New York State Department of Taxation and Finance Taxpayer Services Division Technical Services Bureau

TSB-A-92 (43) S Sales Tax May 27, 1992

STATE OF NEW YORK COMMISSIONER OF TAXATION AND FINANCE

ADVISORY OPINION

PETITION NO. S920309B

On March 9, 1992, a Petition for Advisory Opinion was received from Alcon Surgical, Inc., 6201 South Freeway, Fort Worth, Texas 76134.

The issue raised by Petitioner, Alcon Surgical, Inc., is whether a corneal collagen shield qualifies for the exemption from sales tax provided for by Section 1115(a)(3) of the Tax Law.

Petitioner manufactures and sells various pharmaceuticals, surgical supplies, surgical equipment, and prosthetic devices. Among the products offered is a corneal collagen shield. It is inserted into the eye following surgery to assist in healing. In approximately 24 hours, the shield is dissolved and is absorbed by the body.

An article in the Journal of Cataract Refractory Surgery V. 14, September 1988 by Robert H. Marmer, M.D. entitled <u>Therapeutic and Protective Properties of the Corneal Collagen Shield</u> contained the following discussion of the corneal collagen shield.

The results of these experimental and clinical studies have shown the following:

- 1. The speed of epithelial healing is faster and more complete with the use of the collagen shield.
- 2. There is less stromal edema at the wound sites in collagen treated corneas.
- 3. The shield seems to protect keratocytes adjacent to the wound and keratocyte reaction is diminished,
- 4. Inflammatory reaction and PEN infiltrating on is diminished with use of the shield.
- 5. The surface epithelial bonding appears to be more normal with use of the shield.

Bausch & Lomb describes the physical properties of the Bio-Cot collagen corneal shield as being cast from 100% pure homogenized porcine scleral collagen, which resembles the collagen molecules of the human eye and appears to be clinically compatible with collagen in the human eye. The shield appears to be nonirritating, nontoxic and noninflammatory, with a neutral pH. It is clear, pliable, thin film 0.0127 mm to 0.0710 mm thick in a spherical shape 14.5 mm in diameter and has a 9.0 mm base curve. It is easily applied to the eye and absorbs ocular fluids, which helps it conform to the cornea. After application, the noncross-linked collagen

TSB-A-92 (43) S Sales Tax May 27, 1992

will begin to dissolve in the eye between two and 12 hours. It should be stored at room temperature; contact with heat above 40 degrees or temperatures at or below freezing should be provided. It should not be resterilized

The collagen shield could be used with postoperative or traumatic corneal injuries, nontraumatic corneal conditions, bullous keratopathy, and penetrating and nonpenetrating keratoplasty and refractive surgical procedures. It is also helpful to simplify topical corneal care, to protect from eye lid movement, and as a possible enhancement of the effect of corneal surgical procedures, for example, radial keratotomy. In the future it may become a vehicle for administration of medication. Although it is necessary to exert caution in the use of new protective and therapeutic devices and materials, it appears that few concerns other than the allergy to collagen or porcine products would be likely to cause a problem with the collagen shield. The other entities in the precautionary list may even benefit from the use of the shield. For example, in my clinical experience, the symptoms of keratoconjunctivitis sicca unresponsive to traditional therapy appear to be alleviated substantially with the use of the collagen shield. Certainly an amblyopic or monocular patient with a corneal problem would fare much better with a clear protective and therapeutic device placed in the eye than with medication that could adversely affect his or her vision or with a patch placed over the eye that could be incapacitating.

I believe that medication may be incorporated into the physical make-up of the collagen shield so that it will not only be effective in accelerating healing, but it will also protect against and treat infection and other disorders.

The future of this device is promising and could revolutionize corneal care. Vast potential prospects for clinical application of this device exist.

Section 1105(a) of the Tax Law imposes sales tax upon "[T]he receipts from every sale of tangible personal property, except as otherwise provided in this article."

Section 1115(a)(3) of the Tax Law exempts from the tax on retail sales by Section 1105(a) of the Tax Law:

Drugs and medicines intended for use, internally or externally, in the cure, mitigation, treatment or prevention of illnesses or diseases in human beings, medical equipment (including component parts thereof) and supplies required for such use or to correct or alleviate physical incapacity, and products consumed by humans for the preservation of health but not including cosmetics or toilet articles notwithstanding the presence of medicinal ingredients therein or medical equipment (including component parts thereof) and supplies, other than such drugs and medicines, purchased at retail for use in performing medical and similar services or compensation.

TSB-A-92 (43) S Sales Tax May 27, 1992

In <u>Alcon Laboratories</u>, <u>Inc.</u>, Adv Op Comm T&F, August 2, 1991, TSB-A-91(54)S the Commissioner advised that ophthalmic suture materials qualify for purposes of the exemption contained in Section 1115(a)(3) of the Tax Law as medical supplies.

A corneal collagen shield is not a drug or medicine but is a medical supply for purposes of the exemption contained in Section 1115(a)(3) of the Tax Law since it is a therapeutic device similar to opthalmic suture materials. Alcon Laboratories, Inc., supra, and Journal of Cataract Refractory Surgery, supra. Therefore, the sale of such shield to other than those purchasing the supply at retail for use in performing medical services for compensation is exempt from sales tax. Furthermore, the sale of such shield to a hospital or other organization qualifying for exemption under Section 1116(a) of the Tax Law would be exempt from the imposition of sales tax even if such entity was using the shield in performing medical services for compensation.

DATED: May 27, 1992 s/PAUL B. COBURN
Deputy Director
Taxpayer Services Division

NOTE: The opinions expressed in Advisory Opinions are limited to the facts set forth therein.