products, as described, meet the rest of the definition of drug, and would therefore, be exempt from sales and use tax.¹⁰

4. *Medical hand instruments.* You have provided insufficient information regarding these products.

Please contact me if you have any further questions regarding this matter.

Sincerely,

Lance R. Wilkinson, Administrator
Tax Policy Division

⁹ MCL 205.51a(h); MCL 205.92b(h).

¹⁰ The exemption for prescription drugs for human use is a property based exemption that is also provided for in Michigan’s Constitution. Const 1963, art 8, § 8. Therefore, even though [REDACTED] is likely not selling these products to doctors, dentist, or hospitals pursuant to a prescription, the purchaser may still claim the prescription drug exemption so long as the drug may only be legally dispensed pursuant to a prescription and the purchaser will eventually prescribe the drug to a patient.