PRIVATE TAXPAYER RULING LR09-006

October 27, 2009

This private taxpayer ruling is in response to your letter dated December 18, 2008, as supplemented by your letter dated January 13, 2009 and your March 31, 2009 information submission, in which you requested a private taxpayer ruling. Your request concerns whether *** is subject to transaction privilege tax on its sales of two injectable tissue implants, a pharmaceutical drug, and a surgical adhesive. The injectable tissue implants are *** and ***. The pharmaceutical drug is ***. The surgical adhesive is ***. Pursuant to Arizona Revised Statutes ("A.R.S.") § 42-2101, the Department may issue private taxpayer rulings to taxpayers and potential taxpayers on request.

Statement of Facts:

Below is a restatement of the facts as provided in your request for a private taxpayer ruling made on behalf of ***.

A. ***

*** is a tissue filler implant that is injected by a physician or a nurse under the supervision of a physician. *** consists of calcium hydroxylapatite (CaHA) particles (25 to 45 microns in diameter), suspended in a water-based gel carrier.

*** is sold in individually packaged, single dose syringes. *** 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.

*** 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.

*** 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 *** 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

*** 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). *** is working with the FDA on clinical studies covering the use of *** for additional soft tissue treatments as well as using *** combined with lidocaine, a prescription anesthetic.

B. ***

*** 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. *** consists of calcium hydroxylapatite (CaHA) (75 to 125 microns in diameter) suspended in a gel carrier. The *** implant is injected into the space around the urethra near the bladder. After injection, the *** 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 *** 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.

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

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

C. ***

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 veins 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.

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

D. ***

*** 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. *** 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, unreasonable risk of illness or injury. (U.S. food and Drug Administration web site – “Device Advice,” updated August 4, 2004)

The FDA approvals submitted for your request show the following:

***	*** - Laryngeal Augmentation System – FDA approved as a medical device
***	*** Tissue Marker – FDA approved as a medical device
***	Calcium Hydroxylapatite Implant - Bone Filling and Augmentation Material – FDA approved as a medical device
***	*** - lipoatrophy – FDA approved as a medical device
***	*** - nasolabial folds – FDA approved as a medical device

*** *** - stress urinary incontinence – FDA approved as a medical device

Issues:

I. Whether the following will be deductible as qualifying drugs from transaction privilege tax in Arizona:

a. ***
b. ***
c. ***

II. Whether *** will be deductible as a qualifying prosthetic appliance from transaction privilege tax in Arizona.

Your Position:

Below is a restatement of your position as provided in your correspondence.

Arizona imposes a transaction privilege tax on the business of selling tangible personal property. The tax base is the gross proceeds of sales or gross income derived from the business. All sales of tangible personal property are subject to tax unless specifically exempt by statute.

I. The injectable tissue implants *** and ***

Arizona provides a transaction privilege tax deduction for drugs on the prescription of a member of the medical profession who is licensed by law to administer such substances. A drug is defined as any item that is recognized by an official national pharmacopeia; intended for the diagnosis, cure, mitigation, treatment or prevention of disease; or intended to affect the structure or any function of the human body. *** and *** should qualify as a deductible drug from the tax base for the FDA approved uses.

II. The pharmaceutical drug ***

*** should be approved as a deductible drug from the tax base when used in sclerotherapy treatment to eliminate varicose veins as currently applied for with the FDA by ***.

III. The surgical adhesive ***

Arizona provides a transaction privilege tax deduction for prosthetic appliances that are prescribed or recommended by a license health professional. Prosthetic

> appliances are defined as artificial devices necessary to support or take the place of a part of the body or to increase the acuity of a sense organ. *** should be approved as a deductible prosthetic appliance from the tax base when used in aesthetic surgical procedures as currently applied for with the FDA by ***.

Applicable Law:

Arizona Revised Statutes (A.R.S.) § 23-501 defines “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.R.S. § 42-5023 states that it 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 can be established.”

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. § 42-5061(A)(8) deducts 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.R.S. § 42-5061(A)(9) deducts 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.

Arizona Administrative Code (A.A.C.) R15-5-156(A)(1) defines "drug" as 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).

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

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

A.A.C. R15-5-156(A)(8) defines "prescriber" as a member of the medical, dental, or veterinary profession authorized by federal or state law to prescribe a drug.

A.A.C. R15-5-156(A)(10) defines "prescription drug" as a legend drug or a drug that, according to federal or state law, can be dispensed only upon a written prescription of a prescriber for the drug.

A.A.C. R15-5-156(A)(12) defines “prosthetic appliance” as “an artificial device which 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) provides that gross receipts from sales of prescription drugs, including those used in the course of treating patients and 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 A.A.C. R15-5-156(B) are not subject to tax.

Discussion:

A.R.S. § 42-5061(A)(8) deducts 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(A)(1) defines "drug" as 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).

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 a legend drug or a drug that, according to federal or state law, can be dispensed only upon a written prescription of a prescriber for the drug.

The Federal Food, Drug and Cosmetic Act (FD&C Act) is enforced by the U.S. Food and Drug Administration. The U.S. Food and Drug Administration may approve an article as either a drug or a device. Under the FD&C Act, 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.

In contrast, 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.

I. The injectable tissue implants *** and ***

The A.A.C. R15-5-156(A)(1) definition of a drug 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. The injectable tissue implants *** and *** were approved by the U.S. Food and Drug Administration as a device rather than a drug. Therefore, the gross receipts from sales of the injectable tissue implants *** and *** for the FDA approved uses are not deductible as sales of drugs.

II. The pharmaceutical drug ***

A.R.S. § 42-5061(A)(8) deducts 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(A)(1) defines "drug" as 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. A.A.C. R15-5-156(A)(5) defines "legend drug" as a drug that 21 U.S.C. 353(b)(4)(A) requires to bear the symbol "Rx only" before dispensing. A.A.C. R15-5-156(A)(8) defines "prescriber" as a member of the medical, dental, or veterinary profession authorized by federal or state law to prescribe a drug. A.A.C. R15-5-156(A)(10) defines "prescription drug" as a legend drug or a drug that, according to federal or state law, can be dispensed only upon a written prescription of a prescriber for the drug.

Your request states that *** is in a clinical trial in the United States and not yet approved by the FDA as a drug for use in the U.S. as a treatment for varicose veins.

Given the fact that *** is not approved by the FDA for use in the U.S. as a drug treatment for varicose veins, the gross receipts from sales of *** for use as a treatment for varicose veins do not qualify as deductible sales of drugs.

III. The surgical adhesive ***

A.R.S. § 42-5061(A)(9) deducts 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.A.C. R15-5-156(A)(12) defines "prosthetic appliance" as "an artificial device which fully or partially replaces a part or function of the human body or increases the acuity of a sense organ."

The statutory definitions of "prosthetic appliance" for purposes of the deduction under A.R.S. § 42-5061(A)(9) indicates a prerequisite absence of a body part or a body function. The use of *** parallels the purpose of stitches, staples, or sutures. *** is not 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 gross receipts from sales of *** for use in aesthetic surgical procedures do not qualify as deductible sales of prosthetic appliances.

Ruling:

Based on the facts presented in your request, the Department rules as follows:

I. Gross proceeds from the sale of the injectable tissue implants *** and *** for the FDA approved uses are subject to tax under the retail classification.

II. Gross proceeds from the sale of *** for use as a treatment for varicose veins are subject to tax under the retail classification.

III. Gross proceeds from the sale of *** for use in aesthetic surgical procedures are subject to tax under the retail classification.

The conclusions of this private taxpayer ruling do not extend beyond the facts as presented in your letters and attachments dated December 18, 2008, January 13, 2009, and March 31, 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.