

EXPLANATORY STATEMENT

THERAPEUTIC GOODS (LISTING) NOTICE 2010 (NO. 4)

Docosahexaenoic acid (DHA)-rich oil derived from microalgae *Schizochytrium* sp.

Subsection 9A(5), Therapeutic Goods Act 1989

OUTLINE

Therapeutic Goods (Listing) Notice 2010 (No. 4) (the Listing Notice) is a notice made by the delegate of the Minister for Health and Ageing under subsection 9A(5) of the *Therapeutic Goods Act 1989* (the Act).

The Listing Notice has the effect of requiring that therapeutic goods that are oral preparations containing ‘Docosahexaenoic acid (DHA)-rich oil derived from microalgae *Schizochytrium* sp.’ as a therapeutically active ingredient in combination with other ingredients and that are presented in a therapeutic dosage form for therapeutic use be included in the part of the Australian Register of Therapeutic Goods (the Register) for listed goods.

The Listing Notice commenced on the day after it was registered on the Federal Register of Legislative Instruments.

BACKGROUND

The Act provides for the establishment and maintenance of a national system of controls for the quality, safety, efficacy and timely availability of therapeutic goods that are used in Australia or exported from Australia. The Therapeutic Goods Administration (the TGA) is responsible for administering the Act.

Unless specifically exempted or authorised under the Act, therapeutic goods are required to be included on the Register before being supplied in, imported into, manufactured in or exported from, Australia (sections 19B and 19D of the Act). Medicines are registered or listed on the Register, depending on the ingredients they contain and the therapeutic claims that are being made.

In general, products that contain low risk ingredients are referred to as listed medicines in Australia. Most listed medicines are considered to be of relatively low risk compared to other types of medicines, such as prescription and over-the-counter medicines, as they may only contain ingredients that have been approved by the TGA as being of low risk, and may only make limited therapeutic claims.

Part 1 of Schedule 4 to the *Therapeutic Goods Regulations 1990* (the Regulations) sets out those therapeutic goods that are required to be included in the part of the Register for listed medicines. It does not currently cover oral preparations that contain DHA-rich oil derived from microalgae *Schizochytrium* sp. as a therapeutically active ingredient in combination with other ingredients and that are presented in a therapeutic dosage form for therapeutic use.

Subsection 9A(5) of the Act authorises the Minister for Health and Ageing to publish a notice in the *Commonwealth of Australia Gazette* requiring that specified goods be included in the part of the Register for listed goods and allowing the Minister to specify conditions to which such an inclusion is to be subject. Such notices generally require that goods containing

particular ingredients be included in that part of the Register. Once the notice is in effect, persons may apply for the listing on the Register of new therapeutic goods that contain ingredients or substances of the kind set out in the notice.

If Part 1 of Schedule 4 to the Regulations is amended to require goods that are the subject of a subsection 9A(5) notice be included in the part of the Register for listed goods the notice ceases to have effect (subsection 9A(6) of the Act).

A person can apply for a new ingredient or substance to be approved for inclusion as an active ingredient in listed medicines through the making of a subsection 9A(5) notice. The TGA evaluates such applications and the supporting data provided by the applicant on the basis of safety and quality. The safety-focussed element determines whether the ingredient or substance is of sufficiently low risk to allow its inclusion in listed medicines and the quality-focussed element characterises the precise and correct nature of the ingredient or substance.

DHA-RICH OIL DERIVED FROM MICROALGAE *SCHIZOCHYTRIUM* SP.

An application was received for DHA-rich oil derived from microalgae *Schizochytrium* sp. to be made available for use in listed medicines. This substance is the purified form of the oil that is produced by the organism *Schizochytrium* sp. under closed, sterile conditions. In nature *Schizochytrium* sp. is widely distributed in marine environments.

The oil is primarily a mixture of triglycerides enriched in the omega-3 fatty acid DHA and also contains relatively high levels of the omega-6 fatty acid docosapentaenoic acid. The oil is manufactured in a process similar to that used for edible vegetable oils.

Other marine oils containing triglycerides rich in omega-3 fatty acids that are currently approved active ingredients in listed medicines for oral use include oils from a range of fish species and *Euphausia superba* (Antarctic krill). These substances are available for use in listed medicines without restriction. The DHA-rich oil derived from microalgae *Schizochytrium* sp. alone was considered safe for use as a novel food by the then Australia New Zealand Food Authority (now Food Standards Australia New Zealand) in 2002.

The delegate of the Minister for Health and Ageing has made the Listing Notice, which is a legislative instrument for the purposes of the *Legislative Instrument Act 2003*, to require that oral preparations that contain DHA-rich oil derived from microalgae *Schizochytrium* sp. as a therapeutically active ingredient in combination with other ingredients and that are presented in a therapeutic dosage form for therapeutic use, be included in the part of the Register for listed goods. This will have the effect of permitting the use of DHA rich oil derived from microalgae *Schizochytrium* sp. in oral listed medicines in combination with other ingredients (such as, for example, binders, fillers and other excipients) when the medicine is presented in a therapeutic dosage form for therapeutic use.

The TGA has also prepared a physico-chemical description of DHA-rich oil derived from microalgae *Schizochytrium* sp. in the form of compositional guidelines. Compositional guidelines are intended to assist applicants for inclusion of therapeutic goods on the Register that are or include goods of the kind described in a subsection 9A(5) notice in identifying the specific forms or types of ingredients or substances where, as in this case, there is no standard in the British Pharmacopoeia or other acceptable monographs in relation to the ingredient or substance.

The draft compositional guidelines for DHA-rich oil derived from microalgae *Schizochytrium* sp. will be available on the TGA's internet site (www.tga.gov.au) for consultation for six months from the date of registration of the Listing Notice. The guidelines will then be published on the website in their final form.

CONSULTATION

The making of the Listing Notice is minor and machinery in nature with no or low compliance costs and impact on business, individuals or the economy.