



North Carolina Department of Revenue

Beverly Eaves Perdue
Governor

Kenneth R. Lay
Secretary

July 12, 2010

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

[REDACTED]
[REDACTED]
[REDACTED]

Attention: [REDACTED] Director of State and Local Tax

Re: Private Letter Ruling

Dear Ms. [REDACTED]:

We have your letter dated April 20, 2010, in which you have requested a private letter ruling as to the applicability of North Carolina sales and use tax to a product manufactured and/or distributed by your company. The product in question is a diagnosis dye.

It is our understanding that the diagnostic die in question is a chemical one legend drug under the Federal Drug Administration guidelines. The dye is used to assist in diagnosing diseases in humans. The dye is a substance which produces a chemical reaction in order to detect, measure or produce other substances. The generic of this substance is [REDACTED] [REDACTED]. The substance is a level one chemical type legend drug whose package is marked with the requisite, RX label, however no written prescription is provided to the taxpayer upon the sale of the product.

G.S. 105-164.3(8a) provides that a "drug" is "a compound, substance, or preparation or a component of one of these that meets any of the following descriptions and is not food, a dietary supplement, or an alcoholic beverage:

- a. Is recognized in the United States Pharmacopoeia, Homeopathic Pharmacopoeia of the United States, or National Formulary.
- b. Is intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease.
- c. Is intended to affect the structure or function of the body."

G.S. 105-164.13(13) provides an exemption from sales and use tax for all of the following drugs, including their packaging materials and any instructions or information about the drugs included in the package with them:

- a. Drugs required by federal law to be dispensed only on prescription.
- b. Over-the-counter drugs sold on prescription.
- c. Insulin.

Pursuant to G.S. 105-164.3(8a) and G.S. 105-164.13(13), the sale of the diagnostic dye product is exempt from sales and use tax.

This 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 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 ruling, then the ruling will not afford the taxpayer any protection. It should be noted that this document is not to be cited as precedent and that a change in statute, a regulation, or case law could void this ruling.

Very truly yours,

Administration Officer
Sales and Use Tax Division

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