ST 15-0002-PLR 01/12/2015 DRUGS

This letter concerns the low 1% State rate of tax applicable to drugs, medicines and medical appliances. See 86 Ill. Adm. Code 130.311. (This is a PLR.)

January 12, 2015

Dear XXXX:

This letter is in response to your letter dated June 3, 2014 in which you request information, and the supplemental information you provided on September 10, 2014. 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 www.tax.illinois.gov to review regulations, letter rulings and other types of information relevant to your inquiry.

Review of your request disclosed that all the information described in paragraphs 1 through 8 of Section 1200.110 appears to be contained in your request. This Private Letter Ruling will bind the Department only with respect to COMPANY for the issue or issues presented in this ruling, and is subject to the provisions of subsection (e) of Section 1200.110 governing expiration of Private Letter Rulings. Issuance of this ruling is conditioned upon the understanding that neither COMPANY nor a related taxpayer is currently under audit or involved in litigation concerning the issues that are the subject of this ruling request. In your letter you have stated and made inquiry as follows:

> On behalf of our client, COMPANY ("COMPANY"), we respectfully request a private letter ruling pursuant to the provisions of 2 Ill. Adm. Code 1200.110. Attached please find a fully executed power of attorney authorizing ABC to represent COMPANY with respect to this request.
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> In conformity with the requirements of 2 Ill. Adm. Code 1200.110, COMPANY would like to state the following:
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> 1. A complete statement of the facts is set forth below in Section I.

2. There are no contracts, licenses, agreements or instruments pertinent to the request; however, certain documents referenced in the analysis below are cited and included as Exhibits.

3. The request does not pertain to a particular year. COMPANY is merely seeking guidance on a prospective basis.

4. No audit or litigation is pending before the Department of Revenue ("Department") on the issue raised in this ruling request.

5. To the best of COMPANY's and our knowledge as its representative, the Department has not previously ruled on the same or similar issue for COMPANY or any predecessor entity, nor has a previous request been submitted and withdrawn by COMPANY or any representative on the same or similar issue.

6. A statement of authorities and COMPANY's arguments are set forth below in Section III.

7. Authorities contrary to COMPANY's view are cited in Section IV.

8. No specific trade secret information is set forth in this request, although COMPANY does request that its name, address, location, headquarters, signature line and the product name be deleted from any final published ruling or general information letter.

I. Statement of Facts

COMPANY is a healthcare company specializing in the sale and distribution of innovative pharmaceuticals and medical devices. COMPANY supplies its products, including PRODUCT, to physicians, hospitals, clinics and other treatment centers within and outside of Illinois.

The active ingredient in the drug PRODUCT, which has been approved and is regulated by the U.S. Food and Drug Administration ("FDA"), is "bimatoprost ophthalmic solution." The drug was first approved by the FDA in 2001 under the name "NAME" for reduction of elevated intraocular pressure in patients with open angle glaucoma or ocular hypertension. At the December 5, 2008 meeting of the FDA's Dermatologic and Ophthalmic Advisory Committee ("the Committee"), bimatoprost ophthalmic solution, to be marketed under the trade name of PRODUCT, was unanimously approved as a prostaglandin analog for the treatment of "hypotrichosis" of the eyelashes. Hypotrichosis is defined

as a medical condition evidenced by less than a normal amount of hair on the head or body.[1]

Human hair, regardless of where it is located on the body, has three cycles. It has an anagen, or growth phase; a catagen, or transitional phase; and then a telogen, or arresting phase. In the eyelashes the anagen phase is about one to two months and the telogen phase is about four months. Bimatoprost is a prostamide that is a synthetic structural prostaglandin analogue. It is a lipid compound derived from fatty acids designed to bind to prostaglandin (PG) receptors. PG receptors are present in hair, particularly in the dermal papilla and outer root sheath. Although the precise mechanism of action is unknown, PG receptors are thought to be involved in the development and regrowth of the hair follicle. Bimatoprost increases the length of the anagen phase and also increases the proportion of hairs that are in the anagen phase by converting telogen hairs into anagen hairs. Bimatoprost also increases the size of the dermal papilla (hair bulb), so the new hairs grow thicker, and stimulates pigment cells in the skin and hair follicles (melanogenesis) so the hairs grow darker.

It should be noted that in order to obtain approval for PRODUCT, COMPANY was required to submit extensive data from clinical studies and undergo a rigorous review by the Committee. The Committee meeting minutes, attached hereto as Exhibit A, reflect the following statement:

> 'The committee discussed new drug application (NDA) 22-308, besifloxacin ophthalmic suspension, Bausch & Lomb, Inc., proposed for the treatment of bacterial conjunctivitis and NDA 22-369, bimatoprost ophthalmic solution, 0.03%, COMPANY, Inc., <u>proposed for the treatment of hypotrichosis of the eyelids</u>"[2]

The Committee voted 9 to 0 to approve PRODUCT for use in treating hypotrichosis in response to the question posed of "[d]o you think the benefits outweigh the risks for PRODUCT (bimatoprost ophthalmic solution) 0.03% for the treatment of hypotrichosis of the eyelashes?"[3] Additionally, the Committee recommended by a vote of 5 to 3 that Phase IV human trials be conducted to evaluate the effects of PRODUCT on pediatric and adolescent patients to determine the potential for iris pigmentary changes and any follicular changes over years of usage, the effects on patients with autoimmune disease or undergoing chemotherapy, the

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[1] *The American Heritage® Stedman's Medical Dictionary*. Retrieved March 30, 2014, from Dictionary.com website: http://dictionary.reference.com/browse/hypotrichosis.

[2] Summary Minutes of the Food & Drug Administration Dermatologic and Ophthalmic Drugs Advisory Committee Meeting (December 5, 2008).

[3] *Id.*

effects on patients of various ethnicities, and the effects of application of the drug to the lower eyelash area. The Committee also recommended certain labeling content, including statements that continued use is necessary, defining ocular pigmentation in layman terms, providing information on side effects and drug interactions, identifying under what conditions an ophthalmologist should be consulted and that language should be included to indicate that NAME has been tested in children although PRODUCT to date has not been tested.[4]

It is instructive to note that despite the FDA's separate labeling nomenclature for bimatoprost ophthalmic solution for approved use in treating the medical condition of glaucoma in the case of NAME and hypotrichosis in the case of "PRODUCT", the two drugs are the same formulation, but administered to patients in different ways to treat each medical condition. Whereas NAME is approved by the FDA for administration directly into the eye through eye drops in order to reduce elevated intraocular pressure, PRODUCT is approved as a topical ophthalmic solution for external application to the upper eyelid margin through the use of a sterile, single-use-per-eye disposable applicator.

Both NAME and PRODUCT are the same prescription drug regulated by the FDA, both are indicated for the therapeutic treatment of specific medical conditions established by the FDA, and neither of them can be dispensed or administered except by prescription of a licensed physician.

II. Ruling Requested

COMPANY requests a ruling that sales of PRODUCT, a prescription-only drug marketed by COMPANY and sold to Illinois physicians and clinics, are subject to tax at the reduced state rate of 1% described in 35 ILCS 105/3-10, 110/3-10, 115/3-10 and 120/2-10, and 86 III. Adm. Code 130.31(a)-(b)(1)[sic] because PRODUCT is considered a medicine or drug under Illinois law.

III. Law and Analysis

Pursuant to 86 III. Adm. Code 130.311, with the exception of grooming and hygiene products, a medicine or drug" is defined as "any pill, powder, potion, salve or other preparation for human use that purports on the label to have medicinal qualities." Additionally, 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 a disease, illness, injury or pain constitutes a medical claim.[5]

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[4] *Id.*

[5] 86 Ill. Adm. Code 130.311(b).

In the “Highlighting Prescribing Information" document attached hereto as Exhibit B, under “Indications and Usage” the following statement is made:

> "PRODUCT is a prostaglandin analog, indicated to treat hypotrichosis of the eyelashes by increasing their growth including length, thickness and darkness."

Clearly, this statement indicates that PRODUCT is used in the treatment of the defined medical condition hypotrichosis. A similar statement is contained on the product label itself, attached hereto as Exhibit C, as follows:

> "PRODUCT solution is a prescription treatment for hypotrichosis used to grow eyelashes, making them longer, thicker and darker. Hypotrichosis is another name for having inadequate or not enough eyelashes."

Based upon the statements above included with the product label and detailed prescribing information, it is COMPANY's contention that a requisite medicinal claim is being made for PRODUCT, as a prescription-only drug, such that it should qualify for the reduced 1% state tax rate.

The Department has previously had occasion to construe the medicine or drug reduced rate with respect to the prescription drug Botox® and its various uses in ST 11-0005-PLR (April 5, 2011). In this ruling, the Department held that the drug's use in improving the appearance of moderate to severe glabellar lines associated with procerus and corrugator muscle activity constituted "treatment" of a "medical condition." COMPANY contends that PRODUCT should be accorded similar treatment based on the medicinal claim contained in its product labeling and prescribing information. Hypotrichosis is a recognized medical condition and PRODUCT's labeling clearly indicates its use in the treatment of such condition. Further, PRODUCT is the same formulation as the drug NAME, which has previously been approved for use in the treatment of the medical condition of glaucoma.

IV. Authority Contrary to the Company's Position

COMPANY is not aware of any Illinois authority that addresses the tax treatment of products approved by the FDA that contain bimatoprost ophthalmic solution and that are indicated for uses similar to the uses for which PRODUCT is indicated. Nevertheless, COMPANY notes the following administrative guidance issued by the Department that discuss the treatment of certain substances used for the treatment of facial lines and wrinkles.

The Department previously issued administration guidance in the form of General Information Letter (“GIL”) ST-09-0144-GIL (October 30, 2009), in which it considered the tax treatment of a "tissue filler implant" injected under a patient's skin by a physician or nurse under the supervision of a physician. The substance was described as repairing "defects in soft tissue of the body by initially replacing lost tissue volume and then stimulating the production of new, long-term natural collagen by the body." The substance at issue in this GIL was "most commonly used by doctors in the U.S. for the treatment of moderate to severe facial wrinkles and folds." The Department did not reach a specific determination on the substance in question, but noted under prior 86 Ill. Adm. Code 130.310 (i.e., predecessor to current 86 Ill. Adm. Code 130.311), that "in determining whether a medicine or drug qualifies for the low rate, the Department looks at whether it has medicinal qualities."

However, there was no indication in the GIL that the substance in question contained a medicinal claim on its label as is the case with PRODUCT, rendering the product eligible for the reduced 1% tax rate. Accordingly, the Department's analysis and conclusions in ST-09-0144-GIL did not address the specific questions at issue in this ruling request.

The Department also issued a prior GIL, ST-02-0075-GIL (April 1, 2002), in which the tax treatment of collagen injections by a dermatologist was examined. In this GIL, no conclusion was reached as to whether or not the substance in question was a drug or medicine, although the statement was made that "if the collagen injections were intended by the manufacturer for human use and are purported to have medicinal qualities, they may qualify for the reduced rate of tax at 1%."

While ST-02-0075-GIL restates the applicable rule regarding the fact that products with medicinal qualities will qualify for the low rate of tax, it does not specifically address the application of that rule under facts similar to those provided in this request.

Based on the foregoing analysis, COMPANY contends that sales of PRODUCT in Illinois should be taxed at the reduced 1% state rate, plus any applicable local taxes.

Thank you for your consideration of our request for a private letter ruling and please let us know if you have questions regarding this correspondence or need additional information in order to evaluate this request.

DEPARTMENT’S RESPONSE:

The Department's regulation at 86 Ill. Adm. Code Section 130.311 governs Drugs, Medicines, Medical Appliances and Grooming and Hygiene Products. Those products that qualify as drugs, medicines and medical appliances are taxed at a lower State rate of 1% plus any applicable local taxes. 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.

Simply because a product is sold by "prescription only" does not mean that the product automatically qualifies for the low rate of tax as a medicine or drug. A medicine or drug is defined as 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.

Based upon the representations made in your letter and the additional information provided, we believe that PRODUCT qualifies as a medicine or drug and is eligible for the low State tax rate of 1% plus any applicable local taxes. The label states that "PRODUCT solution is a prescription treatment for hypotrichosis…." This meets the test under the rule that PRODUCT is intended for treatment. In addition, the supplemental information you provided from the National Institute of Health confirms that hypotrichosis is a disease. As a result, PRODUCT's label meets the medicinal claim requirements of the rule.

The factual representations upon which this ruling is based are subject to review by the Department during the course of any audit, investigation, or hearing and this ruling shall bind the Department only if the factual representations recited in this ruling are correct and complete. This Private Letter Ruling is revoked and will cease to bind the Department 10 years after the date of this letter under the provisions of 2 Ill. Adm. Code 1200.110(e) or earlier if there is a pertinent change in statutory law, case law, rules or in the factual representations recited in this ruling.

I hope this information is helpful. If you have further questions concerning this Private Letter Ruling, you may contact me at (217) 782-2844. If you have further questions related to the Illinois sales tax laws, please visit our website at www.tax.illinois.gov or contact the Department's Taxpayer Information Division at (217) 782-3336.

Very truly yours,

Richard S. Wolters
Chairman, Private Letter Ruling Committee

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