ST 11-0003-PLR 02/28/2011 MEDICAL APPLIANCES

A medical appliance is defined as an item which is intended by its manufacturer for use in directly substituting for a malfunctioning part of the body. (This is a PLR) See 86 Ill. Adm. Code 130.311.

February 28, 2011

Dear Xxxxx:

This letter is in response to your letters dated September 9, 2010 and December 23, 2010, 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 September 9, 2010, 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. Attached hereto is a Power of Attorney authorizing us to represent the Company in this matter.

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 seeking 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 Section IV.

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 purposes. The Company and its competitors offer a line of products (the 'Products') whose primary component is hyaluronic acid. The Products, which include brand names such as NAMES, are used by patients to smooth wrinkles and improve facial features and are injected into patients under the skin in gel form. See for instance the label of NAME, a Product sold by the Company, which provides that NAME is indicated '**for the correction of moderate to severe facial wrinkles and folds**.' The hyaluronic acid concentration among Products is similar and the Products have been approved for use by the United States Food and Drug Administration as a Class III Medical Device. In addition, Products can only be used pursuant to a prescription issued by a licensed physician. For instance, the label of NAME provides the following warning: **Caution: Federal Law restricts this device to sale by or on the order of a physician or properly licensed practitioner.**'

The Products' biological and chemical properties, impact on the body and side effects have been documented by dozens of physicians who prescribe the Products for use to patients. A typical analysis is set forth on the XYZ website at XYZ.com.[i] XYZ characterizes NAME as 'a gel of hyaluronic acid produced by bacteria and used for treating facial wrinkles and folds. Hyaluronic acid is a substance that is normally produced by the body. Hyaluronic acid is what gives skin its volume and fullness. . .When NAME is injected into wrinkled skin it adds fullness and reduces the prominence of the wrinkles in the previously wrinkled area.' Another Product is described by physicians in similar fashion as a 'gel implant that includes hyaluronic acid, a natural complex sugar that bolsters the skin elasticity. . .It is biocompatible, supplementing the body's natural hyaluronic acid, which age has depleted.[ii] As explained by yet another physician regarding NAME, 'as you grow older, the amount of hyaluronic acid diminishes, and your skin can cave, causing a wrinkle along the line.' NAME 'is injected into the skin to replace hyaluronic acid that has dissipated over time.'[iii] The Company confirms that the Product descriptions set forth in Exhibits A, B and C are accurate

depictions of (i) the body's natural loss of hyaluronic acid, (ii) the impact of such loss in causing skin wrinkles and (iii) the Products' replenishment of the lost hyaluronic acid which results in skin restoration and reduction or elimination of wrinkles that were initially caused by the body's loss of hyaluronic acid.

III. Ruling Requested

The Company hereby requests a ruling that Product sales 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 130.310(e)(1), because the Products' hyaluronic acid component causes Products to be considered a 'medical appliance' as that term is defined in Regulation 130.310(e)(2). Alternatively, Product sales by distributors to Illinois physicians should be subject to the reduced tax rate of 1% because a Product constitutes a 'medicine or drug' pursuant to Regulation 130.310(e)(1).

IV. Law and Analysis

A. Medical Appliance. The sale of a medical appliance qualifies for the reduced tax rate in Illinois. A 'medical appliance is an item that is intended by its manufacturer for use in directly substituting for a malfunctioning part of the human body.' See Regulation 130.310(e)(2). As described in Section II above, Products are designed 'to replace [the body's] hyaluronic acid that has dissipated over time' by 'supplementing the body's natural hyaluronic acid, which age has depleted.' The hyaluronic acid that is lost naturally by the body can cause a person's 'skin [to] cave, causing a wrinkle along the line.' Accordingly, the body's naturally produced hyaluronic acid, when not depleted, acts to prevent the formation of wrinkles. The Products restore the hyaluronic acid that has been lost and thereby function to reduce or eliminate wrinkles in the same manner as natural hyaluronic acid acts in a person who has not suffered a depletion. Accordingly, the Products are intended to and do in fact provide substitute hyaluronic acid for the body's malfunctioning (i.e., depleted) hyaluronic acid. As a result, the Products should be treated as medical appliances under the plain meaning of Illinois law.

B. Medicine or Drug. 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 130.310(e)(1). The regulation contains certain safe harbor language which, if found on a product label, satisfies the label requirements for a reduced tax rate on the sale of drugs and medicines. Accordingly, the Illinois regulations indicate that a medicinal claim includes a representation on a product label that the substance 'cures (a medical condition),' 'stops pain' or is provided 'for relief (of a medical condition).' See Regulation 130.310(e)(1)(A)(iii), (iv) and (vi).

The label of one of the Products, NAME, is representative of the type of language found on Product labels. NAME's label provides that the 'safety or effectiveness of NAME for the treatment of anatomic regions other than naso-labial folds has not been established in controlled clinical studies.' NAME's labeling also provides that NAME is used 'for the correction of moderate to severe facial wrinkles and folds.' Finally, further evidence that NAME is a medicine or drug is provided by warning labels for NAME's misuse. See the

warning on NAME's label providing that 'localized superficial necrosis may occur after injection in the glabellar area. It is thought to result from the injury, obstruction, or compromise of blood vessels.' Given the foregoing, a Product should be treated as a drug or medicine under Illinois law.

V. Authority Contrary to the Company's Position

A. Medical Appliance. ST-09-0144-GIL (October 30, 2009), 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 observed that 'medical appliances used for cosmetic purposes do not qualify for the new low rate of tax. For example, implants that are used for cosmetic reasons *and are not used to substitute for a malfunctioning part of the body* do not qualify for the low rate of tax.' The Department did not reach a specific conclusion on the substance in question in ST-09-0144-GIL, but noted that 'the tax rate applicable to those items will depend on how they are used (replacing a malfunction of part of the body or for cosmetic purposes).'

The facts upon which the conclusion in ST-09-0144-GIL is based, are distinguishable from facts regarding the composition of Products. In ST-09-0144-GIL, the substance in question had the effect of 'stimulating the production of new, long-term natural collagen by the body.' The hyaluronic acid contained in Products does not 'stimulate' the production of any substance by the body, but instead 'replace[s] hyaluronic acid that has dissipated over time' which 'age has depleted.' Second, it is important to note that ST-09-0144-GIL reinforces the conclusion under Illinois law that products that 'substitute for a malfunctioning part of the body,' are subject to tax at the reduced rate. Clearly, hyaluronic acid substitutes for a malfunctioning part of the body in that it replaces hyaluronic acid (i.e., a natural body substance) that has been lost over time. ST-09-0144-GIL treats the category of substances that *may* have a cosmetic function and those that replace a specific malfunctioning part of the body, as being mutually exclusive. Such is simply not the case with respect to the Products. Since the Products are used in 'directly substituting for a malfunctioning part of the human body,' the Products should be treated as a medical device under the specific language of Regulation 130.310(e)(2) and therefore should be subject to the reduced tax rate as a medical appliance. There is nothing inconsistent with such a conclusion and the observations of the Department in ST-09-0144-GIL.

B. Medicine or Drug. ST-02-0075-GIL (April 1, 2002), which is cited in ST-09-0144-GIL, examines the potential classification of collagen injections by a dermatologist. That letter fails to conclude whether or not the substance is a drug or medicine. 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%.' In this case for the reasons explained above in Section IV.B, the Products satisfy Illinois' standard of a medicine or drug.

Please let us know if you need additional information in order to analyze this ruling request. Thank you.

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.

Your letter dated December 23, 2010, states as follows:

This letter is provided as a supplement (the 'Supplement') to the Ruling Request originally filed on September 9, 2010. This Supplement provides additional information to assist the Department in its review of the Ruling Request. The Company hereby identifies NAME and NAME2 as the products that are the subject of the Ruling Request. (Please note, NAME and NAME2 contain the same substance and properties and are used for similar purposes. The only difference is that NAME2 is more concentrated. Therefore doses of NAME2 are stronger than equivalent doses of NAME.) Attached as Exhibits 1A and 1B are the product approval letters for both NAME and NAME2. These letters were issued by the Department of Health & Human Services Division of the Food and Drug Administration ('FDA') and provide that the use of NAME and NAME2 'are restricted to prescription use in accordance with...the Federal Food, Drug, and Cosmetic Act.' The product labels for NAME and NAME2 are also provided at Exhibits 2A and 2B. The warning on these labels provides '**Caution:** Federal Law restricts this device to sale by or on the order of a physician or licensed practitioner.' Accordingly, neither NAME nor NAME2 can be lawfully used except upon the order of a physician or licensed practitioner.

The additional information provided in this Supplement is intended to establish that NAME and NAME2 qualify for the reduced Illinois Retailer's [sic] Occupation Tax rate of 1% imposed on the sale of medical appliances.

I. Sale of Medical Appliances Taxed at Reduced Rate in Illinois

A. Medical Appliance Defined; Cosmetic Procedures Limited to Cases Where Proper Function of the Body **is Not Promoted**. 'A medical appliance is an item that is used to directly substitute for a malfunctioning part of the human body.' Title 86, Regulation 130.311(d). The Ruling Request explained in detail how the hyaluronic acid in NAME and NAME2 substitutes for the body's depleted hyaluronic acid. Regulation 130.311(d)(4) excludes from medical appliances, 'items transferred incident to cosmetic procedures.' Regulation 130.311(d)(4) further provides that a 'cosmetic procedure means any procedure performed on an individual that is directed at improving the individuals [sic] appearance and that **does not** (i) prevent or treat illness or disease, (ii) promote the proper function of the body, ***or*** (iii) substitute for any part of the body that is lost or diminished because of congenital defects, trauma, infection, tumors or disease.' Accordingly, substances that substitute for a malfunctioning part of the human body and that also treat illness or disease, *or* promote the property function of the body *or* substitute for a part of the body damaged by trauma, infection, tumors or disease, qualify as medical appliances.

We have attached below a number of excerpts from doctor [sic], dermatologists and health spa websites (i.e., the 'Licensed Practitioner Sellers') that advertise, sell and administer NAME and NAME2 and that describe the conditions that create facial wrinkles for which the use of NAME and NAME2 is recommended. These sources make it quite clear that the use of NAME cannot be considered a 'cosmetic procedure'

under Illinois law since NAME **is used** to treat the symptoms of disease, promote the proper function of the body and substitute for parts of the body lost due to trauma, infection and disease. These advertisements and promotions go beyond describing what NAME and NAME2 are used for (i.e., the treatment of facial wrinkles and folds) and instead identify many of the contributing factors that create the medical condition of skin wrinkles and folds in the first place. These causes and conditions have a common thread. They deplete the body's hyaluronic acid, thereby causing the wrinkles and folds that are alleviated or diminished by the restoration of hyaluronic acid through the use of NAME and NAME2.

B. NAME and NAME2 Substitute for a Malfunctioning Part of the Body and Promote the Proper Function of the Body. As explained in the Ruling Request, the primary ingredient in NAME and NAME2 is hyaluronic acid, a substance found naturally in the body whose depletion contributes to the formation of wrinkles and folds. See page 1 of Exhibits 2A and 2B, product labels for NAME and NAME2 providing that the products constitute a sterile 'gel of hyaluronic acid.' By restoring the body's depleted hyaluronic acid, NAME and NAME2 promote the proper function of the body. See the attached advertisements from Licensed Practitioner Sellers, providing that 'NAME works together with the body's own hyaluronic acid to create volume,' and that NAME functions to remedy inefficiencies in the body's own hyaluronic acid by 'replenishing the natural hyaluronic acid in the skin,' and thereby improving 'hydro balance to increase skin elasticity and improve skin structure.' See attached Exhibits A and B.

#1's website provides that 'NAME consists of hyaluronic acid, which is a natural substance already present in the skin. Once in the skin, the 'hyaluronic acid in NAME works together with the body's own hyaluronic acid to create volume.' See Exhibit A, page 2. 'NAME is almost identical to that naturally found in the body and only very slightly modified (0.5 – 1%). Other hyaluronic acid based, injectable implants are often modified by about 20%.' 'NAME...provides volume where the concentration of the bodies [sic] own hyaluronic acid has decreased.' See Exhibit A, page 1. 'Some of the functions of hyaluronic acid in the body are to create increased skin thickness and volume, to give the eye its shape and to lubricate joints.' See Exhibit A, page 2.

#2's website provides that 'lifestyle factors, such as exposure to sun, smoking and drinking' serve to degrade the skin and cause the 'distribution and function of the body's own hyaluronic acid [to be] less efficient.' NAME then acts on these inefficiencies by 'replenishing the natural hyaluronic acid in the skin,' and thereby improving 'hydro balance to increase skin elasticity and improve skin structure.' See Exhibit B, page 3.

Summary. If Licensed Practitioner Sellers have determined that 'NAME works together with the body's own hyaluronic acid to create volume,' and acts to remedy distribution and function inefficiencies in the body's own hyaluronic acid by 'replenishing the natural hyaluronic acid in the skin,' the use of NAME cannot constitute a cosmetic procedure under Illinois law. This is because Regulation 130.311(d)(4) provides that a cosmetic procedure does not occur when the use of an item 'promote[s] the proper function of the body' as NAME clearly does according to Licensed Practitioner Sellers. Accordingly, NAME and NAME2 should qualify for the reduced rate of tax as medical appliances since their use to replenish the body's lost hyaluronic acid, promotes the proper function of the body.

C. NAME and NAME2 Substitute for a Malfunctioning Part of the Body That is Lost as the Result of Congenital Defects, Trauma, Infection, Tumors or Disease. As further

described below, Licensed Practitioner Sellers and other physicians and health care industry writers, have observed and described the contributory impact of certain activities such as smoking, alcohol abuse and environmental factors on the body's loss of hyaluronic acid, thereby leading to the formation of facial wrinkles and folds. Accordingly, it is reasonable to infer that patients purchase NAME and NAME2 as a remedy for facial wrinkles and folds caused by damage from smoking, alcohol abuse and exposure to sun, since as illustrated below, these causes are heavily emphasized by Licensed Practitioner Sellers in their promotion of NAME and NAME2. Substances like NAME and NAME2 that are used by patients to remedy these conditions are therefore not used for a 'cosmetic procedure' under Illinois law as further explained below.

#3. In this article, the author observes that 'Cigarette smoke is second only to sun exposure as the leading cause of skin damage. Smoking interferes with the absorption of vitamin C and A, both of which provide skin protection. Nicotine is a diuretic, promoting dehydration. Smoking also promotes collagen deterioration and often cuts off the blood flow from the surface of the skin, which gives it a dry, pale appearance. In addition, the mechanical actions of smoking (pursing your lips and squinting to keep out smoke) create lines around the mouth and eyes over time.' The article goes on to recommend 'NAME injections' for 'more severe wrinkles' See Exhibit C, page 1.

#4. As mentioned in Section I.B above, #2's website provides that 'lifestyle factors, such as exposure to sun, smoking and drinking' serve to degrade the skin and cause the 'distribution and function of the body's own hyaluronic acid [to be] less efficient.' NAME then acts on these inefficiencies by 'replenishing the natural hyaluronic acid in the skin,' and thereby improving 'hydro balance to increase skinny elasticity and improve skin structure.' See Exhibit B, page 3.

#5's website provides that the 'genetic effects of aging are now known to begin for most people around 60 years of age. Any aging that occurs before that magic number is the result of your environment and lifestyle choices...the toxins we take in also have long-term effects on your skin. Smoking and, to a lesser extent, air pollution also contributes to internal inflammation, just like a sunburn. It is the toxins [that] smoke delivers that causes the most damage, not the ash in the smoke itself.' See Exhibit F, page 2. #5 recommends NAME2 for the wrinkles caused by these factors, noting that NAME2 'is composed of hyaluronic acid, a natural substance that already exists in the body,' and that NAME2 is 'used to smooth moderate to severe facial folds and wrinkles.' See Exhibit F, page 2.

#6's website confirms that a number of factors 'accelerate facial aging.' These factors include 'genetic predisposition, sun damage, cigarette smoking, acne, chicken pox and other medical conditions.' See Exhibit D, page 1. The treatments offered by #6 for these conditions include NAME which according to #6's website acts to 'correct facial wrinkles and folds...[as] the hyaluronic acid in NAME is biodegradable and is compatible with human hyaluronic acid. See Exhibit D, page 2.

#7. This website is consistent with that of other sources cited above by noting that 'poor hydration, sun damage, human genetics, cosmetics and smoking contribute to the appearance of wrinkles and lines on the face.' #7 further notes that the 'wrinkle marks around the mouth are caused by deep sucking movements of facial muscles often associated with cigarette smoking or over-use of a straw.' See Exhibit E, page 1. The website further refers to NAME as 'the finest lip enhancement and skin filler in the

world.' Finally, #7 observes that the treatments of NAME can decrease over time 'as scar tissue below abnormalities breaks up and the body deposits natural resources after each procedure, healing and often restoring the surface to its natural contour.' See Exhibit E, page 2. This healing component of NAME due to the body's deposit of natural resources that break up scar tissue after NAME treatments, arguably constitutes the treatment of illness or disease within the meaning of Regulation 130.311(d)(4).

#8. As indicated above by the various Licensed Practitioner Sellers recommending the use of NAME and NAME2, there can be no doubt that facial wrinkles in many cases are caused by cigarette smoking, sun exposure and other medical conditions. Moreover, Licensed Practitioner Sellers **specifically market** NAME and NAME2 to customers to treat wrinkles resulting from these causes. The conclusions cited above by Licensed Practitioner Sellers regarding the casual relationship between cigarette smoking and facial wrinkles, are supported by a scientific study that chronicles the degradation of the body's hyaluronic acid caused by cigarette smoke. See attached Exhibit G.

Summary. It is clear that NAME and NAME2 substitute for a malfunctioning part of the body (i.e., hyaluronic acid) that has been lost in many cases due to congenital defects, trauma, infection, tumors or disease. See Exhibit C cited above, #3 article that describes how cigarette smoking 'interferes with the absorption of vitamin C and A, both of which provide skin protection' and that the nicotine in cigarette smoke 'is a diuretic, promoting dehydration.' The article then goes on to recommend NAME for treatment of the skin damage, including folds and wrinkles, caused by smoking. See also Exhibit G the article confirming the trauma and loss of hyaluronic acid caused to the body by cigarette smoking. Although the product labels merely indicate that NAME and NAME2 are approved to treat facial folds and wrinkles, these product labels do not examine the underlying causes of the body's loss of hyaluronic acid that creates the wrinkles and folds. These underlying conditions result from a variety of causes, including medically related causes such as cigarette smoking, excess alcohol ingestion and damage arising from sun exposure.

Treatment of the actual underlying cause of the condition is not a prerequisite for application of the reduced tax rate. See Regulation 130.311(d)(1)(A), providing that the reduced rate of tax applies to 'breast implants that restore breasts after loss due to cancer.' The implant does not treat the cancer, but provides an aesthetic benefit by substituting for a body part lost due to illness, infection, tumors or disease. In the same fashion, NAME and NAME2 are not intended to treat medical conditions that arise from cigarette smoking (e.g., skin cancer, lung cancer or tuberculosis), alcohol abuse (e.g., liver damage) or sun exposure. Instead NAME and NAME2 replace or substitute for the human body part (i.e., hyaluronic acid) that is depleted by these conditions and in the process NAME and NAME2 restore the aesthetic benefit (i.e., like the breast implant) lost due to the resulting formation of skin frowns, lines and wrinkles.

II. Dermal Fillers Are Distinguished From Cosmetic Procedures in Other States

Although not controlling with respect to this Ruling Request, we mention here the fact that California exempts dermal fillers like NAME and NAME2 from taxation because of the very clear factual distinctions between dermal fillers and cosmetics. As a result, the California State Board of Equalization (the 'Board,' California's taxing agency responsible for administering the state's sales and use tax laws), has concluded that dermal fillers like NAME and NAME2 are not subject to tax under 2006 regulation

revisions (the 'New Regulation'). The New Regulation exempts from tax, medicines 'approved by the U.S. Food and Drug Administration to diagnose, cure, mitigate, treat or prevent any disease, illness or medical condition regardless of ultimate use.' An ancillary benefit recognized by the Board at the time the New Regulation was adopted is that the New Regulation will 'provide a bright-line test for audit purposes, which will promote efficiency' and 'will avoid involving our audit staff in activities related to confidential patient records.'

A. California Adopted Regulations in 2006 Exempting Dermal Fillers From Taxation. Prior to 2006, the Board's audit staff treated dermal filler products in a manner similar to the treatment of many states. That is, which products were considered exempt when used for a 'medical reason' and non-exempt when used solely for cosmetic appearance purposes. See page 2, Exhibit H, 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, providing that the audit staff's prior policy was to treat the exemption as appropriate for 'medicines when used to correct scarring, but not when used to correct the appearance of lines and wrinkles from aging.' In 2006, however, the Board adopted the New Regulation which treats as non-taxable, 'any product fully implanted or injected in the human body, or any drug or any biologic, when such are approved by the U.S. Food and Drug Administration to diagnose, cure, mitigate, treat or prevent any disease or medical condition regardless of ultimate use.' See Exhibit H, page 1, currently found at Title 18, California Code of Regulations Section 1591(a)(9).

The 2006 Memorandum also specifically addressed dermal fillers, providing as follows: '**Injected Collagen or other Dermal Implants – Collagen and similar skins fillers are injected under a patient's skin to correct contour deficiencies such as wrinkles, acne scars, and surgical scars. Previously, staff considered these implants to be medicines when used to correct scarring, but not when used to correct the appearance of lines and wrinkles from aging. Under the revised definition of medicines, injected collagen and other dermal implants are considered medicines regardless of their ultimate use...to qualify as a medicine...the collagen must be injected. The application of tax to face masks or creams that contain collagen, but are topically applied, is not affected by the recent revisions,'** (i.e., such face masks and creams remain taxable). See Exhibit H, page 2. The conclusion that the New Regulation operates to exempt dermal fillers from tax was supported in part by the FDA's prior acknowledgement that frown lines constituted 'a medical condition.' See Exhibit I, page 2, October 2005 memorandum prepared by Board staff (the '2005 Memorandum'), recommending adoption of proposed language for the New Regulation. See also Exhibit J, page 1.

B. California's New Regulation Provides the Additional Benefit of Avoiding Auditor Investigation of Confidential Patient Documentation. The recommendation by Board staff for adoption of the New Regulation provided additional benefits to Board field auditors. The 2005 Memorandum concludes that the New Regulation will 'provide a bright-line test for audit purposes, which will promote audit efficiency.' 'Moreover,' observed the Board, 'such an approach will avoid involving our staff in activities related to confidential patient records.' See Exhibit I, page 3.

Summary. California's adoption of taxation rules for medical products is of course not binding on Illinois. Nevertheless, there are some parallels between the New Regulation and the Taxpayer's requested treatment of NAME and NAME2 for Illinois purposes. For

instance, one way that California distinguishes non-taxable items from taxable cosmetics is to require that the substance in question be injected under the skin instead of 'topically applied' as a prerequisite to consideration for beneficial tax treatment. This line of demarcation fits comfortably within existing Illinois rules that identify taxable cosmetics. See Regulation 130.311(c)(2), which refers to among other things, 'shampoos, hair conditioners and hair care products' and 'skin creams, lotions, ointments and conditioners' as taxable grooming and hygiene products. See also old Regulation 130.310(c)(3) identifying 'lipsticks, perfume and hair tonics' as taxable cosmetics. NAME and NAME2 of course, are injected under the skin and can only be prescribed and administered by a licensed physician. By raising the bar to require at a minimum injection under the skin for beneficial tax treatment consideration, California eases the burden on Board auditors and avoids situations where the auditors may become entangled in matters of patient confidentiality by attempting to ascertain the underlying reason behind each patient's use. Such avoidance is particularly important given the fact that widespread use of NAME and NAME2 occurs in response to facial wrinkles and lines caused by smoking, alcohol abuse and excess sun exposure, as is evidenced by the advertising undertaken by Licensed Physician Sellers to patients, as illustrated in Section I above.

Finally, the New Regulation's language describing the requirements for exemption, is similar to one of the three Illinois standards that distinguishes a medical appliance from a cosmetic for purposes of the reduced rate of tax. Regulation 130.311(d)(4) provides that a substance is considered to have been used pursuant to a taxable cosmetic procedure if it among other things, 'does not prevent or treat illness.' The New Regulation adopts a similar standard for exemption and concludes that dermal fillers like NAME and NAME2 satisfy this standard. As mentioned above, that definition provides an exemption for products that are 'approved by the U.S. Food and Drug Administration to diagnose, cure, mitigate, treat or prevent any disease, illness or medical condition regardless of ultimate use.'

III. Conclusion

The reduced Illinois tax rate applies to NAME and NAME2 because as discussed in Section I and as advertised by Licensed Physician Sellers, NAME and NAME2 meet the Illinois standard for the reduced tax rate by substituting for a malfunctioning part of the human body. Moreover, NAME and NAME2 do not fail to qualify for the reduced rate since their application to patients is not a cosmetic procedure under Regulation 130.311(d)(4). Specifically, NAME and NAME2 (i) prevent or treat illness or disease (a conclusion supported by California's New Regulation), (ii) promote the proper function of the body (by replenishing and substituting for the body's lost hyaluronic acid, a fact repeatedly verified by Licensed Physician Sellers in Section I.B above), and (iii) substitute for a body part that is lost or diminished as a result of trauma, infection, tumors or disease (by replacing the body's natural hyaluronic acid that is lost due to such causes as toxic cigarette smoke, excess alcohol ingestion and skin disease due to sun exposure, as described in Section I.C, above). Only one of the three is required for the reduced 1% rate of tax under Regulation 130.311 to apply. The second test, promotion of the proper function of the body, would seem to be satisfied in every case since NAME and NAME2 replace the body's lost hyaluronic acid and perform the bodily functions of that lost hyaluronic acid. Given the foregoing, NAME and NAME2 qualify for Illinois' reduced rate of tax as medical appliances.

Please contact me if you have further questions regarding this Supplement or if you need additional information.

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.

A medical appliance is an item that is intended by its manufacturer for use in directly substituting 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. See Section 130.311 of the Department's regulation.

Based upon the representations made in your letter, we do not believe that NAME and NAME2 replace a malfunctioning part of the body and, as such, do not qualify as medical appliances. Similarly, based upon the representations made in your letter, we do not believe that NAME and NAME2 qualify as a medicine or drug. While both are 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. These products do not purport 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

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[i] XYZ.com's website stats that it 'provides easy-to-read, in-depth, authoritative medical information for consumers' that is 'doctor-approved by a network of more than 70 U.S. board-certified physicians.' See Exhibit A.
[ii] See Guide, attached as Exhibit B.
[iii] See WEBSITE.com. See Exhibit C.