Public Summary

Summary for ARTG Entry:	305381 UM Calm
ARTG entry for	Medicine Listed
Sponsor	FIT-BioCeuticals Limited
Postal Address	Care of Blackmores Ltd PO Box 1725, Warriewood, NSW, 2102 Australia
ARTG Start Date	27/06/2018
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 . UM Calm

Product Type Single Medicine Product **Effective Date** 27/06/2018

Permitted Indications

Relieve weariness/tiredness/fatigue/feeling of weakness
Maintain/support healthy cardiovascular system function
Decrease/reduce/relieve muscle cramps when dietary intake is inadequate
Helps reduce occurrence of muscle cramp when dietary intake is inadequate
Helps decrease/reduce/relieve mild muscle spasms/twitches when dietary intake is inadequate
Aid/assist/helps glucose/sugar/carbohydrate metabolism
Aid/assist/helps protein synthesis in the body
Helps maintain/support cellular uptake of (state vitamin/mineral/nutrient)
Aid/assist/helps metabolism of (state vitamin/mineral/nutrient)
Decrease/reduce/relieve symptoms of stress
Maintain/support memory/mental recall
Maintain/support nerve conduction
Aid/assist/helps synthesis of neurotransmitters
Maintain/support nervous system function

Indication Requirements

Product presentation must not imply or refer to lowering or raising blood sugar/glucose levels from outside of the normal healthy range.

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

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

Product presentation must not imply or refer to chronic fatigue syndrome.

Product presentation must not imply or refer to serious musculoskeletal or neurological conditions.

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

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

Contains caffeine [state quantity per dosage unit or per mL or per gram of product] total caffeine [per dosage unit or per mL or per gram]. A cup of instant coffee contains approximately 80mg of caffeine.

Contains milk/milk products.

Not suitable for use in children under the age of 12 months except on the advice of a health professional. (or words to that effect)

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule

Components

1 . Formulation 1

Dosage Form	Powder, oral
Route of Administration	Oral
Visual Identification	

Active Ingredients

alpha casozepine enriched hydrolysed milk protein	**10 mg/g**
calcium glycerophosphate	**39.801 mg/g**
Equivalent: calcium	6.667 mg/g
Camellia sinensis	**33.333 mg/g**
choline bitartrate	**97.324 mg/g**
Equivalent: choline	40 mg/g
glycine	**33.333 mg/g**
inositol	**133.333 mg/g**
magnesium amino acid chelate	**231.884 mg/g**
Equivalent: magnesium	26.667 mg/g
magnesium glycerophosphate	**128.825 mg/g**
Equivalent: magnesium	13.333 mg/g
taurine	**66.667 mg/g**
zinc amino acid chelate	**4.667 mg/g**
Equivalent: zinc	933 microgram/g

Other Ingredients (Excipients)

colloidal anhydrous silica
Flavour
inulin
malic acid
silicon dioxide
Steviol glycosides

Public Summary