Public Summary

Summary for ARTG Entry:	94756 Fish Oil 1000
ARTG entry for	Medicine Listed
Sponsor	Herbs of Gold Pty Ltd
Postal Address	PO Box 3143, KIRRAWEE, NSW, 2232 Australia
ARTG Start Date	10/06/2003
Product Category	Medicine
Status	Active
Approval Area	Listed Medicines

Conditions

Colouring agents used in listed medicine for ingestion, other than those listed for export only under section 25 of the Act, shall be only those included in the list of 'Colourings permitted in medicines for oral use'.

The sponsor shall keep records relating to this listed medicine as are necessary to: (a) Expedite recall if necessary of any batch of the listed medicine, (b) Identify the manufacturer(s) of each batch of the listed medicine. Where any part of or step in manufacture in Australia of the listed medicine is sub-contracted to a third party who is not the sponsor, copies of relevant Good Manufacturing Practice agreements relation to such manufacture shall be kept.

The sponsor shall retain records of the distribution of the listed medicine for a period of five years and shall provide the records or copies of the records to the Complementary Medicines Branch, Therapeutic Goods Administration, upon request.

The sponsor of the listed medicine must not, by any means, intentionally or recklessly advertise the medicine for an indication other than those accepted in relation to the inclusion of the medicine in the Register.

All reports of adverse reactions or similar experiences associated with the use or administration of the listed medicine shall be notified to the Head, Office of Product Review, Therapeutic Goods Administration, as soon as practicable after the sponsor of the goods becomes aware of those reports. Sponsors of listed medicines must retain records of such reports for a period of not less than 18 months from the day the Head, Office of Product Review is notified of the report or reports.

The sponsor shall not supply the listed medicine after the expiry date of the goods.

Where a listed medicine is distributed overseas as well as in Australia, product recall or any other regulatory action taken in relation to the medicine outside Australia which has or may have relevance to the quality, safety or efficacy of the goods distributed in Australia, must be notified to the National Manager Therapeutic Goods Administration, immediately the action or information is known to the sponsor.

Products

1 . Fish Oil 1000

Product Type	Single Medicine Product	**Effective Date**	1/10/2019

Permitted Indications

Helps maintain/support healthy eye development
Helps maintain/support healthy eye development in breast fed healthy infants
Maintain/support eye health in breast fed healthy infants
Maintain/support eye health
Helps maintain/support eye retina health in breast fed healthy infants
Helps maintain/support eye retina health
Maintain/support healthy growth and development in breast fed healthy infants
Maintain/support general health and wellbeing
Anti-inflammatory/relieve inflammation
Maintain/support joint health
Maintain/support healthy blood circulation
Maintain/support cardiovascular system health
Maintain/support healthy cardiovascular system function
Maintain/support heart health
Maintain/support muscle health
Maintain/support muscle function
Helps prevent dietary (state vitamin/mineral/nutrient) deficiency
Maintain/support cognitive function/mental function
Maintain/support brain function

Maintain/support brain function in breast fed healthy infants

Maintain/support brain health

Maintain/support nervous system health

Maintain/support brain/central nervous system development

Maintain/support nervous system function

Decrease/reduce/relieve menstruation pain/dysmenorrhoea

Maintains/support healthy foetal development

Maintain/support skin health

Indication Requirements

Product presentation must not imply or refer to vision correction, faults or serious eye disease e.g. macular degeneration.

If directed to women, Label statement: Advise your doctor of any medicine you take during pregnancy, particularly in your first trimester.

Product presentation must not imply or refer to serious cardiovascular conditions.

Product presentation must not imply or refer to mental illnesses, disorders or conditions.

Product presentation must not imply or refer to neurological conditions or developmental delays.

Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis. Note: this requirement is not intended to apply where the indications referring to osteoporosis specified in column 2 of Table 2 of this instrument are also used.

Label statement: If symptoms persist, talk to your health professional.

Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

No Warnings included on Record

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule

Components

1 . Formulation 1

Dosage Form	Capsule, soft
Route of Administration	Oral

Visual Identification

Active Ingredients

natural fish oil	**1 g**
Equivalent: docosahexaenoic acid	120 mg
Equivalent: eicosapentaenoic acid	180 mg
Equivalent: omega-3 marine triglycerides	300 mg

Other Ingredients (Excipients)

d-alpha-tocopherol

Gelatin

glycerol

purified water

Soya Oil

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