



STATE OF SOUTH CAROLINA
DEPARTMENT OF REVENUE

300A Outlet Pointe Blvd., Columbia, South Carolina 29210
P.O. Box 125, Columbia, South Carolina 29214-0575

SC PRIVATE LETTER RULING #22-1

SUBJECT: Sales of Allergen Extracts – Injectable Biologics Exemption
(Sales and Use Tax)

REFERENCES: S.C. Code Ann. Section 12-36-2120(80) (2014)

AUTHORITY: S.C. Code Ann. Section 12-4-320 (2014)
S.C. Code Ann. Section 1-23-10(4) (2005)
SC Revenue Procedure #09-3

SCOPE: A Private Letter Ruling is an advisory opinion issued to a specific taxpayer by the Department to apply principles of law to a specific set of facts or a particular tax situation. It is the Department’s opinion limited to the specific facts set forth, and is binding on agency personnel only with respect to the person to whom it was issued and only until superseded or modified by a change in statute, regulation, court decision, or another Departmental advisory opinion, providing the representations made in the request reflect an accurate statement of the material facts and the transaction was carried out as proposed.

QUESTION

Are the retail sales of allergen extracts by KEB Inc., as described in the facts, retail sales of injectable biologics “applicable to the prevention, treatment, or cure, of a disease or condition of human beings” and exempt from sales and use tax under Code Section 12-36-2120(80)(a)?

CONCLUSION

The retail sales of allergen extracts by KEB Inc., as described in the facts, are retail sales of injectable biologics “applicable to the prevention, treatment, or cure, of a disease or condition of human beings” and exempt from sales and use tax under Code Section 12-36-2120(80)(a).

FACTS

KEB manufactures and sells extracts of various biological allergens. All of the extracts sold by KEB are derived from living organisms (e.g., nuts, dust mites, molds, pollen), which KEB refines into liquid form. KEB sells its extracts as three distinct products: (1) as testing kits; (2) as

pre-mixed doses of extracts; and (3) as bulk extracts for physicians' offices to compound for individual patients. Each of the products is administered by or pursuant to the supervision of a physician in a physician's office.

A testing kit consists of various extracts pre-loaded onto needles, with the needles arranged in rows. A testing kit is administered by puncturing an individual patient's skin with the rows of needles, causing the needles to force the extracts into the patient's skin. The patient is observed to determine whether the extracts in the grid cause an allergic reaction.

A physician will use either pre-mixed doses or the bulk extracts to mitigate the effects of an individual's allergies. Both the pre-mixed doses and the bulk extracts are administered by hypodermic needle and syringe into the patient's skin.

LAW AND ANALYSIS

Code Section 12-36-2120(80)(a) exempts from sales and use tax the gross proceeds of sales and sales price of:

... injectable medications and injectable biologics, so long as the medication or biologic is administered by or pursuant to the supervision of a physician in an office which is under the supervision of a physician, or in a Center for Medicare or Medicaid Services (CMS) certified kidney dialysis facility. For purposes of this exemption, "biologics" means the products that are applicable to the prevention, treatment, or cure of a disease or condition of human beings and that are produced using living organisms, materials derived from living organisms, or cellular, subcellular, or molecular components of living organisms.

Since the allergen extracts are (1) derived from living organisms, (2) administered by injection, (3) administered by or under the supervision of a physician, (4) administered in an office under the supervision of a physician, and (5) sold for use in human beings, retail sales of extracts by KEB are injectable biologics exempt from sales and use tax if they are considered to be "applicable to the prevention, treatment, or cure, of a disease or condition" under Code Section 12-36-2120(80).

As stated in the facts, the pre-mixed doses of biological allergens and the bulk extracts are used to mitigate an individual's allergies, and therefore, are used in the treatment of such allergies. As such, the retail sale by KEB of pre-mixed doses of extracts and bulk extracts for physicians' offices to compound for individual patients, as described in the facts, are exempt as injectable biologics under Code Section 12-36-2120(80).

Now it must be determined if the testing kits, as described in the facts, consisting of various extracts pre-loaded onto needles are "applicable to the prevention, treatment, or cure, of a disease or condition of human beings."

While not controlling on the Department, the United States Food and Drug Administration’s definition of the phrase “applicable to the prevention, treatment, or cure of diseases or injuries of man” provides guidance as to whether the testing kits used in the diagnosis of an allergy are exempt from the sales and use tax.

The Code of Federal Regulation in 21 CFR Section 600.3(j) defines the phrase “applicable to the prevention, treatment, or cure of diseases or injuries of man” to include an “aid in diagnosis” and reads as follows:

A product is deemed applicable to the prevention, treatment, or cure of diseases or injuries of man irrespective of the mode of administration or application recommended, including use when intended through administration or application to a person as an aid in diagnosis, or in evaluating the degree of susceptibility or immunity possessed by a person, and including also any other use for purposes of diagnosis if the diagnostic substance so used is prepared from or with the aid of a biological product. (Emphasis added)

As such, the retail sale by KEB of a testing kit as an aid in diagnosis, as described in the facts, is “applicable to the prevention, treatment, or cure of a disease or condition of human beings,” and therefore, is exempt as an injectable biologic under Code Section 12-36-2120(80).

SOUTH CAROLINA DEPARTMENT OF REVENUE

s/W. Hartley Powell

W. Hartley Powell, Director

April 7, 2022
Columbia, South Carolina