PRIVATE TAXPAYER RULING LR11-012

August 15, 2011

This private taxpayer ruling is in response to your letter dated September 13, 2010, as supplemented by your letter dated January 14, 2011, in which you requested a private taxpayer ruling on behalf of your client, . . . ("the Company"). Specifically, you requested a private taxpayer ruling regarding the applicability of transaction privilege tax to sales of Product X and Product Z. 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 the Company's future transactions and tax liabilities accruing from the date the taxpayer receives this ruling, to provide guidance on prospective actions the Company may choose to undertake in substantially similar transactions.

Statement of Facts

The following facts are excerpted from your letter dated September 13, 2010:

> The Company is headquartered in . . . [State X], and is engaged in the sale of medical products for dermatological purposes. The Company and its competitors offer a line of products (the "Products") whose primary component is hyaluronic acid. The Products . . . are used by patients to smooth wrinkles and improve facial features and are injected into patients under the skin in gel form. See for instance the label of [Product X], a Product sold by the Company, which provides that [Product X] is indicated "for the correction of moderate to severe facial wrinkles and folds." The hyaluronic acid concentration among Products is similar and the Products have been approved for use by the United States Food and Drug Administration as a Class III Medical Device. In addition, Products can only be used pursuant to a prescription issued by a licensed physician. For instance, the label of [Product X] provides the following warning: "Caution: Federal Law restricts this device to sale by or on the order of a physician or properly licensed practitioner."
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> The Products' biological and chemical properties, impact on the body and side effects have been documented by dozens of physicians who prescribe the Products for use to patients. A typical analysis is set

> forth on the . . . website at . . . .[1] [Website] characterizes [Product X] as "a gel of hyaluronic acid produced by bacteria and used for treating facial wrinkles and folds. Hyaluronic acid is a substance that is normally produced by the body. Hyaluronic acid is what gives skin its volume and fullness. . .When [Product X] is injected into wrinkled skin it adds fullness and reduces the prominence of the wrinkles in the previously wrinkled area.". . . . As explained by yet another physician regarding [Product X], "as you grow older the amount of hyaluronic acid diminishes, and your skin can cave, causing a wrinkle along the line." [Product X] "is injected into the skin to replace hyaluronic acid that has dissipated over time."[2]

The following facts are excerpted from your letter dated January 14, 2011:

> . . . . The Company hereby identifies [Product X] and [Product Z] as the products that are the subject of the Ruling Request. (Please note, [Product X] and [Product Z] contain the same substance and properties and are used for similar purposes. The only difference is that [Product Z] is more concentrated. Therefore doses of [Product Z] are stronger than equivalent doses of [Product X].) . . . [The product approval letters for both Product X and Product Z] were issued by the Department of Health & Human Services Division of the Food and Drug Administration ("FDA") and provide that the use of [Product X] and [Product Z] "are restricted to prescription use in accordance with . . . the Federal Food, Drug and Cosmetic Act." . . . . The warning on [the product labels for Product X and Product Z provide] "Caution: Federal Law restricts this device to sale by or on the order of a physician or licensed practitioner." Accordingly, neither [Product X] nor [Product Z] can be lawfully used except upon the order of a physician or licensed practitioner.
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> . . . .
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> [Product X] and [Product Z] Are Advertised and Promoted by Licensed Physician Sellers as Replacing Hyaluronic Acid, a Part of the Human Body That Creates Skin Thickness and Volume. . . . [T]he labels for [Product X] and [Product Z] provide that these products are indicated "for the correction of moderate to severe facial folds and wrinkles." The indication portion of the label, however, does not offer additional information as to the causes of the folds and wrinkles for which [Product X] and [Product Z] are recommended treatments.

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[1] . . . website states that it "provides easy-to-read, in-depth, authoritative medicinal information for consumers" that is "doctor-produced by a network of more than 70 U.S. board-certified physicians."
[2] . . .

> We have attached below a number of excerpts from doctor, dermatologist and health spa websites (i.e., the "Licensed Practitioner Sellers") that advertise, sell and administer [Product X] and [Product Z] and that describe the conditions that create facial wrinkles for which the use of [Product X] or [Product Z] is recommended. These advertisements and promotions go beyond describing what [Product X] and [Product Z] are used for (i.e., the treatment of facial wrinkles and folds) and instead identify many of the contributing factors that create the medical condition of skin wrinkles and folds in the first place. These causes and conditions have a common characteristic. They all deplete the body's hyaluronic acid, thereby causing the wrinkles and folds that are alleviated or diminished by the restoration of hyaluronic acid through the use of [Product X] and [Product Z]. . . . .
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> . . . [T]he loss of the body's natural hyaluronic acid may result from a variety of causes, including smoking, alcohol abuse and excess sun exposure. [Product X] and [Product Z] replace this lost body substance and thereby facilitate the restoration of a body feature (i.e., unwrinkled skin), that is characteristic of a person with normal levels of hyaluronic acid. See . . . product labels for [Product X] and [Product Z], describing the products as a sterile "gel of hyaluronic acid." Moreover, it is reasonable to infer that patients purchase [Product X] and [Product Z] to remedy facial wrinkles and folds caused by damage from smoking, alcohol abuse and exposure to sun, since . . . these causes are heavily emphasized by Licensed Practitioner Sellers promoting sales of [Product X] and [Product Z].

Issue

Whether the gross proceeds from the sale of Product X and Product Z are subject to Arizona transaction privilege tax or meet the exemption under A.R.S. § 42-5061(A)(9) for prosthetic appliances?

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)(9) exempts from the retail classification "[p]rosthetic appliances as defined in § 23-501 prescribed or recommended by a health professional licensed pursuant to title 32, chapter 7, 8, 11, 13, 14, 15, 16, 17 or 29." These chapters refer to podiatrists, doctors of chiropractic, dentists, physicians and surgeons, naturopathic physicians, nurses, osteopathic physicians and surgeons, and homeopathic physicians.

A.R.S. § 23-501(7) defines a "prosthetic appliance" as "an artificial device necessary to support or take the place of a part of the body, or to increase the acuity of a sense organ."

A.A.C. R15-5-156(A)(12) defines a "prosthetic appliance" as "an artificial device that fully or partially replaces a part or function of the human body or increases the acuity of a sense organ."

A.A.C. R15-5-156(B)(4) provides that gross receipts from sales of prosthetic appliances, prescribed or recommended by a statutorily-authorized individual, are not subject to tax.

A.A.C. R15-5-156(C) states that gross receipts from the sale of component and repair parts for any tangible personal property that is exempt under subsection (B) are not subject to tax.

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. A.R.S. § 42-5061(A)(9) exempts from the retail classification "[p]rosthetic appliances as defined in § 23-501 prescribed or recommended by a health professional licensed pursuant to title 32, chapter 7, 8, 11, 13, 14, 15, 16, 17 or 29." These chapters refer to podiatrists, doctors of chiropractic, dentists, physicians and surgeons, naturopathic physicians, nurses, osteopathic physicians and surgeons, and homeopathic physicians.

A.R.S. § 23-501(7) defines a "prosthetic appliance" as "an artificial device necessary to support or take the place of a part of the body, or to increase the acuity of a sense organ." A.A.C. R15-5-156(A)(12) further defines a "prosthetic appliance" as "an artificial device that fully or partially replaces a part or function of the human body or increases the acuity of a sense organ."

The U.S. Food and Drug Administration may approve an article as either a drug or a device. As provided in the supplemental materials submitted to the Department with your January 14, 2011 letter, the U.S. Food and Drug Administration has approved Product X and Product Z as Class III medical devices. 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—
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> > (1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,
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> > (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
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> > (3) intended to affect the structure or any function of the body of man or other animals, and
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> 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.

The Department has previously stated that articles approved by the U.S. Food and Drug Administration as devices do not meet the definition of a drug. Thus, the exemption from the retail classification for sales of drugs is inapplicable.

Hyaluronic acid is a naturally occurring substance found in the human body. High concentrations are found in soft connective tissue, especially the skin, in the fluid surrounding the eyes and in some cartilage and joint fluids. On average, a person has approximately 15g of hyaluronic acid in their body, one-third of which is lost and replaced each day. Over time, hyaluronic acid gradually depletes.[3]

As stated above, Product X and Product Z are injected into the skin to replace hyaluronic acid that has been depleted over time. A prosthetic appliance is defined as "an artificial device necessary to support or take the place of a part of the body, or to increase the acuity of a sense organ."[4] The part of the body at issue in this taxpayer

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[3] *See e.g.,* Averbeck M et al. (2007) Differential regulation of hyaluronan metabolism in the epidermal and dermal compartments of human skin by UVB irradiation. J Invest Dermatol 127:687-697; Erickson, Kim (May 2008) hyaluronic acid: hope in a jar. Better Nutrition Vol. 70, Issue 5: 48-49; The American Society of Plastic Surgeons website at http://www.plasticsurgery.org/Cosmetic-Procedures/Dermal-Fillers-Hyaluronic-Acid.html.

[4] A.R.S. § 23-501(7)

information ruling request is the skin. Product X and Product Z, however, are neither *necessary* to support the skin nor do they take the place of skin. Rather, they replace a component, hyaluronic acid, of the skin. Thus, neither Product X nor Product Z meet the definition of an exempt prosthetic appliance.[5]

Conclusion and Ruling

Neither Product X nor Product Z meet the definition of an exempt prosthetic appliance. Sales of Product X and Product Z by Company are subject to Arizona transaction privilege tax.

This private taxpayer ruling does not extend beyond the facts presented in your letters dated September 13, 2010 and January 14, 2011.

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 only applicable 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. In addition, this private taxpayer ruling only applies to transactions that occur or tax liabilities that accrue from and after the date the taxpayer receives the ruling.

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[5] The Department has previously stated that a tissue filler implant does not meet the definition of a prosthetic appliance as it does not fully or partially replace a part or function of the human body except when sold for the following FDA approved uses: vocal augmentation to treat speech impediments caused typically by a stroke or neurological disorder or as a peri-urethral bulking agent to treat women who have stress urinary incontinence.