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Commissioner

# State of Alabama Department of Revenue

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## ALABAMA DEPARTMENT OF REVENUE REVENUE RULING 2012-002

**This document may not be used or cited as precedent. Ala. Code §40-2A-5(a) (2011 Replacement Volume).**

**TO:** Requestor

**FROM:** Commissioner of Revenue  
Alabama Department of Revenue

**DATE:** OCTOBER 24, 2012

**RE:** WHETHER THE SALE OF TWO PRODUCTS USED TO PROMOTE THE HEALING OF MUSCULOSKELETAL INJURIES AND DISEASES ARE SUBJECT TO SALES AND USE TAX

### FACTS

The facts as represented by the Requester are as follows<sup>1</sup>:

Requester 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. Requester has requested a revenue ruling regarding whether its sales of two of its products, Product X and Product Y to hospitals and surgery centers in this state are subject to tax.

Product X 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. 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 human bone. The granules are interspersed within the

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<sup>1</sup> This revenue ruling, like all revenue rulings is the Alabama Department of Revenue's interpretation of the law or regulations as applied to the facts and assertions contained in the request for the ruling. If any facts or conclusions asserted by the requestor were misstated or misleading, or if facts that are relevant or material to a proper legal determination of this revenue ruling are omitted by the requestor, this revenue ruling may be void.

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 and stem cell attachment. Product X is available in pads, strips, blocks, plugs and paste. Upon saturation with bone marrow aspirate, X 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.

Product X has been approved by the FDA as a Class II device for prescription use only and will be sold by Requester to hospitals and surgery centers in Alabama for use in surgery. Product X is a completely artificial bone substitute and not absorbed by the body.

Product Y was developed as a fully synthetic replacement to autograft in hindfoot and ankle surgery. The product consists of two components: recombinant human platelet-derived growth factor (rhPDGF-BB) and beta-tricalcium phosphate (B-TCP). The product is supplied as a kit for a single use only. At the point of use, the two primary components are combined in entirety, mixed and subsequently applied to the surgical site. The B-TCP component of Y is a highly porous, resorbable and osteoconductive scaffold which provides a framework for bone regeneration, aids in preventing soft tissue infiltration and promotes stabilization of the blood clot. The rhPDGF-BB acts by stimulating the recruitment and proliferation of a variety of cell types. Product Y 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.

Product Y is a combination drug-device product pending approval by the FDA as a Class III medical device and will be sold by Requester to hospitals and surgery centers in Alabama for use in surgery. Product Y is gradually resorbed by the body and turned into bone.

### ISSUES

- (1) Whether Requester's sales of Product X to hospitals and surgery centers in Alabama are subject to sales or use tax?
- (2) Whether Requester's sales of Product Y to hospitals and surgery centers in Alabama are subject to sales or use tax?

### LAW AND ANALYSIS

Ala. Code §40-23-4.1(b) exempts from gross sales tax medicines prescribed by physicians for human consumption or intake that are filled by licensed pharmacists or sold to the patient by a physician. The exemption applies to medicines purchased by hospitals, infirmaries, sanitariums, nursing homes, medical clinics and physicians for

use or consumption in rendering medical services to patients and sales of exempt medicines are exempt regardless of whether they are diagnostic in nature or they are used in preventing, treating or mitigating diseases. Ala. Regulation No. 810-6-3-.47.01.

Medicine is not defined in the Alabama revenue code. Where no statutory definition exists, a word must be given its normal, generally accepted meaning. *State v. American Brass*, 628 So. 2d 920 (Ala. Civ. App. 1993). The Oxford English Dictionary defines the term medicine as “a substance or preparation used in the treatment of illness; a drug; esp. one taken by mouth. The Black’s Law Dictionary defines medicine as “a substance intended for use in the diagnosis, cure, treatment, or prevention of a disease.” In *Alcon Laboratories v. State of Alabama*, Docket S. 06-910 (Admin. Law Div. 5/7/2007), the court defined medicine as “an agent, such as a drug, used to treat disease or injury” and defined drug as “a substance used in the diagnosis, treatment or prevention of a disease.”

Product Y is a substance used to treat injury of the bone and aids the surgeon in providing fusion of the bone. It is consumed by the body, and its properties are gradually used, absorbed and consumed by the body and replaced by bone. When Product Y is prescribed by a physician and filled by a licensed pharmacist or sold to a patient by a physician, sales of Product Y to hospitals and surgery centers in Alabama are exempt from the sales and use tax.

Product X is a synthetic bone replacement substance that aids in bone void filling and fracture repair. It provides a surface for bone remodeling and is not absorbed by the body, nor are its properties changed within the body. Product X differs from Product Y in that it is akin to other devices used in surgical procedures like stents, rods and plates. Such devices are not medicines or drugs under the commonly understood meaning of the words, and thus are not exempt from sales and use tax.

#### HOLDING

Requester’s sales of Product X to hospitals and surgery centers in Alabama are not exempt from the sales and use tax. Requester’s sales of Product Y to hospitals and surgery centers in Alabama are exempt from the sales and use tax.

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JULIE P. MAGEE, Commissioner  
Alabama Department of Revenue

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