

**TENNESSEE DEPARTMENT OF REVENUE
LETTER RULING 11-27**

WARNING

Letter rulings are binding on the Department only with respect to the individual taxpayer being addressed in the ruling. This presentation of the ruling in a redacted form is informational only. Rulings are made in response to particular facts presented and are not intended necessarily as statements of Department policy.

SUBJECT

Application of the Tennessee sales and use tax to the sale of dermal fillers.

SCOPE

This letter ruling is an interpretation and application of the tax law as it relates to a specific set of existing facts furnished to the department by the taxpayer. The rulings herein are binding upon the Department and are applicable only to the individual taxpayer being addressed.

This letter ruling may be revoked or modified by the Commissioner at any time.

Such revocation or modification shall be effective retroactively unless the following conditions are met, in which case the revocation shall be prospective only:

- (A) The taxpayer must not have misstated or omitted material facts involved in the transaction;
- (B) Facts that develop later must not be materially different from the facts upon which the ruling was based;
- (G) The applicable law must not have been changed or amended;
- (D) The ruling must have been issued originally with respect to a prospective or proposed transaction; and
- (E) The taxpayer directly involved must have acted in good faith in relying upon the ruling; and a retroactive revocation of the ruling must inure to the taxpayer's detriment.

FACTS

[TAXPAYER] manufactures a product called [PRODUCT NAME], which is a dermal filler that contains [INGREDIENT], and [INGREDIENT]. [INGREDIENT] is a drug listed in the United States Pharmacopeia (“USP”). [PRODUCT NAME] is for human use.

By letter dated October 27, 2006, the United States Food and Drug Administration (the “FDA”) approved the Taxpayer’s premarket approval application for [PRODUCT NAME]. The FDA restricted the sale, distribution, and use of [PRODUCT NAME] to prescription use in accordance with 21 C.F.R. § 801.109 (pertaining to prescription devices). The FDA further restricted the use of [PRODUCT NAME] within the meaning of Section 520(e) of the Federal Food, Drug, and Cosmetic Act (pertaining to control of devices intended for human use).

[PRODUCT NAME] is currently used for the elimination of nasolabial folds (commonly referred to as “smile lines”) and is being investigated for other uses. Over time, the skin loses its ability to repair itself as the underlying elastin and collagen fibers break down, which can result in the development of facial wrinkles and folds. [PRODUCT NAME] is injected into the patient’s skin tissue, where it replaces the missing collagen in the smile lines and provides a support structure for the skin in that area. Eventually, the [INGREDIENT] will be absorbed by the patient’s body; the [INGREDIENT] will not be absorbed, however, and thus will provide permanent elimination of smile lines.

The Taxpayer sells [PRODUCT NAME] to physicians, such as dermatologists or cosmetic surgeons, who have been trained by the Taxpayer to properly inject it. Consistent with the FDA approval of the product, a patient may only obtain [PRODUCT NAME] pursuant to a prescription.

QUESTIONS

1. Are sales of a dermal filler such as [PRODUCT NAME] exempt for purposes of the Tennessee sales and use tax?
2. If the sale of a dermal filler such as [PRODUCT NAME] is exempt for purposes of the Tennessee sales and use tax, what are the steps necessary to reflect the tax-exempt status?

RULINGS

1. Yes. The sale of a dermal filler such as [PRODUCT NAME] is exempt from the Tennessee sales and use tax as a prescription drug, provided that the product is dispensed pursuant to a prescription and is for human use.
2. The Taxpayer must comply with the general documentation requirements set forth under TENN. CODE ANN. § 67-6-523 (2006). Because the exemption for prescription drugs is a product exemption that does not depend on the status of the purchaser, the documentation requirements with respect to purchasers claiming exemption from taxation, found under TENN. CODE ANN. § 67-6-409(a) (Supp. 2010), are not applicable in the case of sales of [PRODUCT NAME].

ANALYSIS

Under the Retailers' Sales Tax Act, TENN. CODE ANN. § 67-6-101 *et seq.*, the sale of tangible personal property, which includes dermal fillers such as [PRODUCT NAME], is generally subject to sales and use tax. The sale of an item of tangible personal property is exempt for purposes of the Tennessee sales and use tax only if the sale comes within the scope of a statutory exemption.

Note that the burden is on the taxpayer to establish entitlement to an exemption from taxation. The Tennessee Supreme Court has stated that “[a]lthough the rule is well-established that taxing legislation should be liberally construed in favor of the taxpayer and strictly construed against the taxing authority, it is an equally important principle of Tennessee tax law that ‘exemptions from taxation are construed against the taxpayer who must shoulder the heavy and exacting burden of proving the exemption.’” *American Airlines, Inc. v. Johnson*, 56 S.W.3d 502, 506 (Tenn. Ct. App. 2000) (quoting *Rogers Group, Inc. v. Huddleston*, 900 S.W.2d 34, 36 (Tenn. Ct. App. 1995)). The Tennessee Supreme Court has also stated that the burden is on the taxpayer to establish the exemption, and any well-founded doubt is sufficient to defeat a claimed exemption from taxation. *American Airlines*, 56 S.W.3d at 506 (citing *Tibbals Flooring Co. v. Huddleston*, 891 S.W.2d 196, 198 (Tenn. 1994); *United Cannery, Inc. v. King*, 696 S.W.2d 525, 527 (Tenn. 1985)).

1. Sales of dermal fillers are exempt for purposes of the Tennessee sales and use tax.

The sale of dermal fillers such as [PRODUCT NAME] is exempt for purposes of the Tennessee sales and use tax pursuant to TENN. CODE ANN. § 67-6-320(a) (Supp. 2010) because a dermal filler is a drug for human use dispensed pursuant to a prescription.

TENN. CODE ANN. § 67-6-320(a) provides that “any drug, including over-the-counter drugs,¹ for human use dispensed pursuant to a prescription” is exempt from the Tennessee sales and use tax.² TENN. CODE ANN. § 67-6-102(35) (Supp. 2010) defines the term “drug” as a “compound, substance or preparation, and any component of a compound, substance or preparation”³ that

¹ [PRODUCT NAME] is not an over-the-counter drug, because the FDA requires that it be dispensed pursuant to a prescription. TENN. CODE ANN. § 67-6-102(62)(A) defines the term “over-the-counter drug” in pertinent part as a “drug that contains a label that identifies the product as a drug as required by 21 C.F.R. 201.66 [pertaining to labeling of over-the-counter drugs].”

² Note that TENN. CODE ANN. § 67-6-320(a) expressly excludes “grooming and hygiene products” from the exemption for prescription drugs. [PRODUCT NAME] is not a grooming or hygiene product because it does not come within the scope of TENN. CODE ANN. § 67-6-102(45), which defines “grooming and hygiene products” as “soaps and cleaning solutions, shampoo, toothpaste, mouthwash, antiperspirants, and suntan lotions and screens,” regardless of whether such items meet the definition of “over-the-counter drugs” under TENN. CODE ANN. § 67-6-102(62)(A).

³ Note that the definition of “drug” expressly excludes compounds, substances, and preparations that are properly classified for Tennessee sales and use tax purposes as food, food ingredients, dietary supplements, or alcoholic beverages. [PRODUCT NAME] does not come within the definition of any of these items. *See* TENN. CODE ANN. § 67-6-102(35).

(A) is recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia, or official National Formulary; (B) is intended for use in the “diagnosis, cure, mitigation, treatment, or prevention” of disease; or (C) is intended to “affect the structure or any function of the body.” TENN. CODE ANN. § 67-6-102(70) defines the term “prescription” as an “order, formula or recipe issued in any form of oral, written, electronic, or other means of transmission by a duly licensed practitioner authorized by the laws” of Tennessee. The definition of the term “prescription” includes orders written on a patient’s chart by a duly licensed practitioner.⁴

Accordingly, to come within the exemption for prescription drugs under TENN. CODE ANN. § 67-6-320(a), [PRODUCT NAME] must 1) come within the definition of a “drug” under TENN. CODE ANN. § 67-6-102(35); 2) be for human use; and 3) be dispensed pursuant to a prescription.

First, [PRODUCT NAME] meets the definition of a “drug” under TENN. CODE ANN. § 67-6-102(35)(C) because it is a compound, substance, or preparation that is intended to affect the structure of the patient’s body. [PRODUCT NAME] is a dermal filler that replaces broken down collagen and elastin when injected into the patient’s skin tissue, resulting in the permanent elimination of “smile lines” on the patient’s face. The Taxpayer has stated that the [INGREDIENT] contained in the product will eventually be absorbed by a patient’s body, but that the [INGREDIENT] that are also contained in the product will not be absorbed. As a result, [PRODUCT NAME] permanently affects the structure of the patient’s skin.

[PRODUCT NAME] meets the second requirement because it is for human use.⁵ [PRODUCT NAME] also meets the third requirement because it is dispensed pursuant to a prescription.⁶

The sale of [PRODUCT NAME] is therefore exempt for purposes of the Tennessee sales and use tax under TENN. CODE ANN. § 67-6-320(a).

2. Documentation requirements

The Taxpayer must comply with the general documentation requirements set forth under TENN. CODE ANN. § 67-6-523 (2006). Because the exemption for prescription drugs is a product exemption that does not depend on the status of the purchaser, the documentation requirements

⁴ See Tennessee Department of Revenue Important Notice #07-18 (December 2007) for further information. The Notice is available on the Department’s website at <http://state.tn.us/revenue/notices/sales/sales07-18.pdf>.

⁵ Because the exemption is available only if the product is dispensed pursuant to a prescription for human use, any sales of the product not for human use will be subject to the Tennessee sales and use tax.

⁶ As noted above, TENN. CODE ANN. § 67-6-102(70) broadly defines the term “prescription” as an “order, formula or recipe issued in any form of oral, written, electronic, or other means of transmission by a duly licensed practitioner authorized by the laws” of Tennessee. The definition of the term “prescription” includes orders written on a patient’s chart by a duly licensed practitioner.

with respect to purchasers claiming exemption from taxation, found under TENN. CODE ANN. § 67-6-409(a), are not applicable in the case of sales of [PRODUCT NAME].⁷

TENN. CODE ANN. § 67-6-523 generally requires all taxpayers to establish and maintain records that are adequate for auditors to use in determining the correct amount of the taxpayer's tax liability. The Taxpayer should therefore keep records of all sales of [PRODUCT NAME], including copies of invoices and purchase orders. Records of business transactions must be retained for a minimum of three years from December 31 of the year in which the associated Tennessee sales and use tax return was filed.

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APPROVED: Richard H. Roberts
Commissioner of Revenue

DATE: 06/20/2011

⁷ Tenn. Code Ann. § 67-6-409(a)(2) generally requires a seller to obtain a copy of the purchaser's authorization for exemption. The exemption certificate contains the information required under Tenn. Code Ann. § 67-6-409(a)(1), including: the purchaser's name, address, type of business, reason for exemption, and a tax identification number issued by Tennessee or another governmental authority. Note as well that the Taxpayer is not required to obtain copies of prescriptions for [PRODUCT NAME]; such prescriptions will be unavailable at the time of the sale because the Taxpayer's customers will dispense the product at a later date.