New York State Department of Taxation and Finance
Office of Counsel
Advisory Opinion Unit

TSB-A-13(26)S
Sales Tax
September 9, 2013

STATE OF NEW YORK
COMMISSIONER OF TAXATION AND FINANCE

ADVISORY OPINION PETITION NO. S120416A

The Department of Taxation and Finance received a Petition for Advisory Opinion from Petitioner, [redacted]. Petitioner asks whether its new combination drug-device products, Augment ® Bone Graft (ABG) and Augmatrix™ Bicomposite Bone Graft (ABBG), qualify for the exemptions for products consumed for the preservation of health in Tax Law § 1115(a)(3) or for the prosthetic aid exemption in § 1115(a)(4). We conclude that the products do not qualify as exempt prosthetic aids, but that they do qualify for the preservation of health exemption in § 1115(a)(3).

Facts

Petitioner is a biotechnology company specializing in the development and commercialization of innovative drug-device combination products to promote the healing of musculoskeletal injuries and diseases, including orthopedic, spine and sports injury applications. It asks about the sales tax treatment of two products it has developed.

ABG

ABG is a combination product pending marketing approval by the FDA as a Class III Medical Device. ABG was developed as a fully synthetic replacement to autograft in hindfoot and ankle surgery. ABG consists of two components: recombinant human platelet-derived growth factor (rhPDGF-BB) and beta-tricalcium phosphate (B-TCP). It is supplied as a kit for a single use only. At the point of use, the two primary components are mixed and subsequently applied to the surgical site. The B-TCP component of ABG is a highly porous, resorbable, and osteoconductive scaffold that provides a framework for bone regeneration, aids in preventing soft tissue infiltration, and promotes stabilization of the blood clot. The recombinant human platelet-derived growth factor (rhPDGF-BB), also known as becaplermin, acts by stimulating the recruitment, and proliferation of a variety of cell types. ABG is placed on defects, such as gaps between bones where a surgeon is trying to achieve fusion. It provides a scaffold for natural occurring tissue (bone) regeneration and is gradually resorbed by the body, and turned into bone. The presence of the protein stimulates this naturally occurring biological process. Petitioner will sell ABG to hospitals and surgery clinics in New York for use in hindfoot and ankle surgeries. ABG is not used in cosmetic surgery.

ABBG

ABBG is a sterile, synthetic, non-pyrogenic material intended for use in combination with autologous bone marrow for bone void filling and fracture repair of the pelvis and extremities. It is designed not to cause inflamatory or fever responses. The product material is a

composition of carbonated apatite and bovine type I collagen. Carbonated apatite is a form of calcium phosphate that closely resembles the mineral phase of natural human bone. The granules are interspersed within the collagen, providing an enhanced osteoconductive scaffold to support bone remodeling. The scaffold is highly porous with ample surface area for absorption of bone marrow aspirate ("BMA") and stem cell attachment. The ABBG product family is available in a variety of configurations: pads, strips, blocks, plugs, and paste. Upon saturation with BMA, ABBG may be manipulated as desired. This flexible structure allows the grafts to be shaped based on patient anatomy and surgical environment. Pads, strips, blocks and plugs may be compressed, folded, trimmed or layered. Hydrated paste may be molded. ABBG has been approved by the FDA as a Class II device for prescription use only. Petitioner will sell ABBG to hospitals and surgery centers in the State for use in orthopedic surgery. It is not used in cosmetic surgery.

Analysis

Section 1105(a) of the Tax Law imposes sales tax on retail sales of tangible personal property. The petition inquires about the applicability of one of the exemptions from that tax, § 1115(a)(4). That section exempts prosthetic aids, artificial devices and component parts hereof purchased to correct or alleviate physical incapacity in humans. Under the Sales and Use Tax Regulations, for property to qualify as a prosthetic aid, it must, among other things, either completely or partially replace a missing body part or the function of a permanently inoperative or permanently malfunctioning body part and that is primarily and customarily used for such purposes (*see* 20 NYCRR § 528.5[b][1]). Both ABG and ABBG appear to work by helping to speed the process of bone regeneration after surgery. Thus, they do not become a replacement for a permanently malfunctioning body part, and, accordingly, do not qualify as exempt prosthetic aids (*see* TSB-A-09[48]S).

Section 1115(a)(3) exempts from sales and use tax the following ". . . products consumed by humans for the preservation of health, but not including cosmetics or toilet articles notwithstanding the presence of medicinal ingredients therein." Regulation § 528.4 provides that "[p]roducts consumed by humans for the preservation of health include other substances used internally or externally, which are not ordinarily considered drugs or medicines." Under this explanation of the "preservation of health" exemption, both products at issue here qualify for the exemption because both are used in connection with orthopedic surgery to promote bone regeneration and healing after surgery (*see* TSB-A-12[1]S).

The Department has previously ruled that certain products implanted by medical professionals into a patient in order to facilitate healing and gradually resorbed by the body constitute medical equipment or supplies and thus are taxable when purchased by the medical professionals for use in rendering medical services for compensation (*see* TSB-A-09(48)S [collagen implant injected into bladder tissue to treat urinary incontinence]; TSB-A-02(14)S [bone void filler implanted to treat weakened and diseased bone]; TSB-A-92(77)S [tissue regeneration device placed beneath gums to treat periodontal disease]; and TSB-A-92(43)S [corneal collagen shield inserted to assist in healing of postoperative or traumatic corneal

injuries]). These Advisory Opinions are hereby overruled, as we now conclude that these products should be considered products consumed by humans for the preservation of health and should not be considered medical supplies. As a result, they are exempt when purchased by the medical professionals under section 1115(a)(3) of the Tax Law and 20 NYCRR 528.4.

DATED: September 9, 2013

/S/
DEBORAH R. LIEBMAN
Deputy Counsel

NOTE: An Advisory Opinion is issued at the request of a person or entity. It is limited to the facts set forth therein and is binding on the Department only with respect to the person or entity to whom it is issued and only if the person or entity fully and accurately describes all relevant facts. An Advisory Opinion is based on the law, regulations, and Department policies in effect as of the date the Opinion is issued or for the specific time period at issue in the Opinion. The information provided in this document does not cover every situation and is not intended to replace the law or change its meaning.