New York State Department of Taxation and Finance
Office of Counsel
Advisory Opinion Unit

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Sales Tax
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STATE OF NEW YORK
COMMISSIONER OF TAXATION AND FINANCE

ADVISORY OPINION PETITION NO. S121226A

The Department of Taxation and Finance received a Petition for Advisory Opinion from [redacted] "Petitioner". Petitioner asks whether its activities constitute "research and development in the experimental or laboratory sense" for purposes of Tax Law §§ 1115(a)(10) and 1115(b)(ii), such that certain purchases it makes are exempt from the sales and use tax.

We conclude that Petitioner's testing services result in the development of a new product, the improvement of an existing product, or the development of a new use for an existing product. Therefore, Petitioner is engaging in exempt research and development activities in the experimental or laboratory sense within the meaning of Tax Law §§ 1115(a)(10) and 1115(b)(ii) and it may make certain purchases exempt from sales tax.

Facts

Petitioner is a laboratory services corporation that provides clinical testing services at its facilities located around the world, including one facility located in New York State. Petitioner states that its New York laboratory is dedicated to providing testing services for various pharmaceutical clients looking to develop new drugs, as well as clients looking to improve drugs already approved by the United States Food and Drug Administration (FDA). In particular, the laboratory assists in testing both the safety and effectiveness of experimental pharmaceutical drugs offered to human patients during clinical trials. All data produced during the testing is released to the client for eventual submission by the client to the FDA as the client pursues various stages of the development of new drugs. The laboratory is dedicated exclusively to testing related to its clients' clinical trials, and Petitioner's staff is led by a team of medical doctors and PhD level scientists.

Petitioner offers standardized testing platforms with consistent test methodologies and result reporting. The lab is accredited by the College of American Pathologists. Petitioner provides timely laboratory test results and related demographic data in support of its clinical testing. The goal is to provide custom laboratory and related study management services while ensuring full regulatory compliance.

Petitioner describes human clinical trials as having four general phases.

• Phase I -- Involves screening for safety and an initial administration of the drug to a small group of individuals to evaluate safety, determine dosage range, and identify side effects.

• Phase II -- Involves establishing the protocol for the clinical trial as well as administering the drug to a larger group to determine the effectiveness and safety of the drug. Petitioner's client establishes the protocol, but the client may request Petitioner's input on the testing steps established by the protocol.
• Phase III -- The drug is given to large groups to confirm effectiveness, monitor side effects, compare the drug to commonly used treatments, and collect information necessary for improving the dosage and safety of the drug. A unique identifier is provided for each test subject, and the studies are blinded in such a way that Petitioner does not know if a sample belongs to a patient receiving a new drug or a placebo.
• Phase IV – Studies are conducted after a drug has been approved for release to ascertain the drug's long-term risks, benefits and optimal uses.

Petitioner exclusively provides laboratory services to its clients for the purpose of developing new pharmaceutical drugs, improving pharmaceutical drugs that have already received FDA approval, or developing new benefits and uses associated with existing pharmaceuticals. Petitioner's team assists the pharmaceutical clients in all facets of the studies, including custom set up and logistics planning, daily query resolution, and final data calculations. Although Petitioner offers testing services for all four clinical trial phases, nearly all testing conducted at the New York location supports phase II and III clinical testing. Petitioner does perform a small amount of Phase IV testing at its New York facility.

Petitioner also provides project management services. Petitioner's project managers work with the pharmaceutical clients to:

• Plan and document all laboratory requirements and custom reporting services for the study;
• Manage all set-up activities to ensure that study databases, laboratory supplies, and investigator site training are in place. Depending on the contract it has with a client, Petitioner may provide site training for client investigators who work at clinical trial sites, evaluate documentation provided to these investigators, and/or prepare a laboratory manual for the sites to reference when processing and shipping samples to Petitioner;
• Present laboratory requirements and procedures;
• Monitor studies. Petitioner may contact a testing site if it failed to provide all the necessary information requested on the requisition form designed for that testing protocol. During the clinical trial, Petitioner also monitors the mechanics of the testing occurring at its facility.
• Supply study metrics to monitor key performance indicators and overall study progress; and/or
• Conduct all study closeout activities for data lock and final data submission.

Petitioner's laboratory has five separate components:

(1) Intake -- Lab assistants process human blood samples and codes are assigned to samples to identify the test subject as well as the trial protocol. Defective samples are also screened. During processing of the samples, two test tubes are created. The first tube is sent to

one of Petitioner's labs for safety testing and the other tube is sent to another of Petitioner's labs to test for efficacy. The screening of defective samples is necessary to guarantee accurate and detailed test results. Without Petitioner's screening practices at the intake level, defective samples could enter the testing pool and taint test results. Furthermore, the intake lab codes and formats the samples so that the trial protocol and testing requirements are apparent to the testing labs. As a result, intake processing is a required first step in all of Petitioner's testing. Test tubes, lab tables, lab chairs, computers, printers and processing equipment are among the items employed to process the samples and assign identification codes. Industrial refrigerators are used to store the samples until ready for each step in testing.

(2) Safety Testing -- Licensed technologists conduct various tests that monitor cholesterol, blood cell count and other factors to determine if the drug is harming the patient. These tests are more routine in nature. In addition to the items also used during the intake process, Safety Testing requires the use of testing machinery, flasks, slides, microscopes and other laboratory equipment. Petitioner's safety testing provides the pharmaceutical client with the data and test results necessary for acquiring FDA approval for the studied drug. Side effect results, appropriate dosage amounts, and hazard information are identified.

(3) Efficacy Testing -- Licensed technologists conduct highly technical testing for the specific condition the client is seeking to alleviate to determine whether the drug is effective in producing the desired impact. These tests could include molecular, genetic or radioactive testing, depending on the specific testing required by the clinical trial protocol. Efficacy testing requires many of the same supplies and testing tools used during Intake and Safety Testing and the results will be provided by the client to the FDA as part of the approval process.

(4) Additional Testing -- Occasionally, pharmaceutical clients request additional testing to determine whether a drug has any unintended benefits and uses. These additional testing procedures use special testing machinery and procedures in an effort to look for unanticipated results.

(5) Infectious Disease Testing -- Infectious disease testing is implemented only where the trial protocol demands specific testing procedures pertaining to infectious diseases such as Hepatitis C. Infectious disease testing is isolated from the routine safety and efficacy testing. Traditional Petri dish and incubation procedures are utilized to screen out samples of individuals who have diseases that could compromise testing.

In addition to the testing labs, Petitioner's facility has a specific laboratory designated for assay development. The purpose of this research is to develop testing assays that can be used for examining specific cells to determine whether they contain particular markers. In other words, these tests identify whether a specific condition exists. Examples of such assays developed for testing purposes on a mass market basis would include strep throat swab tests and pregnancy tests. This lab produces new testing assays for its clients, who then use them for ongoing research.

Petitioner's facility maintains a large supply of industrial refrigerators that are used for storing samples before, during and after testing, as well as for storing other materials used in the testing process. In addition, the facility maintains an on-site quality assurance group and other administrative departments, including information technology (IT) and Global Data Services.

Petitioner's on-site quality assurance group works closely with each department to document and monitor adherence to the highest standard operating procedures required worldwide. This ensures that the tests are valid for drug approval in various countries. The group's goal is to ensure quality, consistency and full regulatory compliance through a single quality standard and set of operating procedures. The quality assurance group conducts rigorous internal audits to ensure that Petitioner's quality standards for its processes are achieved. In addition, through Petitioner's central laboratories' Information Technology and Global Data Services Departments, Petitioner is able to offer its pharmaceutical clients a global repository for study data gathered for that client at various trial sites. The data compiled by Petitioner for a particular client is restricted to use by that client, and Petitioner's contracts have a strict confidentiality clause. The facility also maintains traditional payroll and human resources departments.

In performance of its testing, Petitioner purchases laboratory supplies, equipment and other materials for use in Petitioner's research and development activities. These items include lab coats, goggles, gloves, test tubes, flasks, reagents, microscopes, slides, lab tables, lab chairs, sterilizers, industrial refrigerators, technical journals, testing/processing machinery, printers, centrifuges, Petri dishes and other supplies and laboratory equipment. In addition, Petitioner purchases large amounts of electricity and natural gas for direct use in powering its testing machinery, lab refrigerators and other laboratory operations.

Analysis

We conclude that Petitioner's activities in the five components described above and the assay development constitute "research and development in the experimental or laboratory sense" for purposes of Tax Law §§ 1115(a)(10) and 1115(b)(ii).

The Tax Law provides an exemption for tangible personal property used directly and predominantly in research and development in the experimental or laboratory sense. Generally, research and development in the experimental or laboratory sense means research that has as its ultimate goal the "basic research in a scientific or technical field of endeavor, the advancing the technology in a scientific or technical field of endeavor, the development of new products, the improvement of existing products, or the development of new uses for existing products." *See* 20 NYCRR § 528.11(b). This research and development exemption does not include the activities of "ordinary testing or inspection of materials or products for quality control or the performance of efficiency surveys, management studies, consumer surveys, advertising, promotions or research in connection with literary, historical or similar projects." *See* Tax Law §§ 1115(a)(10), 1115(b)(ii); 20 NYCRR § 528.11(b)(2). Direct use in research and development means actual use in the research and development operation. Tangible personal property for direct use would broadly include materials worked on, and machinery, equipment and supplies used to perform the actual research and development work. Usage in activities collateral to the actual research and development process is not deemed to be used directly in research and development. *See* 20 NYCRR § 528.11(c)(1). Predominantly used in research and development means that the item is used directly in production "over fifty percent of the time. . . ." *See* 20 NYCRR § 528.11(c)(2).

Petitioner states that the only testing its facility provides is the testing of samples from various stages of clinical trials conducted to determine the safety and efficacy of new drugs and medicines being developed by its clients that have not yet received FDA approval for a particular use. Petitioner and its employees process its tests in such a manner as to provide data to clients seeking FDA approval. Based upon the Petitioner's description of its activities, Petitioner's test processing services are performed for a client seeking to develop a new product or improve an existing product. Occasionally, Petitioner also will assist clients in determining whether an existing drug has any unintended benefits or alternative uses. In each of these cases, Petitioner is engaging in exempt research and development activities in the research and developmental sense within the meaning of Tax Law §§ 1115(a)(10) and 1115(b)(ii). *See* 20 NYCRR § 528.11(b)(1); TSB-A-09(21)S; TSB-A-97(51)S; TSB-A-88(4)S. Accordingly, Petitioner's purchases of tangible personal property for use or consumption directly and predominantly in testing samples related to the development of clinical trial drugs qualify for the exemption from sales tax under Tax Law § 1115(a)(10). *See* 20 NYCRR § 528.11(c)(3); TSB-A-97(51)S.

However, not all of Petitioner's activities are "directly and predominately" involved in research and development. For example, Petitioner also offers a project management service. While that service is not subject to tax pursuant to Tax Law § 1105(c), tangible personal property used by Petitioner in performing that service, including stationery or supplies used in preparing written reports, would not qualify for exemption under Tax Law § 1115(a)(10) because they are not used directly and predominately in research and development. Accordingly, such purchases would be subject to tax under section Tax Law § 1105(a). The exemption also does not include the activities of "ordinary testing or inspection of materials or products for quality control" so tangible personal property used by Petitioner predominantly for this purpose would not qualify for the exemption. Other items, such as goggles or lab coats, may be used in a manner that is indirectly related to the research and development activities. These items would also not qualify for the exemption. Petitioner must demonstrate how individual items of tangible personal property are used in order to establish an entitlement to this exemption.

Petitioner may make untaxed purchases of tangible personal property that qualify for the exemption by giving the supplier(s) a properly completed form ST-121, Exempt Use Certificate within 90 days of the purchase date.

Finally, Petitioner asks whether its purchases of electricity and natural gas are exempt from sales and use tax pursuant to Tax Law § 1115(b)(ii) as purchases for use or consumption directly and exclusively in research and development in the experimental or laboratory sense. Tax Law § 1115(b)(ii) provides an exemption for gas and electricity, and gas and electric service used or consumed directly and exclusively in research and development in the experimental or laboratory sense. However, use in activities collateral to the actual research and development process is not deemed to be used directly in the research and development process. As noted above, for the purposes of this exemption, the sales tax regulations define the term "directly" as "actual use in the research and development operation" and "exclusively" used in research and development to

mean that 100% percent of the electricity or gas is used for such a purpose. *See* 20 NYCRR § 528.11(c).

While Petitioner is engaged in research and development in the experimental or laboratory sense, not all of the electricity and natural gas it uses are directly and exclusively used for such purpose. For example, the portion of electricity used to power payroll and human resource computers is subject to tax, as is the electricity used by Petitioner in its storage of study data for its clients. Likewise, the natural gas consumed to heat or cool the portions of the building where these activities occur would likewise not be exempt from tax. Electricity or gas used in assay development would be exempt under Tax Law § 1115(b)(ii) only if the assay development process itself qualifies as the research and development of a new assay or test. Electricity and steam consumed as part of Petitioner's project management services are not used exclusively in research and development, and therefore are subject to tax.

Petitioner must maintain adequate records with respect to the allocation of gas and electricity used directly and exclusively in research and development and that used for non-exempt purposes. Petitioner has the burden of showing that the utilities are used in an exempt manner. Therefore, Petitioner must, when claiming a refund or credit, submit an engineering survey or documentation of the formula applied to arrive at the amounts of exempt utility purchases. *See* 20 NYCRR § 528.11(c)(4)(iii); TSB-A-88(4)S.

DATED: March 20, 2015

/S/
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NOTE: An Advisory Opinion is issued at the request of a person or entity. It is limited to the facts set forth therein and is binding on the Department only with respect to the person or entity to whom it is issued and only if the person or entity fully and accurately describes all relevant facts. An Advisory Opinion is based on the law, regulations, and Department policies in effect as of the date the Opinion is issued or for the specific time period at issue in the Opinion. The information provided in this document does not cover every situation and is not intended to replace the law or change its meaning.