Public Summary

Summary for ARTG Entry:	122592	Natural Life Royal Jelly 1000 mg

ARTG entry for	Medicine Listed
Sponsor	Lifetime Health Products Pty Ltd
Postal Address	7/121a Old Pittwater Rd, Brookvale, Sydney, NSW, 2100 Australia
ARTG Start Date	12/10/2005
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 . Natural Life Royal Jelly 1000 mg

Product Type	Single Medicine Product	**Effective Date**	14/06/2019

Permitted Indications

Antioxidant/Reduce free radicals formed in the body

Maintain/support general health and wellbeing

Indication Requirements

No Indication Requirements included on Record

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

Not to be taken by asthma and allergy sufferers [In 3 mm type, prominent on front]. AND This product contains royal jelly which has been reported to cause severe allergic reactions and in rare cases fatalities, especially in asthma and allergy sufferers [in 1.5 mm type].

Not suitable for children.

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

Royal jelly lyophilised	**200 mg**
Equivalent: 10-hydroxy-2-decenoic acid	12 mg

Other Ingredients (Excipients)

calcium carbonate
d-alpha-tocopherol
Gelatin
glycerol
hydrogenated vegetable oil
lecithin
purified water
Soya Oil
yellow beeswax

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