

**TENNESSEE DEPARTMENT OF REVENUE  
LETTER RULING # 12-21**

**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**

The application of the Tennessee sales and use tax prescription drug exemption to the sale of in-vitro diagnostic reagents.

**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;
- (C) 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] (the "Taxpayer") sells in-vitro diagnostic reagents (the "Diagnostic Reagents") to hospitals and other healthcare facilities in Tennessee. The Diagnostic Reagents are licensed by the United States Food and Drug Administration (the "FDA") and are used to identify certain properties of blood or blood components for the purpose of determining compatibility in transfusions. For example, the Diagnostic Reagents are used to identify blood groups, blood type, red cell antibodies, red cell antigens, platelet antibodies, and for crossmatching. The accurate testing of blood and blood components prior to transfusion is required by the FDA in order to prevent a potentially life-threatening reaction. The Diagnostic Reagents do not require a prescription, but may be used in a test performed under the orders of a licensed physician.

## RULING

If tests using the Diagnostic Reagents are performed only under the orders of a licensed physician, will the reagents be exempt under TENN. CODE ANN. § 67-6-320(a) (2011)?

Ruling: No. The Diagnostic Reagents are not exempt from the Tennessee sales and use tax under TENN. CODE ANN. § 67-6-320(a) (2011), regardless of whether tests using the reagents are performed under the orders of a licensed physician. Retail sales of the Diagnostic Reagents are accordingly subject to the Tennessee sales and use tax.

## ANALYSIS

Under the Retailers' Sales Tax Act, TENN. CODE ANN. §§ 67-6-101 to -907 (2011), the retail sale in Tennessee of tangible personal property, including prescription and over-the-counter drugs and other substances, is subject to the Tennessee sales and use tax unless an exemption from taxation applies.

TENN. CODE ANN. § 67-6-320(a) (2011) provides an exemption for “any drug, including over-the-counter drugs, for human use dispensed pursuant to a prescription.”<sup>1</sup> Thus, the Diagnostic Reagents will be exempt for purposes of the Tennessee sales and use tax under TENN. CODE ANN. § 67-6-320(a) if the reagents are 1) a drug; 2) for human use; and 3) dispensed pursuant to a prescription.

Because the Diagnostic Reagents do not meet the second and third requirements for exemption under TENN. CODE ANN. § 67-6-320(a), this letter ruling will not address whether the reagents are a drug.<sup>2</sup>

The Diagnostic Reagents do not satisfy the second requirement because they are not for human use.

Neither the Retailers' Sales Tax Act nor the Tennessee courts have defined the phrase “for human use” for purposes of the sales and use tax. However, the Tennessee Department of Revenue has historically interpreted TENN. CODE ANN. § 67-6-320(a) to require the drug in question to be *directly* used *by* a human. Prior to 2007,<sup>3</sup> the exemption applied to sales of “any prescription drug or

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<sup>1</sup> Note, however, that the exemption does not apply to grooming and hygiene products. TENN. CODE ANN. § 67-6-320(a).

<sup>2</sup> The term “drug” is defined as “a compound, substance or preparation, and any component of a compound, substance or preparation, other than food and food ingredients, dietary supplements or alcoholic beverages” that is

- (A) Recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, or official National Formulary, and supplement to any of them;
- (B) Intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease; or
- (C) Intended to affect the structure or any function of the body.

TENN. CODE ANN. § 67-6-102(35) (2011). Some diagnostic reagents may be considered a drug. For example, the Streamlined Sales Tax Project's Compliance Review and Interpretations Committee has issued a recommendation whereby a chemical reagent contained in an infectious disease test kit would be properly considered a drug. STREAMLINED SALES TAX GOVERNING COMMITTEE, INTERPRETIVE OPINION RECOMMENDATION 2007-01 (May 23, 2007).

<sup>3</sup> In 2007, Tennessee adopted the prescription drug exemption language found in the Streamlined Sales and Use Tax Agreement. The State of Tennessee has been an associate member of the Streamlined Sales Tax Project since 2005. Since that time, the state has amended the Retailers' Sales Tax Act to adopt the definitions and certain other provisions found in the Streamlined Sales and Use Tax Agreement.

medicine issued by a licensed pharmacist in accordance with an individual prescription written *for the use of a human being*” by a licensed practitioner of the healing arts. TENN. CODE ANN. § 67-6-320(a) (2006) (emphasis added). The phrase “for the use of a human being” indicates that the exemption requires *direct* use or consumption by a particular individual. Because Tennessee’s amendment of the prescription drug exemption in 2007 was not intended to change the requirements regarding human use, this historical interpretation is still valid under the current version of the exemption.

Tennessee’s long-standing interpretation of the exemption is supported by the wording of other state prescription drug exemptions. For example, Michigan’s version of the exemption formerly applied to drugs dispensed pursuant to a prescription “for the use of a designated person.” See *Birchwood Manor, Inc. v. Comm’r of Revenue*, 680 N.W.2d 504, 510 (Mich. Ct. App. 2004) (discussing exemption along with a section of the Michigan state constitution exempting prescription drugs dispensed “for human use”). Michigan has since amended this statutory phrase to read “for human use.” See MICH. COMP. L. ANN. § 205.94d(1)(a) (West, Westlaw through P.A. 2012, No. 297, of the 2012 Regular Session, 96th Legislature). Also informative is Alabama’s version of the exemption, which applies to prescription drugs for “human consumption or intake.” ALA. CODE § 40-23-4.1(a) (West, Westlaw through the end of the 2012 Regular and 1st Special Sessions). Likewise, Arkansas’ statute exempts drugs prescribed by physicians “for human use,” ARK. CODE ANN. § 26-52-406(a) (West, Westlaw current through 2012 Fiscal Session), where “physician” is defined as a licensed medical practitioner authorized to prescribe drugs “that are used for human consumption.” ARK. ADMIN. CODE 006.05.212-GR-38(B)(2).

In this case, the Diagnostic Reagents are not for human use. Rather, the Diagnostic Reagents are used in a laboratory test to identify certain properties of blood or blood components. While such use may occur in conjunction with the treatment of a human, the reagents are not directly consumed, applied, ingested, or otherwise used by a human. Thus, the Diagnostic Reagents do not satisfy the second requirement under TENN. CODE ANN. § 67-6-320(a).

The Diagnostic Reagents also fail to satisfy the third requirement, because they are not dispensed pursuant to a prescription.

TENN. CODE ANN. § 67-6-102(69) (2011) 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 Taxpayer has stated that the Diagnostic Reagents may be used in a test performed under the orders of a licensed physician. While such orders may be properly considered a prescription, the orders are for a laboratory test used to identify certain properties of blood or blood components. In other words, it is the *laboratory test* that is prescribed by the physician. The Diagnostic Reagents are simply a product used to perform that test; the physician does not issue any prescription whereby Diagnostic Reagents are dispensed to the patient. Thus, the Diagnostic Reagents do not satisfy the third requirement under TENN. CODE ANN. § 67-6-320(a).

The burden is on the taxpayer to establish entitlement to an exemption from taxation. The Tennessee Supreme Court has stated that “exemptions are strictly construed against the taxpayer, who has the burden of proving entitlement to the exemption.” *Steele v. Indus. Dev. Bd. of the Metro. Gov’t of Nashville & Davidson Cnty.*, 950 S.W.2d 345, 348 (Tenn. 1997); see also *Am. Airlines, Inc. v. Johnson*, 56 S.W.3d 502, 506 (Tenn. Ct. App. 2000) (quoting *Rogers Grp., Inc. v. Huddleston*, 900 S.W.2d 34, 36 (Tenn. Ct. App. 1995)) (“Although 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.’”). The Tennessee Supreme Court has also recognized that any well-founded doubt is sufficient to defeat a claimed exemption from taxation. *See 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)).

With respect to the Diagnostic Reagents, a well-founded doubt exists sufficient to defeat a claimed exemption from taxation under TENN. CODE ANN. § 67-6-320(a).

Accordingly, the Diagnostic Reagents are not exempt from the Tennessee sales and use tax under TENN. CODE ANN. § 67-6-320(a). Because no other exemption applies under the facts provided, retail sales of the Diagnostic Reagents are subject to the Tennessee sales and use tax.

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APPROVED: Richard H. Roberts  
Commissioner of Revenue

DATE: 10-15-12