

ST 24-0035-GIL 10/29/2024 FOOD, DRUGS, & MEDICAL APPLIANCES

This letter discusses drugs and medical appliances. 86 Ill. Adm. Code 130.311.
(This is a GIL.)

October 29, 2024

NAME
COMPANY
ADDRESS

Dear NAME:

This letter is in response to your letter dated October 10, 2024, in which you requested information. The Department issues two types of letter rulings. Private Letter Rulings (“PLRs”) are issued by the Department in response to specific taxpayer inquiries concerning the application of a tax statute or rule to a particular fact situation. A PLR is binding on the Department, but only as to the taxpayer who is the subject of the request for ruling and only to the extent the facts recited in the PLR are correct and complete. Persons seeking PLRs must comply with the procedures for PLRs found in the Department’s regulations at 2 Ill. Adm. Code 1200.110. The purpose of a General Information Letter (“GIL”) is to direct taxpayers to Department regulations or other sources of information regarding the topic about which they have inquired. A GIL is not a statement of Department policy and is not binding on the Department. See 2 Ill. Adm. Code 1200.120. You may access our website at <https://tax.illinois.gov/> to review regulations, letter rulings and other types of information relevant to your inquiry.

The nature of your inquiry and the information you have provided require that we respond with a GIL. In your letter you have stated and made inquiry as follows:

I am writing on behalf of COMPANY1 D/B/A COMPANY, a company that sells dental fluoride varnish exclusively to dental offices for professional use. We are seeking a tax ruling regarding the sales tax applicability to our fluoride varnish products.

Our fluoride varnish is classified as a Class II medical device, regulated by the U.S. Food and Drug Administration (FDA), and requires a 510(k) clearance. The product is used by dental professionals and is applied directly to patients’ teeth during dental appointments. It is not provided as a take-home treatment or over-the-counter product for consumers.

We would like to request clarification on whether the fluoride varnish we sell is exempt from Illinois sales tax under the medical devices exemption or is subject to a special tax rate due to its classification as a regulated medical device. Given that the varnish is used exclusively in professional settings

by licensed dental providers, we seek confirmation on the tax status of these products.

If additional information is required, please feel free to contact me at PHONE or EMAIL. We appreciate your time and consideration and look forward to your response.

DEPARTMENT'S RESPONSE:

The Illinois Retailers' Occupation Tax Act imposes a tax upon persons engaged in this State in the business of selling tangible personal property to purchasers for use or consumption. See 35 ILCS 120/2; 86 Ill. Adm. Code 130.101. In Illinois, Use Tax is imposed on the privilege of using, in this State, any kind of tangible personal property that is purchased anywhere at retail from a retailer. See 35 ILCS 105/3; 86 Ill. Adm. Code 150.101. These taxes comprise what is commonly known as "sales" tax in Illinois. If the purchases occur in Illinois, the purchasers must pay the Use Tax to the retailer at the time of purchase. If the purchases occur outside Illinois, purchasers must self-assess their Use Tax liability and remit it directly to the Department.

With respect to prescription and nonprescription medicines, drugs, medical appliances, products classified as Class III medical devices by the United States Food and Drug Administration that are used for cancer treatment pursuant to a prescription, as well as any accessories and components related to those devices, modifications to a motor vehicle for the purpose of rendering it usable by a person with a disability, and insulin, blood sugar testing materials, syringes, and needles used by human diabetics, the tax is imposed at the rate of 1%. 35 ILCS 120/2-10. Please see the Department's regulation at 86 Ill. Adm. Code Section 130.311, which is its regulation governing Drugs, Medicines, Medical Appliances, and Grooming and Hygiene Products. Those items that do not qualify for the low rate of tax are taxed at the general merchandise rate of 6.25% plus applicable local taxes.

A medicine or drug is any pill, powder, potion, salve, or other preparation for human use that purports on the label to have medicinal qualities. A written claim on the label that a product is intended to cure or treat disease, illness, injury, or pain, or to mitigate the symptoms of such disease, illness, injury, or pain constitutes a medicinal claim. See Section 130.311 for examples of medicinal claims. Examples of qualifying products include prescription drugs or medicines and nonprescription drugs or medicines such as aspirin or other pain relievers that purport on the label to have medicinal qualities.

The term "nonprescription medicines and drugs" does not include grooming and hygiene products. Grooming and hygiene products include, but are not limited to, soaps and cleaning solutions, shampoo, toothpaste, mouthwash, antiperspirants, and suntan lotions and screens, unless those products are available by prescription only. If an item

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is a nonprescription grooming and hygiene product, it will be taxed at the State 6.25% general merchandise rate regardless of any medicinal claims made on the product's label.

A medical appliance is an item that is used to directly substitute for a malfunctioning part of the human body. Included in the exemption as medical appliances are such items as artificial limbs, dental prostheses and orthodontic braces, crutches and orthopedic braces, wheelchairs, heart pacemakers, and dialysis machines (including the dialyzer). Corrective medical appliances such as hearing aids, eyeglasses and contact lenses qualify for exemption. Moreover, generally, home glucose monitors, test strips and related supplies used to treat human diabetes also qualify for the 1% State rate of tax. See subsection (d) of 86 Ill. Adm. Code 130.311.

I hope this information is helpful. If you require additional information, please visit our website at <https://tax.illinois.gov/> or contact the Department's Taxpayer Information Division at 800-732-8866.

Very truly yours,

Richard S. Wolters
Associate Attorney

RSW:slc