Public Summary

Summary for ARTG Entry:	322173 Wild Alaskan Salmon Oil
ARTG entry for	Medicine Listed
Sponsor	Factors Group Australia Pty Ltd
Postal Address	Unit B 10-16 South Street, Rydalmere, NSW, 2116 Australia
ARTG Start Date	22/08/2019
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 . Wild Alaskan Salmon Oil

Product Type	Single Medicine Product	**Effective Date**	22/08/2019

Permitted Indications

Maintain/support healthy eye function

Maintain/support eye health

Maintain/support general health and wellbeing

Anti-inflammatory/relieve inflammation

Helps enhance/promote bone health

Maintain/support bone health

Helps in the maintenance of healthy blood lipids/blood fats

Helps maintain/support healthy cholesterol

Maintain/support cardiovascular system health

Maintain/support healthy cardiovascular system function

Maintain/support cognitive function/mental function

Indication Requirements

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

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.

Product presentation must not imply or refer to lowering blood lipids, blood fats and triglycerides.

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

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

Product presentation must not imply or refer to lowering or raising blood cholesterol levels from outside of the normal healthy range

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

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, enteric
Route of Administration	Oral
Visual Identification	

Active Ingredients

natural fish oil	**1.2 g**
Equivalent: eicosapentaenoic acid	96 mg
Equivalent: docosahexaenoic acid	84 mg
Equivalent: colecalciferol	1.5 microgram

Other Ingredients (Excipients)

d-alpha-tocopherol
Gelatin
glycerol
pectin
potable water
sorbitol

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