TENNESSEE DEPARTMENT OF REVENUE
LETTER RULING # 22-04

Letter rulings are binding on the Department only with respect to the individual taxpayer being addressed in the ruling. 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 applicability of Tennessee sales and use tax to the manufacture and sale of drugs for clinical trials.

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") provides research, development, and manufacturing services to [REDACTED] companies (the "Clients"). The Taxpayer operates a facility in [CITY, STATE] that manufactures [REDACTED] products that are intended for the use in the diagnosis, cure, mitigation, treatment, or prevention of disease (the "Products"). The Products are FDA-authorized for use in clinical trials. The Taxpayer has applied for and received the Manufacturing and Processing Industrial Machinery, Energy Fuel and Water Sales and Use Tax Exemption Certificate for the [CITY] facility.

At the [CITY] facility, the Clients pay for services to be performed in a variety of suites, such as manufacturing suites, innovation laboratories, and quality control testing laboratories. These suites and laboratories serve various functions within the Taxpayer's manufacturing process. In the innovation laboratories, the Taxpayer conducts custom studies to evaluate and improve the manufacturing process of a particular Product. The Taxpayer then manufactures the Product in the manufacturing suites. Finally, the Taxpayer uses the quality control testing laboratories to test and release the Products for delivery to the Taxpayer's Clients.

The Taxpayer's employees perform the work in these suites and laboratories pursuant to contractual specifications from the Clients. The Clients never have independent control or use of the suites or laboratories. The Taxpayer supplies the equipment in the manufacturing suite, but the Clients may also supply equipment if necessary. The Clients also supply the Taxpayer with cells or genes from individuals enrolled in clinical trials for the manufacture of Products.

The Clients engage the Taxpayer for the purpose of obtaining the Products. The Taxpayer derives the majority of its revenue from what it characterizes as manufacturing services. Under a Master Development and Manufacturing Services Agreement (the "Agreement"), the Taxpayer's "manufacturing process" is typically defined as:

> All steps, processes, activities, and operations necessary to produce (and actually performed by or on behalf of [the Taxpayer] in producing) Product, including the manufacturing, production, quality assurance, equipment validation, processing, formulation, fill, finish, packaging, labeling, handling, quality control testing, stability testing, and the Release, warehousing, and storage of Product.

The Taxpayer charges its Clients separate fees for the various stages of the manufacturing process. The primary sources of revenue from the Taxpayer's manufacturing operations are Suite Reservation Fees and Batch Fees.

Suite Reservation Fees

Pursuant to the Agreement and subsequent statement of work, the Taxpayer reserves for each Client shared or dedicated production line(s) in a manufacturing suite within the Taxpayer's [CITY] facility, in consideration for that Client's monthly payment of a Suite Reservation Fee. The Taxpayer charges additional fees for quality control testing laboratories. These manufacturing suites and quality control testing laboratories are operated by the Taxpayer's employees as part of the drug manufacturing process. The fees are referred to collectively in the Agreement as the "Suite Reservation Fees."

Utilizing the reserved production line(s) in the suite, the Taxpayer manufactures the Product for that specific Client. The Taxpayer's services include the provision of various equipment (e.g., [EQUIPMENT]), which the Taxpayer furnishes in each manufacturing suite. The Suite Reservation Fee also covers the costs associated with the maintenance of the manufacturing suite and the equipment provided therein.

Batch Fees

Under the Agreement, a "Batch" is a specific quantity of the Product that is produced during a manufacturing cycle. The "Batch Fees" are the fees that a Client pays the Taxpayer to purchase each Batch of Product. The Taxpayer manufactures each Batch in accordance with the specifications provided by each Client. The Taxpayer separately invoices its Clients for Batch Fees or, if included on an invoice with other charges, the Batch Fees are separately stated on the invoice. After the Taxpayer certifies that a Batch complies with a Client's specifications, the Taxpayer releases the Product for delivery to that Client, at the Taxpayer's premises.

Clinical Trials

After accepting delivery from the Taxpayer of the Products at the Taxpayer's facility in [CITY, STATE], the Clients transport the Products to other locations for use in clinical trials or research laboratories. Pursuant to the written orders of the licensed physician overseeing the clinical trial, the Clients (or their intermediaries) dispense the Products as received from the Taxpayer, without making any further modifications to the active parts of the Products. None of the Products are available without a prescription. The Products are utilized by the Clients in one or more of the clinical research phases, and the benefits obtained by the Clients and clinical participants will vary across those phases.

Phase 1: During Phase 1 studies, researchers test a new Product in normal volunteers (usually 20 to 80 healthy people), who typically receive a monetary stipend. As a result of the Phase 1 trial, researchers answer questions related to how the new Product works in the body, the side effects associated with increased dosage, and early information about how effective it is to determine how best to administer the drug to limit risks and maximize possible benefits.

Phase 2: In Phase 2 studies, researchers administer the Product to a group of patients (several hundred individuals) with the disease or condition for which the Product is being developed. Phase 2 studies provide researchers with additional safety data. Researchers use this data to refine research questions, develop research methods, and design new Phase 3 research protocols.

Phase 3: Researchers design Phase 3 studies to demonstrate whether a Product offers a treatment benefit to a specific population. Sometimes known as pivotal studies, these studies involve 300 to 3,000 participants who have the disease or condition for which the Product is being developed. Phase 3 studies provide researchers with most of the safety data. Because these studies are larger and longer in duration (typically years instead of months), the results are more likely to show whether and to what extent long-term or rare side effects may develop.

Phase 4: Phase 4 trials are carried out once the Product has been approved by the FDA during the post-market safety monitoring. These studies involve thousands of participants who have the disease or condition for which the Product has been approved.

In addition to its current manufacture of Products for clinical trials, the Taxpayer anticipates that it will manufacture commercial supplies of certain FDA-approved drugs. The Taxpayer will sell these commercialized drugs to the Clients who will then resell the drugs to their respective customers in the chain of commerce, or the Clients will sell the drugs directly to patients.

RULINGS

1. Do the Suite Reservation Fees constitute fees for non-taxable services, which are not subject to Tennessee sales and use tax?

   Ruling: Based on the facts provided, the Suite Reservation Fees are properly characterized as part of the sales price of the Products manufactured by the Taxpayer or when providing research services (e.g., innovation laboratories), which are part of the sales price of nontaxable research services. If a Product manufactured by the Taxpayer is subject to the Tennessee sales and use tax, then the related Suite Reservation Fees are subject to the Tennessee sales and use tax as part of the sales price of the Product. If the Product is not subject to the Tennessee sales and use tax, then the Suite Reservation Fees related to the manufacture of that Product are likewise not subject to tax.

2. Are the Products manufactured by the Taxpayer and sold from the Taxpayer's facilities in [CITY, STATE] exempt from Tennessee sales and use tax as prescription drugs?

   Ruling: Yes. The Products manufactured by the Taxpayer and sold to the Clients for use in the clinical trials are exempt from Tennessee sales and use tax as prescription drugs under TENN. CODE ANN. § 67-6-320(a) (2018).

3. When the Taxpayer sells the Products that it manufactures to its Clients, and the Clients subsequently dispense the Products to patients, are the Taxpayer's sales of such Products exempt from Tennessee sales and use tax as sales for resale?

   Ruling: No. The Taxpayer's sales of its Products to its Clients for use in clinical trials are not sales for resale because merely transferring or administering the Products to patients who participate in clinical trials does not constitute a subsequent, bona fide sale.

4. Does the Taxpayer qualify for the Tennessee sales and use tax research and development exemption under TENN. CODE ANN. § 67-6-102(46)(M) and TENN. CODE ANN. § 67-6-206 (Supp. 2021) with respect to its own purchases of machinery, apparatus, and equipment used in the Taxpayer's operations?

   Ruling: Based on the facts provided, the Taxpayer would qualify for the research and development sales and use tax exemption with respect to its own purchases of machinery, apparatus, and equipment when such equipment is primarily used in providing research and development services. Machinery, apparatus, and equipment necessary to and primarily for the manufacture of Products that are sold to Clients would qualify for the manufacturing and processing sales and use tax exemption.

ANALYSIS

1. The Suite Reservation Fees are subject to sales tax if the related Products are subject to sales tax, and fees for the innovation laboratories are not subject to sales tax.

Based on the facts provided, the Suite Reservation Fees for manufacturing suites and quality control testing laboratories are properly characterized as part of the sales price of the Products manufactured by the Taxpayer. "Sales price" means the total amount of consideration for which personal property or services are sold, including the cost of labor or service costs, and expenses of the seller.[1]

If a Product manufactured by the Taxpayer is subject to the Tennessee sales and use tax, then the related Suite Reservation Fees are subject to the Tennessee sales and use tax as part of the sales price of the Product. If the Product is not subject to the Tennessee sales and use tax, then the Suite Reservation Fees related to the manufacture of that Product are likewise not subject to tax.

The Suite Reservation Fees for the reservation of a manufacturing line or a quality control testing laboratory at the Taxpayer's facility where the Taxpayer's employees fabricate and test the manufactured Products are part of the manufacturing process. Importantly, the Taxpayer does not lease out the manufacturing line or a laboratory to the Client, for the Client's independent use; rather, the Taxpayer's own employees utilize the facility to manufacture the Client's desired product. Thus, the manufacturing line and quality control testing laboratories are an integral part of the Taxpayer's manufacturing process and are not furnished to Clients for a purpose other than the manufacture of the Products; as such, the reservation of the manufacturing line and quality control testing laboratories, as well as the services of the Taxpayer's employees rendered in those facilities, are labor and service costs, and expenses of the seller.[2]

It follows, then, that the Suite Reservation Fees related to the manufacturing processes are included in the sales price of the Products. Thus, the taxability of such Suite Reservation Fees depends on whether the related Products are subject to Tennessee sales and use tax.

The Taxpayer suggests that the fees for the innovation laboratories should be treated in the same manner as the Suite Reservation Fees for purposes of the Tennessee sales and use tax. However, the fees for the innovation laboratories, where custom studies are conducted to evaluate and improve the manufacturing process for a Product, are charges for providing research services to Clients.

Research is not included as a specifically enumerated service that is subject to Tennessee sales tax.[3] Therefore, the fees for the custom studies performed in the innovation laboratories are charges for a nontaxable service.

2. *The Products manufactured for and used by Clients in clinical trials are exempt from Tennessee sales and use tax as a sale of prescription drugs.*

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[1] TENN. CODE ANN. § 67-6-102(85)(A)(i)-(ii) (Supp. 2021).

[2] The definition of "sale" includes "the fabrication of tangible personal property for consumers who furnish, either directly or indirectly, the materials used in fabrication work, …." TENN. CODE ANN. § 67-6-102(84)(A). *See also* TENN. COMP. R. & REGS. 1320-05-01-.41 (1983) stating that charges for labor, production, or fabrication are not deductible from the sale of "made to order" tangible personal property where the materials are selected or furnished by customers. The Taxpayer's Clients provide biological materials to the Taxpayer for manufacturing Products to the Clients' specifications. The Clients are effectively selecting and furnishing materials for "made to order" tangible personal property. Since the Suite Reservation Fees encompass labor, production, and fabrication services, the fees are included in the total proceeds of the sale of the Products.

[3] *See* TENN. CODE ANN. § 67-6-201.

Under TENN. CODE ANN. § 67-6-320(a), any drug for human use dispensed pursuant to a prescription is exempt from Tennessee sales and use tax. TENN. CODE ANN. § 67-6-102(35) (Supp. 2021) defines "drug" 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:
>
> (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.

First, the Products manufactured by the Taxpayer generally meet the definition of "drug" because they are a type of "compound, substance or preparation" used in the "diagnosis, cure, mitigation, treatment, or prevention of disease." The Products are approved by the FDA for use in clinical trials, which are research studies conducted on people and designed to answer specific questions about the safety or effectiveness of drugs, vaccines, other therapies, or new ways of using experimental treatments.[4] In the Taxpayer's case, the clinical trials are conducted to answer safety and effectiveness questions about the development of new cell and gene-based immunotherapy and regenerative medicines. In phase 1 of the clinical trial, healthy participants are administered the Products, while in phases 2, 3, and 4 of the clinical trials, patients with a disease or condition are administered the Products. Although the Products are still in the trial phase, and some of the participants are healthy, the goal of using the Products in the clinical trials is for the diagnosis, cure, mitigation, treatment, or prevention of disease. As such, the Products used in the clinical trials fall under the definition of "drug."

Second, the Products are undoubtedly for human use when administered during the clinical trials. Importantly, the drugs are dispensed to clinical trial participants under the orders of a supervising physician. Additionally, none of the drugs manufactured by the Taxpayer for the clinical trials are available without a prescription. As such, the Products manufactured for use in clinical trials are exempt from Tennessee sales and use tax as prescription drugs.[5] Relatedly, since the Suite Reservation Fees are part of the sales price of the Products, and the Products are exempt from the Tennessee sales and use tax, then the Suite Reservation Fees are not subject to the Tennessee sales and use tax.

3. The Taxpayer's sales of its Products to its Clients for use in clinical trials are not sales for resale.

[4] Clinical Trials: What Patients Need to Know, U.S. Food & Drug, https://www.fda.gov/patients/clinical-trials-what-patients-need-know (last visited May 10, 2022).

[5] The specific application of the law depends on how the clinical trial is structured. If the facts differ from the general description provided, then the analysis and outcome may differ.

Under the Retailer's Sales Tax Act,[6] the retail sale in Tennessee of tangible personal property and specifically enumerated services are subject to the Tennessee sales and use tax, unless an exemption applies. Under Tennessee law, a sale for resale is exempt from Tennessee sales and use tax if it is made in strict compliance with rules and regulations promulgated by the commissioner.[7] A "resale" is a subsequent, bona fide sale of the taxable item by the purchaser, and a "sale for resale" means the sale of a taxable item intended for subsequent resale by the purchaser.[8]

The Taxpayer has suggested that because the end-users of the Products are the Clients' patients, sales from the Taxpayer to its Clients are generally sales for resale. However, for the exemption to apply, there needs to be a bona fide sale of the products from the Client to an intermediary or to the patient for the transaction to meet the requirements of a "sale for resale." Simply transferring the Products to the patients or administering the Products to patients as part of the patient's participation in a clinical trial does not constitute a bona fide sale; rather, under such circumstances, the Client would generally be considered the end user and consumer of the Product.

Accordingly, while prescription drugs are exempt from sales and use tax in Tennessee, to the extent the Taxpayer's Products include items that do not fall within the scope of the prescription drug exemption, an actual resale must occur and the exemption for sales for resale must be documented. Without an actual resale accompanied by the appropriate documentation, the sale for resale exemption does not apply and the sale of the Product to the Client is a retail sale.

4. *The Taxpayer likely qualifies for the research and development exemption with respect to certain of its activities relating to the innovation laboratories.*

TENN. CODE ANN. § 67-6-206(a) provides a Tennessee sales and use tax exemption for the purchase of industrial machinery. The industrial machinery exemption applies to machinery, apparatus, and equipment that is necessary to, and primarily for the fabricating or processing of tangible personal property for resale.[9] In addition, a research and development exemption exists under TENN. CODE ANN. § 67-6-102(46)(M) which defines "industrial machinery," in relevant part, as "machinery, apparatus, and equipment . . . necessary to, and primarily for, the purpose of research and development." TENN. COMP. R. & REGS. 1320-05-01-.128(2)(a) (2016) requires that "research and development" have one of the following as its ultimate goal:

1. Basic research in a scientific field of endeavor;

2. Advancing knowledge or technology in a scientific or technical field of endeavor;

[6] Tennessee Retailer's Sales Tax Act (codified at TENN. CODE ANN. §§ 67-6-101 to -907 (2018 & Supp. 2021)).

[7] *See CAO Holdings, Inc. v. Trost,* 333 S.W. 3d 73 (Tenn. 2010); *see also* TENN. COMP. R. & REGS. 1320-05-01-.68(1) (2008) which requires that the purchaser of the item for resale present a valid certificate of resale, and the dealer must maintain that certificate on its premises. TENN. COMP. R. & REGS. 1320-05-01-.68(2) provides that without a valid resale certificate, the transaction will be treated as a retail sale.

[8] TENN. CODE ANN. § 67-6-102(81)(A).

[9] TENN. CODE ANN. § 67-6-102(46)(A)(i).

3. The development of a new product, whether or not the new product is offered for sale;

4. The improvement of an existing product, whether or not the improved product is offered for sale;

5. The development of new uses of an existing product, whether or not a new use is offered as a rationale to purchase the product; or

6. The design and development of prototypes, whether or not a resulting product is offered for sale.

The Taxpayer's purchases of machinery, apparatus and equipment used primarily for research and development qualify for the exemption to the extent that the ultimate goal of the research and development is one of the goals under TENN. COMP. R. & REGS. 1320-05-01-.128(2)(a).

The Taxpayer offers its research services and Product manufacturing to companies working through the stages of the clinical trial process and/or in research labs in order to develop new or improved products. The Taxpayer uses its innovation laboratories to develop better ways of making the Products. The manufacturing suites and quality control suites are necessary for making Products that are for resale to Clients. Clients use the manufactured Products in clinical trials with the ultimate goal of developing new or improved therapies or medicines.

As such, the Taxpayer's own purchases of machinery, apparatus, and equipment used for manufacturing Products for sale and subsequent use by Clients in clinical trials qualify as tax-exempt industrial machinery being used primarily to fabricate or process tangible personal property for resale and consumption off the premises under Tenn. Code Ann. §§ 67-6-102(46)(A)(i) and 67-6-206. Since a majority of the Taxpayer's revenue is from manufacturing Products for sale to the Clients, the Taxpayer may also qualify for reduced rates on energy, fuel, and water used at its [CITY] facility and a tax exemption for purchases of industrial supplies under TENN. CODE ANN. § 67-6-206(b) and TENN. COMP. R. & REGS. 1320-05-01-.40.

The Taxpayer's own purchases of machinery, apparatus, and equipment primarily used in providing research services such as equipment primarily used in custom studies in innovation laboratories to develop better ways to improve the manufacture of a drug qualify as tax-exempt research and development under TENN. CODE ANN. §§ 67-6-102(46)(M) and 67-6-206(a).

It should be noted that the Taxpayer has already received the Manufacturing and Processing Industrial Machinery, Energy Fuel, and Water Sales and Use Tax Exemption Certificate for the tax-exempt purchase of qualified industrial machinery. As a practical matter, TENN. COMP. R. & REGS. 1320-05-01-.128(3) requires that those who wish to make tax-exempt purchases of research and development machinery that is not primarily used for fabrication must apply for authorization from the Commissioner of Revenue and receive the Research and Development Sales and Use Tax Exemption Certificate. The Research and Development application is available on the Department's website.

APPROVED: David Gerregano
Commissioner of Revenue

DATE: 6/17/2022