

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.)

April 15, 2011

Dear Xxxxx:

This letter is in response to your letter dated January 13, 2011, in which you requested a Private Letter Ruling. 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 dated January 13, 2011, you have stated and made inquiry as follows:

Our client respectfully requests a Private Letter Ruling in accordance with Title 02, Part 1200, Section 1200.110 of the Illinois Department of Revenue Regulations. We have previously submitted to you a Power of Attorney authorizing us to represent the Company.

I. Requirements of Regulation 1200.110(b)

The following information is provided in accordance with the requirements of Regulation 1200.110(b).

1. A complete statement of the facts is set forth below in Section II.
2. There are no Contracts, Licenses, Agreements and Instruments Relevant to the Request.

3. No audit or litigation is pending with the Department on the issue raised in this ruling request. The request does not pertain to a particular year. The Company is merely seeing guidance on a going forward basis.
4. Statement regarding taxpayer and representative representation is set forth at the conclusion of this ruling request.
5. Statement of authorities and Company's arguments are set forth below in Sections IV and VI.
6. Authorities contrary to the Company's view are cited in Section V.
7. No specific trade secret information is set forth in this request although the 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.
8. Power of attorney form is attached. Signatures contained at the end of this ruling request.

II. Facts

The Company is headquartered in CITY/STATE, and is engaged in the sale of medical products for dermatological and other uses. One of the Company's products is sold under the trade name PRODUCT. PRODUCT contains botulinum toxin and is used to treat facial wrinkles and folds and other medical conditions. As set forth on its product label, PRODUCT is indicated for (i) 'the treatment of adults with cervical dystonia to reduce the severity of abnormal head position and neck pain in both toxin-naïve and previously treated patients,' and (ii) 'the temporary improvement in the appearance of moderate to severe glabellar lines associated with procerus and corrugator muscle activity in adult patients.' See Exhibit A, PRODUCT's product label. See also Exhibit B, page 1, PRODUCT's approval letter from the Department of Health & Human Services Division of the Food and Drug Administration ('FDA').

III. Ruling Requested

The Company hereby requests a ruling that sales of PRODUCT by distributors to Illinois physicians, are subject to tax at the reduced rate of 1% described in 35 Illinois Compiled Statutes ('ILCS') Section 105/3-10, 110/3-10, 115/3-10 and 120/2-10, and Regulation 130.31(a)-(b)(1), [sic] because PRODUCT is considered a medicine or drug under Illinois law.

IV. Law and Analysis

Medicine or Drug. Except for grooming and hygiene products, 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 a disease, illness, injury or pain, constitutes a medicinal claim.' See Title 86, Regulation 130.311(b). This regulation further provides a non-exclusive list of examples of product label language that would satisfy the 'medicinal claim' standard necessary to obtain the

reduced tax rate. For instance, Regulation 130.311 provides that a medicinal claim includes a representation on a product label that the substance ‘heals (a medical condition),’ ‘cures (a medical condition),’ is provided ‘for relief (of a medical condition),’ or ‘stops pain.’ See Regulation 130.311(b)(1)(B)-(D) and (F).

As mentioned in Section II above and as set forth on the product label, PRODUCT is indicated for ‘the treatment of adults with cervical dystonia to reduce the severity of abnormal head position and neck pain.’ Moreover, PRODUCT may be prescribed for the ‘temporary improvement in the appearance of moderate to severe glabellar lines associated with procerus and corrugator muscle activity in adult patients.’ See Exhibit A, page 1. The FDA has referred to such glabellar lines (i.e., ‘moderate to severe frown lines between the eyebrows’) as constituting a ‘medical condition.’ See Exhibit C, page 1, FDA Talk Paper, April 15, 2002, issued by the FDA in conjunction with its approval of Botox, a medicine or drug containing botulinum toxin like PRODUCT and used for purposes similar to the purposes for which PRODUCT is used.¹ Since the FDA has concluded that facial lines and wrinkles constitute a ‘medical condition,’ PRODUCT which provides ‘temporary improvement’ for this medical condition should be considered to provide ‘relief (of a medical condition)’ within the meaning of Regulation 310.311(b)(1)(D). [sic]

Accordingly, under either one of its indicated uses, PRODUCT qualifies for the reduced rate of tax under Regulation 130.311(d). That is, when PRODUCT is used to treat cervical dystonia (i.e., the first indication on the product label, see Exhibit A), the medicinal claim on the label is that such use reduces ‘the severity of abnormal head position and neck pain.’ Thus, the use of PRODUCT to treat cervical dystonia is undertaken in conjunction with a medicinal claim on the label that is similar to the safe harbor example of Regulation 130.311(b)(1)(F) that the substance ‘stops pain.’ Similarly, when PRODUCT is used to treat glabellar lines, a medical condition according to the FDA (i.e., the second indication on the product label, see Exhibit A), such use is undertaken in conjunction with a medicinal claim on the label that is similar to the safe harbor example of Regulation 130.311(b)(1)(D) that the substance is provided ‘for relief (of a medical condition).’ Moreover, the FDA specifically refers to PRODUCT as a ‘drug.’ See PRODUCT’s Approval Letter, Exhibit B, page 2, where the FDA notes that ‘we have determined that a REMS is necessary for PRODUCT (abobotulinumtoxinA) to ensure that the benefits of the drug outweigh the risk of distant spread of botulinum toxin after local injection.’

V. Authority Contrary to the Company’s Position

The Company is not aware of any Illinois authority that addresses the tax treatment of products approved by the FDA that contain botulinum toxin and that are indicated for uses similar to the uses for which PRODUCT is indicated. Nevertheless, the Company notes the following rulings issued by the Department that discuss the treatment of certain substances used for the treatment of facial lines and wrinkles.

A. ST-09-0144-GIL (October 30, 2009). This ruling addresses the treatment of a ‘tissue filler implant’ that is injected under a patient’s skin by a ‘physician or nurse under the supervision of a physician.’ The substance is 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 ST-09-0144-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

conclusion on the substance in question in ST-09-0144-GIL, but noted under prior Regulation 130.310 (i.e., predecessor to current Regulation 130.311), that ‘in determining whether a medicine or drug qualifies for the low rate, the Department looks at whether it has medicinal qualities.’

There is no indication, however, in ST-09-0144-GIL that the substance in question contained a medicinal claim on its label as is the case with PRODUCT and as authorized by Regulation 130.311(b)(1) as qualifying for the reduced rate of tax. Accordingly, the Department’s analysis and conclusions in ST-09-0144-GIL did not address the specific questions at issue in this ruling request.

B. ST-02-0075-GIL (April 1, 2002). This ruling is cited in ST-09-0144-GIL and examines the potential classification of collagen injections by a dermatologist. Letter ST-02-0075-GIL, however, fails to conclude whether or not the substance in question was a drug or medicine, although as stated in ST-09-0144-GIL regarding ST-02-0075-GIL, ‘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%.’

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

VI. Botox is Considered to Treat a Medical Condition by the FDA and Other States

As discussed in Section IV above, the FDA has concluded that glabellar lines constitute a ‘medical condition.’ See Exhibit C. The Californian State Board of Equalization (‘the Board’) reached the same conclusion in revisions made to its sales and use tax regulations in 2006 when discussing Botox. See page 1, Exhibit E, August 31, 2006, memorandum (the ‘2006 Memorandum’) from the Chief of the Board’s Tax Policy Division to local District Administrators and District Principal Auditors, noting that the Board’s audit ‘staff can assume that doctors only give patients injections of Botox® and Botox® Cosmetic when they are treating a medical condition. Accordingly, these products should be considered medicines.’ The conclusion by the Board’s Tax Policy Division Chief that Botox treats a ‘medical condition’ is consistent with the FDA’s determination that glabellar lines constitute a ‘medical condition.’ See Exhibit C. As discussed in Section IV above and illustrated at Exhibit D, licensed physicians have referred to PRODUCT as ‘Botox’s twin or first cousin.’ Therefore, the same conclusion regarding treatment of a medical condition should apply to PRODUCT which like Botox, contains botulinum toxin and like Botox, treats the medical condition of glabellar lines.

Based on the foregoing, PRODUCT should be taxed at Illinois’ reduced rate. Please let us know if you have questions regarding this correspondence or need additional information in order to analyze this ruling request. Thank you.

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To the best of our knowledge, the Department has not previously ruled on the same or similar issue for which a ruling is requested in this letter, for the Company or a predecessor. In addition, to the best of our knowledge, neither the Company nor a

representative has previously submitted the same or similar issue to the Department in a ruling request that was withdrawn before the letter ruling was issued.

DEPARTMENT'S RULING:

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, 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. While PRODUCT may be obtained only by prescription, as pointed out above, that is not the test. Rather, the label for a "pill, powder, potion, salve, or other preparation for human use" must purport to have medicinal qualities. The label for PRODUCT purports to make such a claim.

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 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,

Terry D. Charlton
Chairman, Private Letter Ruling Committee

TDC/DB:msk

¹ Most licensed physician sellers of PRODUCT and Botox note little differences between the two. See attached Exhibit D, website page of the GUIDE, where DR. a board certified plastic surgeon engaged in private practice in CITY, notes that 'PRODUCT is so similar to Botox that is referred to as Botox's twin or first cousin.' We can provide the Department with opinions of other medical professionals to the same effect if requested.