PRIVATE TAXPAYER RULING LR09-005

October 26, 2009

This private taxpayer ruling is in response to a letter dated May 18, 2007, as supplemented by letters dated June 25, 2007, September 4, 2007, and October 13, 2009, in which your company, . . . ("Company"), requested a private taxpayer ruling regarding transaction privilege tax liability for sales of . . . ("X"), a product manufactured by Company*. Pursuant to Arizona Revised Statutes ("A.R.S.") § 42-2101, the Department may issue private taxpayer rulings to taxpayers and potential taxpayers on request. In accordance with A.R.S. § 42-2101(I), the Department issues this private taxpayer ruling, addressing Company's future transactions and tax liabilities accruing from the date the taxpayer receives this ruling, to provide guidance on prospective actions Company may choose to undertake in substantially similar transactions.

Statement of Facts

Below is a restatement of the significant facts, as provided in a May 18, 2007 letter:

> [X] is categorized by the FDA [U.S. Food and Drug Administration] as a Class III Medical Device, which is the most extensively regulated class under the "Medical Device Amendments of 1976" by the FDA. [X] is permanent, injectable dermal filler used for the correction of skin depressions caused by traumatic scars, acne scars, viral infections and wrinkles. [X] primarily consists of bovine collagen and polymethylmethacrylate (PMMA) microspheres. The PMMA is non-phagocytosable by microphages or giant cells and non-degradable by enzymes. Therefore, the microspheres remain intact in the dermal/sub dermal junction of skin, forever.
>
> [Company's] product, [X], is injected as an outpatient procedure by only Company trained physicians such as dermatologists, plastic surgeons, cosmetic surgeons, etc.

The following information was provided in a September 4, 2007 letter:

> [X] 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 hydrocholoride, an anesthetic. Please note that lidocaine hydrocholoride is a drug and is listed in the United States Pharmacopeia (USP).
>
> The Food and Drug Administration defines a medical device as such:

* The original private taxpayer ruling request was made by . . . ("Company Y"). Company acquired X out of the bankruptcy of Company Y.

> "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, or
> - 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."

[Emphasis added.]

> [X] has been approved by the United States FDA, as a medical device. Each medical device that is to be distributed commercially in the United States requires either prior 510(k) clearance or a PMA [Premarket Approval Application] approval from the FDA. Medical devices are classified into one of three classes—Class I, Class II, or Class III—depending on the degree of risk associated with each medical device and the extent of control needed to ensure safety and effectiveness. [X] 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, preclinical data, clinical trials, manufacturing information and labeling to demonstrate to the FDA's satisfaction the safety and effectiveness of the device.

Issue

Whether X, a permanent, injectable dermal filler used for the correction of skin depressions caused by traumatic scars, acne scars, viral infections, and wrinkles, is an exempt "prescription drug" under A.R.S. § 42-5061(A)(8).

Taxpayer's Position

Below is a restatement of your position as provided in your letter dated June 25, 2007:

> [X] meets the definition of a "prescription drug" as outlined in Arizona Administrative Code (A.A.C.) R15-5-156(A)(10)(a) in that the US Food and Drug Administration has classified [X] as a class 3 medical device that can be dispensed only upon the written prescription of a prescriber for the product, in this case only a physician (21 CFR 801). The label clearly states "CAUTION: Federal Law restricts this device to physician use only" which restricts its

> dispension by anyone other than a physician. This restriction clearly identifies this product as being a drug under the definition of the Arizona Administrative Code.

Applicable Law

A.R.S. § 42-5008 levies a transaction privilege tax measured by the amount or volume of business transacted by persons on account of their business activities.

A.R.S. § 42-5061(A) states that "[t]he retail classification is comprised of the business of selling tangible personal property at retail. The tax base for the retail classification is the gross proceeds of sales or gross income derived from the business."

A.R.S. § 42-5023 states that "[i]t is presumed that all gross proceeds of sales and gross income derived by a person from business activity classified under a taxable business classification comprise the tax base for the business until the contrary is established."

A.R.S. § 42-5061(A)(8) exempts from the retail classification "[d]rugs and medical oxygen, including delivery hose, mask or tent, regulator and tank, on the prescription of a member of the medical, dental or veterinarian profession who is licensed by law to administer such substances."

A.A.C. R15-5-156(B)(1) states that gross receipts from sales of "[p]rescription drugs, including those used in the course of treating patients" are not subject to tax.

A.A.C. R15-5-156(A)(2) defines "drug on a prescription" as a "prescription drug."

A.A.C. R15-5-156(A)(10) defines "prescription drug" as the following:

> [a] legend drug or a drug that, according to federal or state law, can be dispensed only:
>
> a. Upon a written prescription of a prescriber for the drug;
>
> b. Upon an oral prescription by the prescriber for the drug that federal or state law requires be reduced promptly to a form of writing by the prescriber and then filed by a pharmacist or the prescriber; or
>
> c. By refilling a written or oral prescription if refilling is authorized by the prescriber for the drug either in the original prescription or by oral order that is reduced promptly to writing and then filed by a pharmacist or the prescriber.

A.A.C. R15-5-156(A)(5) defines "legend drug" as "a drug that 21 U.S.C. [United States Code] 353(b)(4)(A) requires to bear the symbol "Rx only" before dispensing."

A.A.C. R15-5-156(A)(1) defines "drug" as the following:

> an article that, according to federal or state law, is:
>
> a. Recognized in the official United States Pharmacopeia, official Homeopathic Pharmacopeia of the United States, official National Formulary, or any supplement to these documents; or
>
> b. Intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or animals; or
>
> c. Not food and is intended to affect the structure or any function of the body of humans or animals; or
>
> d. Intended for use as a component of any article specified in subsections (a), (b), or (c).

Discussion

A.R.S. § 42-5061 imposes the transaction privilege tax under the retail classification. The retail classification is comprised of the business of selling tangible personal property at retail. However, A.R.S. § 42-5061(A)(8) exempts "[d]rugs and medical oxygen, including delivery hose, mask or tent, regulator and tank, on the prescription of a member of the medical, dental or veterinarian profession who is licensed by law to administer such substances."

A.A.C. R15-5-156(A)(2) defines "drug on a prescription" as a "prescription drug." A.A.C. R15-5-156(A)(10), in turn, defines a "prescription drug" as the following:

> a legend drug or a drug that, according to federal or state law, can be dispensed only:
>
> a. Upon a written prescription of a prescriber for the drug;
>
> b. Upon an oral prescription by the prescriber for the drug that federal or state law requires be reduced promptly to a form of writing by the prescriber and then filed by a pharmacist or the prescriber; or
>
> c. By refilling a written or oral prescription if refilling is authorized by the prescriber for the drug either in the original prescription or by oral order that is reduced promptly to writing and then filed by a pharmacist or the prescriber.

Therefore, before determining whether an item meets the definition of a "prescription drug," it must meet either the definition of a "drug" or a "legend drug."

[X] does not meet the A.A.C. R15-5-156(A)(5) definition of a legend drug, as it is not required to bear the symbol "Rx only" before dispensing. A.A.C. R15-5-156(A)(1) defines a drug as the following:

> an article that, according to federal or state law, is:
>
> > a. Recognized in the official United States Pharmacopeia, official Homeopathic Pharmacopeia of the United States, official National Formulary, or any supplement to these documents; or
> >
> > b. Intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or animals; or
> >
> > c. Not food and is intended to affect the structure or any function of the body of humans or animals; or
> >
> > d. Intended for use as a component of any article specified in subsections (a), (b), or (c).

The U.S. Food and Drug Administration may approve an article as either a drug or a device. As you have stated in the facts provided to the Department, the U.S. Food and Drug Administration has approved [X] as a Class III medical device. 21 U.S.C. § 321(h) (2006) defines the term "device" as follows:

> The term "device" (except when used in paragraph (n) of this section and in sections 331(i), 343(f), 352(c), and 362(c) of this title) means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is--
> > (1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,
> >
> > (2) 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, or
> >
> > (3) intended to affect the structure or any function of the body of man or other animals, and
>
> which does not achieve 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 its primary intended purposes.

In contrast, 21 U.S.C. § 321(g)(1) (2006) defines the term "drug" as the following:

> (A) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and

> (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and
>
> (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and
>
> (D) articles intended for use as a component of any article specified in clause (A), (B), or (C). A food or dietary supplement for which a claim, subject to sections 343 (r)(1)(B) and 343 (r)(3) of this title or sections 343 (r)(1)(B) and 343 (r)(5)(D) of this title, is made in accordance with the requirements of section 343 (r) of this title is not a drug solely because the label or the labeling contains such a claim. A food, dietary ingredient, or dietary supplement for which a truthful and not misleading statement is made in accordance with section 343 (r)(6) of this title is not a drug under clause (C) solely because the label or the labeling contains such a statement.

As can be seen upon comparing the federal and state definitions above, the A.A.C. R15-5-156(A)(1) definition of a drug, for purposes of analyzing whether [X] meets the definition, is substantively identical to the U.S.C. § 321(g)(1) definition of a drug. The Department has interpreted A.R.S. § 42-5061(A)(8) to only apply to articles approved by the U.S. Food and Drug Administration as a drug, rather than other articles such as devices. [X] was approved by the U.S. Food and Drug Administration as a device rather than a drug.

Conclusion and Ruling

The Department rules that [X] does not meet the definition of an exempt prescription drug for purposes of determining whether sales made in Arizona are subject to transaction privilege tax.

The conclusions in this private taxpayer ruling do not extend beyond the facts presented in the letters dated May 18, 2007, June 25, 2007, September 4, 2007, and October 13, 2009.

This response is a private taxpayer ruling and the determinations herein are based solely on the facts provided in your request. The determinations are subject to change should the facts prove to be different on audit. If it is determined that undisclosed facts were substantial or material to the Department's making of an accurate determination, this taxpayer ruling shall be null and void. Further, the determination is subject to future change depending on changes in statutes, administrative rules, case law or notification of a different Department position.

The determinations in this private taxpayer ruling are applicable only to the taxpayer requesting the ruling and may not be relied upon, cited nor introduced

into evidence in any proceeding by a taxpayer other than the taxpayer who has received the private taxpayer ruling.

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