



## North Carolina Department of Revenue

Beverly Eaves Perdue  
Governor

David W. Hoyle  
Secretary

December 19, 2012

Account ID: [REDACTED]  
Federal ID: [REDACTED]

[REDACTED]  
[REDACTED]  
[REDACTED]

Attention: [REDACTED]

Re: [REDACTED] Private Letter Ruling

Dear Mr. [REDACTED]

We are in receipt of your October 8, 2012 letter requesting a private letter ruling concerning your above-referenced client's plasmapheresis process, including the application of sales and use tax and/or manufacturer's privilege tax levies and exemptions to purchases of equipment, machinery, and supplies utilized by your client. You state [REDACTED] has not been contacted by the Department of Revenue concerning its sales and use tax liabilities, for the purpose of verifying a sales and use tax refund claim, or for the purpose of a sales and use tax audit."

In your letter, you state [REDACTED] is engaged in the manufacture of Source Plasma through plasmapheresis, in which plasma is removed from whole blood and prepared for use in the manufacture of pharmaceuticals. 'Source Plasma' is defined by the U.S. Food and Drug Administration as 'the fluid portion of human blood collected by plasmapheresis and intended as source material for further manufacturing use. 21 C.F.R. § 640.60."

You also state "[p]lasmapheresis is a process in which the fluid part of the blood, known as plasma, is removed from whole blood by a cell separator. An individual is connected to an automated plasmapheresis machine using a disposable harness. The harness, a singular item, acts as the tubing device through which all blood and other fluid products flow both from and into the individual. The machine extracts whole blood from the individual through a needle attached to one end of the disposable harness. As the centrifugation process begins, anticoagulant is combined with the whole blood to prevent coagulation in the tubing and centrifuge bowl during the plasma manufacturing process. The anticoagulant also ensures that the Source Plasma produced is sustained in the desired state during the quality control testing phase of production, storage and shipping. The cell separator, which is part of the machine, spins the blood at high speed in a centrifuge to extract plasma from the whole blood, which is retained in a packaging bottle for freezing and shipment.

"The plasmapheresis machine returns the other components of the blood except the plasma to the individual by the same intravenous needle. Near the end of the plasmapheresis production process, the machine injects a saline solution into the individual in order to replace the fluid in the blood stream and prevent potential side effects."

"The Source Plasma and the packaging bottles in which it is collected are fast-frozen in free-standing freezers located at the plasmapheresis manufacturing facility. Rapid freezing of the Source Plasma is necessary in order to preserve the antibody levels in the plasma.

"Prior to shipment of the plasma to pharmaceutical manufacturers, representative samples from each unit of Source Plasma are sent to a laboratory for testing for the presence of certain viruses . . . . If it is determined that any of the viruses tested for are present in the sample plasma, the unit of plasma from which the sample was drawn must be destroyed.

" is planning to conduct the plasma testing process at a new facility . . . that it would operate. This . . . would involve the purchase and operation of automated high-volume testing machines and the purchase of reagents for the testing process.

"The testing machine is a fully automated, high-volume screening instrument designed to enhance the safety of the plasma supply . . . . The automated testing machine reduces the risk of accidents, errors, and tampering in this testing process. has plans to purchase several of these machines for the testing facility."

The governs the guidelines for testing Source Plasma, which includes a requirement "that Source Plasma be stored for 60 days prior to further manufacturing . . . . will purchase freezers to be installed at the testing facility, where the Source Plasma will be kept prior to shipment to and other pharmaceutical manufacturers . . . . The Source Plasma will be kept in these freezers for a portion of the 60-day period required by the . . . Source Plasma is unusable and of no value or utility for use in pharmaceutical manufacturing until both the testing process and the 60-day evaluation period are complete. The Source Plasma is shipped to the [customers] in the packaging bottles, which are packaged in boxes with separators.

" plasma product is solely used as an ingredient in pharmaceutical manufacturing and . . . is 'Source Plasma' . . . . Approximately 99% of the Source Plasma is sold and shipped to parent, located in with the remaining 1% sold to other pharmaceutical manufacturers for further manufacture into pharmaceuticals.

N.C. Gen Stat. § 105-164.4(a) provides that "[a] privilege tax is imposed on a retailer at the [applicable rate] of the retailer's net taxable sales or gross receipts, as appropriate. The general rate of tax is four and three-quarters percent (4.75%). . . ." N.C. Gen Stat. §§ 105-467, 105-468, 105-483, 105-498, 105-507.2, and 105-537 levy the local rates of tax due on products subject to tax per N.C. Gen. Stat. § 105-164.4(a) at the general State sales tax rate.

N.C. Gen Stat. § 105-164.6(a) provides that "[a]n excise tax at the applicable rate set in G.S. 105-164.4 is imposed on [tangible personal property or digital property purchased, leased or rented inside or outside this State for storage, use or consumption in this State, and services sourced to this State]. The applicable rate is the rate and maximum tax, if any, that would apply to the sale of the product. A product is subject to tax under this section only if it is subject to tax under G.S. 105-164.4."

N.C. Gen Stat. § 105-164.13(5a) exempts from sales and use tax the sale at retail and the use, storage, or consumption in this State of "[p]roducts that are subject to tax under Article 5F of . . . Chapter" 105.

N.C. Gen Stat. § 105-164.13(8) exempts from sales and use tax the sale at retail and the use, storage, or consumption in this State of "[s]ales to a manufacturer of tangible personal property that enters into or becomes an ingredient or component part of tangible personal property that is manufactured. This exemption does not apply to sales of electricity."

N.C. Gen Stat. § 105-164.13(23)a. exempts from sales and use tax the sale at retail and the use, storage, or consumption in this State of "[s]ales of . . . [w]rapping paper, labels, wrapping twine, paper, cloth, plastic bags, cartons, packages and containers, cores, cones or spools, wooden boxes, baskets, coops and barrels . . . and like articles sold to manufacturers, producers and retailers, when such materials are used for packaging, shipment or delivery of tangible personal property which is sold either at wholesale or retail and when such articles constitute a part of the sale of such tangible personal property and are delivered with it to the customer."

N.C. Gen Stat. § 105-164.13(23)b exempts from sales and use tax the sale at retail and the use, storage, or consumption in this State of “[a] container that is used as packaging by the owner of the container or another person to enclose tangible personal property for delivery to a purchaser of the property and is required to be returned to its owner for reuse.”

N.C. Gen Stat. § 105-187.51(a)(1) imposes a privilege tax on “[a] manufacturing industry or plant that purchases mill machinery or mill machinery parts or accessories for storage, use, or consumption in this State . . . .” N.C. Gen Stat. § 105-187.51(b) provides “[t]he tax is one percent (1%) of the sales price of the machinery, part, or accessory purchased. The maximum tax is eighty dollars (\$80.00) per article . . . .”

The Department provides the following responses applicable to sales and purchases by your client of the specific items set out in your letter of October 8, 2012.

**1. Soft goods and freezers used as the plasmapheresis facilities**

- a. The following items purchased by your client for its use in the plasmapheresis process as previously discussed are subject to the 1% rate of privilege tax on the purchase price with a maximum tax of \$80.00 per article pursuant to N.C. Gen Stat. § 105-187.51.
  - i. Fistulas (needles)
  - ii. Disposable centrifuge bowls
  - iii. Disposable harnesses
  - iv. Plasmapheresis machines
  - v. Free-Standing freezers used to fast-freeze Source Plasma
- b. Sodium chloride (saline solution), which is injected into the remaining whole blood elements after plasma has been separated but prior to re-introduction into the donor’s body through the fistula are subject to the general State and applicable local rates of tax.

**2. Packaging materials for shipment of plasma samples to testing facilities**

- a. The following items purchased by your client for use in shipping bottles of Source Plasma samples from the plasmapheresis facility to a testing facility are subject to the 1% rate of privilege tax on the purchase price with a maximum tax of \$80.00 per article pursuant to N.C. Gen Stat. § 105-187.51.
  - i. Tube trays
  - ii. Tubes and caps
  - iii. Shipping containers
  - iv. Shipping gel packs

**3. Testing facility**

- a. The following items purchased by your client for use as previously discussed in testing and storing Source Plasma at its prospective testing facility qualify for the 1% rate of privilege tax on the purchase price with a maximum tax of \$80.00 per article pursuant to N.C. Gen Stat. § 105-187.51.
  - i. Reagents used to test Source Plasma
  - ii. Automated High-Volume Testing Machines used to test Source Plasma
- b. Freezers used to store the Source Plasma during the 60-day period as previously discussed are subject to the general State and applicable local rates of tax.

**4. Anticoagulant**

- a. Sodium citrate for use as an anticoagulant in the plasmapheresis process as previously discussed is exempt from sales and use tax pursuant to N.C. Gen. Stat. § 105-164.13(8).

**5. Packaging materials**

- a. The following packaging materials used for packaging, shipment or delivery of Source Plasma sold either at wholesale or retail that become a part of the sale are exempt from sales and use tax pursuant to N.C. Gen Stat. § 105-164.13(23)a. If any of the following items are used by your client for other purposes, sales and purchases of such may not be exempt from sales and use tax.
  - i. Packaging bottles
  - ii. Cardboard shipping cartons
  - iii. Packaging bottle labels
  - iv. Shipping case labels
  - v. Tape
  - vi. Cardboard partition separators
  
- b. Any purchases of containers for packaging and delivery of Source Plasma sold to [REDACTED] and other pharmaceutical manufacturers where your client requires the containers be returned to your client are subject to the general State and applicable local rates of tax unless use of the container meets the exemption requirements afforded per N.C. Gen. Stat. § 105-164.13(23)b.

This letter ruling is based solely on the facts submitted to the Department of Revenue for consideration of the transactions described. If the facts and circumstances given are not accurate, or if they change, then the taxpayer requesting this ruling may not rely on it. If a taxpayer relies on this letter ruling and the Department discovers, upon examination, that the fact situation of the taxpayer is different in any material aspect from the facts and circumstances given in this letter ruling, the letter ruling will not afford the taxpayer any protection. It should be noted that this letter ruling is not to be cited as precedent and that a change in statute, a regulation, or case law could void this ruling.

If you have any questions, you may reach me at the number listed below.

Very truly yours,

[REDACTED]  
Administration Officer  
Sales and Use Tax Division

[REDACTED]  
cc: [REDACTED], Director – Sales and Use Tax Division  
[REDACTED], Assistant Director – Sales and Use Tax Division