

**TENNESSEE DEPARTMENT OF REVENUE
REVENUE RULING # 14-13**

Revenue rulings are not binding on the Department. This ruling is based on the particular facts and circumstances presented, and is an interpretation of the law at a specific point in time. The law may have changed since this ruling was issued, possibly rendering it obsolete. The presentation of this ruling in a redacted form is provided solely for informational purposes, and is not intended as a statement of Departmental policy. Taxpayers should consult with a tax professional before relying on any aspect of this ruling.

SUBJECT

The application of the Tennessee sales and use tax exemption under TENN. CODE ANN. § 67-6-329(a)(12) (Supp. 2014) for industrial materials.

SCOPE

Revenue Rulings are statements regarding the substantive application of law and statements of procedure that affect the rights and duties of taxpayers and other members of the public. Revenue Rulings are advisory in nature and are not binding on the Department.

FACTS

The Taxpayer is a U.S. Food and Drug Administration (“FDA”) registered manufacturer and distributor of blood products and an FDA licensed producer of source plasma.

The Taxpayer maintains its corporate headquarters in Tennessee. The Taxpayer’s Tennessee operations include [NUMBER OF] whole blood donation centers and a laboratory for testing and processing blood and source plasma. Outside of the state, the Taxpayer owns and operates [NUMBER OF] whole blood donation facilities and [NUMBER OF] plasma donation facilities. The Taxpayer is also affiliated, through common ownership, with [NUMBER OF] other companies that operate whole blood and plasma collection centers inside and outside of Tennessee. The Taxpayer purchases all of the whole blood collected by its affiliated companies’ blood donation centers.

The Taxpayer’s Tennessee laboratory facility tests samples of each donor’s whole blood extracted at its blood donation centers as well as blood purchased from its related companies. It also tests samples of source plasma collected at the Taxpayer’s plasma donation centers as well as source plasma specimens collected by its affiliated companies.

Blood Products

The Taxpayer processes whole blood to make human serum, recovered plasma, frozen plasma, red blood cells, leukocytes, platelet rich plasma, and platelet concentrates (the “Blood Products”) for sale to customers. After whole blood is extracted from individual donors and sent to the

Taxpayer's Tennessee laboratory, the Taxpayer separates a blood sample from each donor's whole blood. The Taxpayer performs several tests on each blood sample, including a federally-mandated¹ test for infection from the following communicable diseases:

- (1) Human immunodeficiency virus (HIV), type 1;
- (2) Human immunodeficiency virus (HIV), type 2;
- (3) Hepatitis B virus;
- (4) Hepatitis C virus;
- (5) Human T-lymphotropic virus, type I; and
- (6) Human T-lymphotropic virus, type II.

The Taxpayer uses a variety of machines and reagents to test the blood samples for the listed communicable diseases. The reagents that the Taxpayer adds to the blood samples trigger a chemical reaction indicating the presence or absence of specific antibodies, viruses, or proteins. The reagents are consumed in the testing process. If the tests show that any of the listed communicable diseases are present in the blood sample, all blood, blood components, and samples from that particular donor are destroyed, and the donor is permanently prohibited from making future donations.

After the whole blood is cleared for use, the Taxpayer's laboratory personnel mechanically separate the whole blood into the Blood Products to meet the specifications of each customer's particular order. The Taxpayer uses different physical and chemical processes to break down the blood into the various components.² The Taxpayer then ships the Blood Products directly to its customers.

Source Plasma

The Taxpayer processes whole blood to make source plasma (the "Source Plasma") for sale to customers. Personnel at the Taxpayer's plasma donation centers and the donation centers of the Taxpayer's affiliates screen potential plasma donors to determine their medical histories. Once approved, the donors proceed to the donor floor where plasmapheresis, the plasma extraction process, takes place.

"Plasmapheresis" is defined under federal law as "the procedure in which blood is removed from the donor, the plasma is separated from the formed elements, and the red blood cells are returned to the donor."³ Trained technicians connect the individual donor to the automated plasmapheresis machine using a disposable harness. The harness contains the tubing device through which all blood and other fluid products flow both from and into the individual donor. The machine extracts whole blood from the individual through a needle attached to one end of the disposable harness. An anticoagulant is added to the blood, and the blood is spun at high speeds in a centrifuge to extract the plasma from the whole blood. The plasma proceeds to a packaging

¹ See 21 C.F.R. § 610.40 (2014). Additionally, the Taxpayer tests the blood sample to determine blood type and Rh (Rhesus factor) and conducts a serological test for syphilis.

² For example, to produce the Taxpayer's Red Blood Cell product, the Taxpayer extracts red blood cells from the whole blood by using centrifugation and removes the plasma layer.

³ 21 C.F.R. § 606.3(e) (2014).

bottle for freezing and shipment, and the remaining cell components are returned to the individual by the same intravenous needle.

A specimen of the Source Plasma is extracted for testing, and the remaining Source Plasma is immediately placed into inventory and fast-frozen in free-standing freezers located at the plasma donor center.

Once the plasma has been separated and inventoried, the Source Plasma specimens are sent to the Taxpayer's Tennessee laboratory. The Taxpayer performs a series of federally-mandated⁴ tests for the same communicable diseases for which it tests the whole blood samples. The screening tests employ testing machines and use a variety of reagents, all of which are consumed during the tests. If the Taxpayer determines that any of the viruses or communicable diseases for which it tests are present in a specimen, it destroys the unit of plasma from which the sample was drawn, and the donor is prohibited from donating in the future.

In addition to testing for viral contamination, the Taxpayer tests to determine if the Source Plasma is suitable for fractionation. Fractionation is a process that separates the proteins in the Source Plasma into various components and renders the plasma suitable for the manufacture of injectable therapeutic products. If the Source Plasma is suitable for fractionation, the Taxpayer sells it to customers for use in pharmaceutical manufacturing. If plasma passes screening for communicable diseases but is not suitable for fractionation, it is downgraded and further processed by the Taxpayer at its Tennessee laboratory.

RULING

Are the reagents that the Taxpayer utilizes in testing the whole blood used to produce the Blood Products and in testing the Source Plasma exempt from the Tennessee sales and use tax?

Ruling: The reagents the Taxpayer utilizes in the testing of whole blood used to produce the Blood Products and in the testing of the Source Plasma are exempt from the Tennessee sales and use tax as industrial materials used in the processing of tangible personal property for resale if the reagents come in direct contact with the whole blood used to produce the Blood Products or Source Plasma and are consumed within twenty-five days.

ANALYSIS

Under the Retailers' Sales Tax Act, TENN. CODE ANN. § 67-6-101 *et seq.*, the sale of tangible personal property is generally subject to the Tennessee sales and use tax. However, TENN. CODE ANN. § 67-6-329(a)(12) (Supp. 2014) exempts from the Tennessee sales and use tax "industrial materials . . . for future processing, manufacture or conversion into articles of tangible personal property for resale where the industrial materials . . . are used directly in fabricating, dislodging, or sizing." TENN. COMP. R. & REGS. 1320-5-1-.40(2) (1974) ("Rule 40(2)") explains that "[m]aterials and supplies coming in direct contact with and which are consumed within twenty-

⁴ 21 C.F.R. § 640.67 (2014)

five (25) consecutive calendar days, in the processing of manufactured products” are not subject to the sales and use tax.

Because the Retailer’s Sales Tax Act does not define the term “processing,” the Tennessee Supreme Court in *Beare Co. v. Tenn. Dep’t of Revenue* defined the term for purposes of sales and use tax exemptions as “essentially a transformation or conversion of materials or things into a different state or form from that in which they originally existed—the actual operation incident to changing them into marketable products.”⁵

By extracting and converting whole blood into Blood Products and Source Plasma, the Taxpayer engages in the processing of Blood Products and Source Plasma for resale. Because the Taxpayer is required by federal law to test any donated whole blood and Source Plasma for communicable diseases,⁶ and because the Taxpayer destroys a unit of whole blood or Source Plasma from which the sample is taken if the sample shows evidence of a communicable disease, its use of the reagents and testing of the whole blood and Source Plasma is a necessary step in the processing of Blood Products and Source Plasma for resale. To perform the mandatory testing for both the whole blood in processing Blood Products and the Source Plasma, the Taxpayer purchases reagents that it adds to the whole blood and source plasma samples.

Based on the foregoing, if the Taxpayer utilizes the reagents for testing purposes in the processing of Blood Products or Source Plasma, and if the reagents come into direct contact with the whole blood used to produce the Blood Products or Source Plasma and are consumed within twenty-five days, such materials will be exempt from the sales and use tax pursuant to TENN. CODE ANN. § 67-6-329(a)(12) and Rule 40(2).

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APPROVED: Richard H. Roberts
Commissioner of Revenue

DATE: November 6, 2014

⁵ 858 S.W.2d 906, 908 (Tenn. 1993) (quoting *Gressel Produce Co. v. Kosydar*, 297 N.E.2d 532, 535 (Ohio 1973)).

⁶ See 21 C.F.R. §§ 610.40; 640.67