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COMPLEMENTARY MEDICINES - HEALTH SUPPLEMENTS SAFETY AND EFFICACY

This guideline is intended to provide recommendations to applicants wishing to submit applications for the registration of Health Supplements. It represents the South African Health Product Regulatory Authority's current thinking on the quality, safety, and efficacy of these medicines. It is not intended as an exclusive approach. The SAHPRA reserves the right to request any additional information to establish the safety, quality and efficacy of a medicine in keeping with the knowledge current at the time of evaluation. Alternative approaches may be used but these should be scientifically and technically justified. The SAHPRA is committed to ensure that all registered medicines will be of the required quality, safety and efficacy. It is important that applicants also adhere to the administrative requirements to avoid delays in the processing and evaluation of applications.

Guidelines and application forms are available from the office of the SAHPRA website **www.sahpra.org.za**

Further Annexures associated, but not yet included, with this guideline will be published for public comment prior to implementation.

First publication released for comment	November 2014
Deadline for comment	26 February 2015
Version 2 - deletion of quality aspects for inclusion in separate guideline	June 2016
Version 3 - addition of Annexures G and I for comment	April 2016
Version 3_1 – addition of Annexure J for comment	April 2017
Version 3_2 – addition of Annexure H, K and L for comment	June 2018
Version 4 – guideline format, amendment of general provisions of the guideline and addition of Annexure G-L for implementation.	June 2020
Version 4_1 – addition of Annexures M and N for comment	March 2021
Deadline for comment	30 June 2021
Version 4_2 – addition of Annexure O for comment, publication of propose amendment to Annexures C, F, H, J and M for public comment.	10 September 2021
Deadline for comment	10 December 2021

BOITUMELO SEMETE-MAKOKOTLELA

CHIEF EXECUTIVE OFFICER

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In the interest of focus, only the proposed additional Annexure is included to amend version 4 of the guideline published in June 2020 ***(7.04_SE_Health_Supplements_Jun20_v4)***

Sections 1 - 4 are unchanged as in version 4 published June 2020.

Annexures A - L are unchanged as in version 4 published June 2020.

Annexures O is now published for comment.

Proposed amendments to Annexures E, F, H, M are published for comment.

ANNEXURE O - Allowable Levels and Claims: Other Substances

PROPOSED AMENDMENTS: Annexures C, F, H, J and M

In assessing the safety, efficacy and quality of health supplement and preparations the attached Annexures have been developed to guide the use of the substances listed therein when used in Complementary Medicines as Health Supplements.

For any substance listed in the Health Supplement Annexures, comment may be submitted to the SAHPRA for consideration for the inclusion of any substance in the Health Supplement Annexures addressing the following for any motivated changes:

- The recognition of another international regulatory body with a similar regulatory mechanism/standard as a nutritional substance, dietary supplement, nutritional form or health supplement. Please note that this forms **part** of the consideration of the motivation and is not the sole basis for making a decision for an amendment.
- Where any dosage range is proposed to be changed, the adjusted safety profile of the substance that the new dosage profile represents, including:
  - Therapeutic profile;
  - Minimum effective doses;
  - Maximum safe values (with specific age range values as appropriate);
  - Known side effects;
  - Contraindications; and
  - All known interactions (including interactions with medicines, other complementary medicines, health supplements, disease processes or diagnostics procedures).
- The amendment of any wording of the proposed health claim (indication) of the substance, including any supportive clinical evidence in support of the health claim and levels proposed. Such proposed amendment must continue to be in line with the definition of a health supplement.
- Any other literature or motivation in substantiation of such substance as a health supplement and which refer to the conditions under which it is to be used eg: demonstrating evidence for safety at the specified dose or clinical evidence for the particular effect intended. Demonstrating limited clinical efficacy for a disease-based indication is not evidence of health maintenance.

All information submitted should be summarised, contextualised and motivated clearly. If supporting documentation is submitted a concise written case must be made for their consideration clearly identifying the parts of the documentation which support the proposed position.

New substances proposed to be introduced to the annexures should be submitted by way of Annexure B submissions in terms of Guideline 7.04.

Comment should be submitted in the attached comment form together with any relevant and appropriately labelled Appendices. These comment documents can be submitted at www.sahpracm.org.za – "Guidelines" – "Documents for Comment" by the deadline indicated.

5 UPDATE HISTORY

Date	Reason for update	Version & publication
Nov 2014	First publication released for comment Deadline for comment - 26 Feb 2015	v1 Nov 2013
June 2016	Deletion of 2 Quality Requirements for inclusion in separate guideline Inclusion of new section 2 ZACTD format Amendments to 1 i), 1.1, 1.2, 3.1, 3.2, 3.2.1, 4, Annexure E	v2 June 2016
April 2016	Addition of Annexures G and I for comment	v3 April 2016
April 2017	Addition of Annexure J for comment	v3_1 April 2017
June 2018	Addition of Annexure H, K and L for comment	v3_2 June 2018
June 2020	Addition of SAHPRA branding, naming and process and minor editing Section 1: Document sources, Definitions, updated list of annexures Section 3.2: PIL statement Glossary: updated for legislative changes Annexure A: Correction of line direction Annexure B: Amendment of format required Annexure C: Amendment and addition of substance listing Annexure E: Table formatting, Vitamin B3 sources and children maximums, Folic acid - sources and maximum amended. Annexure F: Clarification of which minerals are excluded for use in children, Boron - minimum amended, Chromium - maximum amended, Iodine - maximum amended, Selenium - maximum amended, Zinc - source statement added regarding Zinc picolinate. Annexure G-L: Added to Guideline 7.04.	v4 June 2020
March 2021	Addition of Annexures M and N for comment	V4_1 March 2021
September 2021	Addition of Annexure O for comment Publication of proposed amendments to Annexures C, F, H, J and M for comment	V4_2 September 2021

ANNEXURE O

Allowable levels and claims: Other

Note: Any claims provided may be used with any of the stipulated dosage ranges.

Minimum: Minimum Daily Levels Required for use of Health Supplement Claim

Maximum: Maximum Daily Levels Permitted as Health Supplement

General Statements:

Warning:

If symptoms worsen, consult a relevant health care provider.

Not suitable for children unless under the care of a relevant health care provider.

Consult a relevant health care provider prior to use if you are pregnant or breastfeeding.

Duration of Use:

If more than one duration of use statement is indicated for a particular product formulation, only the shortest applicable duration of use statement is required on the labelling.

Consult a relevant health care provider for prolonged use.

Instructions for use:

Take with meals unless otherwise instructed by a relevant health care provider.

Enteric coated tablets: Swallow whole do not crush or chew.

Ingredient	Health Supplement Claim	Specified Warning(s)	Dosage
5HTP *5-Hydroxy-L-tryptophan* *L-5-Hydroxytryptophan* *5-hydroxy tryptamine* ***Sources:*** *Griffonia simplicifolia* (DC.) Baill. [seed]. Concentrated or standardised extracts of *G. simplicifolia* are considered discipline-specific medicines and not health supplements. For health supplement use, only the pure compound, isolated from *G. simplicifolia*, may be used.	Helps to promote healthy mood balance. Used as a sleep aid	Consult a relevant health care provider prior to use if you are taking carbidopa or medicines/supplements with serotonergic activity. These may include, but are not limited to, L-tryptophan, S-Adenosylmethionine (SAMe), St. John's wort, antidepressants, pain killers, over the counter cough and cold medication containing dextromethorphan, anti-nausea medication and anti-migraine medication. Stop use and consult a relevant health care provider if you show signs of weakness, oral ulcers, abdominal pain accompanied by severe muscle pain or if you experience skin changes. Avoid taking with alcohol or products that cause drowsiness. *Sleep aid:* Consult a relevant health care provider if sleeplessness persists continuously for more than 4 weeks (chronic insomnia).	*Healthy mood balance* 150 to 220 mg of 5-HTP, per day; *Sleep aid* 100 to 220 mg of 5-HTP, per day.
Agar *Gelidium amansii extract* *Japanese isinglass* *Seaweed mucilage*	Assists with gastro-intestinal health. Enhances intestinal health.	Taking this product without adequate fluid may cause it to swell and block your throat or oesophagus and may cause choking. Do not take this	Maximum: 16,5 g, divided into three doses of 2,75 to 5,5 g. Only for internal use when the

Ingredient	Health Supplement Claim	Specified Warning(s)	Dosage
Sources: *Gelidium amansii* (Parts: Whole plant) *Gelidium amansii* and other red algae whole plant (thallus) of the families Gelidiaceae and Gracilariaceace and the relevant red algae of the class *Rhodophyceae*		product if you have difficulty in swallowing. If you experience chest pain, vomiting, or difficulty in swallowing or breathing after taking this product, seek immediate medical attention. Contraindication: Gastric bypass.	medicine contains less than 150 µg of iodine per maximum daily dose.
Betaine hydrochloride *1-carboxy-N,N,N-trimethylmethanaminium, chloride* *glycine betaine hydrochloride* *trimethylglycine hydrochloride* ***Sources:*** *Beta vulgaris*	Helps to support digestion/digestive aid.	Consult a relevant health care provider prior to use if you have a peptic ulcer or excess stomach acid. *Products providing 780 mg or more of Betaine hydrochloride as a medicinal ingredient or as a source ingredient, per day:* Consult a relevant health care provider prior to use if you have high cholesterol.	Adults 18 years and older only: 180 mg to 1 500 mg per day.
Brewer's Yeast *Torula yeast:* *Candida utilis* ***Sources:*** Dried yeast of sources: *Saccharomyces cerevisiae* *Saccharomyces fragilis* *Saccharomyces boulardii*	Helps support intestinal/gastrointestinal health. Assists to establish a favourable gut flora. Source of B vitamins and protein.	Consult a relevant health care provider prior to use if you have fever, vomiting, bloody diarrhoea or severe abdominal pain. Stop use and consult a relevant health care provider if symptoms of digestive upset (e.g. diarrhoea) occur, worsen and/or persists beyond 3 days. *Contraindication(s):* Do not use this product if you have an immune-compromised condition	Minimum: $1,0 \times 10^7$ CFU/day

Ingredient	Health Supplement Claim	Specified Warning(s)	Dosage
		(e.g. AIDS, lymphoma, patients undergoing long-term corticosteroid treatment).	
Cannabidiol	See Guideline 7.06 for guidance on use as a Health Supplement.		
Charcoal activated *activated carbon* *medicinal carbon* *vegetable charcoal* ***Sources:*** *Common charcoal heated in the presence of a gas.*	Activated charcoal contributes to reducing excessive flatulence after eating. Digestion support.	When for internal use, the medicine requires the following warning statement on the medicine label: "Products containing activated charcoal should be used with caution in children or individuals with malabsorption conditions since it may interfere with absorption of nutrients." Activated charcoal may interact with other medicines. Activated charcoal is not recommended for long-term use.	Adults 18 years and older only: 200 mg capsules: 1 or 2 per day.
Chlorella ***Sources:*** *Chlorella vulgaris* *Chlorella pyrenoidosa* (source must be broken cells only)	Source of antioxidants. Source of vitamins and/or minerals. Source of protein. Source of (an) (essential) amino acid(s)	As for Iodine and Potassium.	Maximum: 6 g of broken cells Ensure that iodine and potassium levels as status in the relevant annexures are not exceeded. Iodine is a mandatory component of Chlorella: Only for external use when the concentration of iodine in the medicine (excl. salts derivatives or iodophors) is 2,5 % or less. Only for internal use when the

Ingredient	Health Supplement Claim	Specified Warning(s)	Dosage
			medicine contains less than 150 µg of iodine per maximum recommended daily dose.
Choline *(beta-hydroxyethyl)trimethylammonium* *2-Hydroxy-N,N,N-trimethylethanaminium* *Choline bitartrate* *Choline chloride* *Choline dihydrogen citrate* *Choline orotate* *Lecithin* *Phosphatidylcholine*	Helps to support liver function. A factor in the maintenance of good health.		27,5 mg to 1 000 mg per day
Co-enzyme Q10 *2,5-Cyclohexadiene-1,4-dione, 2-[(2E,6E,10E,14E,18E,22E,26E ,30E,34E)-3,7,11,15,19, 23,27,31,35,39-decamethyl-2,6,10,14,18,22,26,30,34, 38-tetracontadecaenyl] -5,6-dimethoxy-3-meth* *Coenzyme Q10* *CoQ10* *Ubidecarenone* *Ubiquinone-1* ***Sources:*** *Agrobacterium rhizogenes* *Agrobacterium tumefaciens* *Aspergillus clavatus* *Escherichia coli* *Gluconobacter suboxydans* *Leucosporidium scotti* *Paracoccus denitrificans*	An antioxidant. Helps to maintain and / or support cardiovascular health.	Consult a relevant health care provider prior to use if you are taking blood pressure medication. *Products providing more than 100 mg of Coenzyme Q_{10} per day* Consult a health care practitioner prior to use if you are taking blood thinners.	*Antioxidant:* Maximum: 300 mg *Cardiovascular health:* 30 to 300 mg per day.

Ingredient	Health Supplement Claim	Specified Warning(s)	Dosage
Rhodobacter sphaeroides *Rhodospirillum rubrum* *Saccharomyces cerevisiae* *Schizosaccharomyces pombe*			
Inositol *Inositol dihydrate* *Inositol hexanicotinate* *Inositol monophosphate*	No claim can be supported based on this medicinal ingredient. Inositol must be combined with at least one other medicinal ingredient listed in Annexure E (Vitamins), Annexure F (Minerals) or the following specified ingredients: Beta-carotene, Choline, Lutein, Lycopene, or L-Methionine, from which the wording for the claim must be drawn.	Warnings applicable to the ingredients with which Inositol is combined must apply.	Maximum: 650 mg
Methylsulphonylmethane *MSM* *Dimethyl sulfone* *Sulfonylbismethane*	For joint health. A factor in maintaining joint health. Joint health, mobility and joint comfort	Not to be taken at bedtime. Do not consume if you have allergies to sulphur.	Maximum: 6 000 mg. 1 500 to 6 000 mg per day for minimum of 4 weeks to see beneficial effects. Not to exceed 2 000 mg per single dose.
para-Aminobenzoic acid *PABA* *4-Aminobenzoic acid* *Para-Aminobenzoic acid, ethyl ester* ***Sources:*** *Saccharomyces cerevisiae*	No claim can be supported based on this medicinal ingredient. PABA must be combined with at least one other medicinal ingredient listed in Annexure E (Vitamins), Annexure F (Minerals),	Stop use if hypersensitivity or allergy occurs. Contact a relevant health care provider if you are taking sulphonamides.	18 years and older: 1 200 mg per day

Ingredient	Health Supplement Claim	Specified Warning(s)	Dosage
	Beta-carotene, Choline, Lutein, Lycopene, or L-Methionine, from which the claim is drawn.		
Propolis	See Guideline 7.06 for guidance on use as a Health Supplement. *(To be published for comment)*		
Spirulina *Spirulina represents a biomass of cyanobacteria (blue-green algae)* ***Sources:*** *Arthrospira platensis* – whole cell *Arthrospira maxima* – whole cell	Source of/Provides antioxidants. Contributes to maintaining normal immune responses to seasonal and environmental allergens. Uses based on constituent potency at or above the minimum doses indicated in the dose section below: Source of beta-carotene (see permitted claims for beta-carotene). Source of iron (see permitted claims for iron). Source of protein for the maintenance of good health. Source of protein which helps build and repair body tissues. Source of (an) essential amino acid(s) for the maintenance of good health. Source of (an) (essential) amino acid(s) involved in muscle protein	Acceptable dosage forms by age group: Children 2 years: The acceptable dosage forms are limited to emulsion/suspension and solution/liquid preparations. Children 3-5 years: The acceptable dosage forms are limited to chewables, emulsion/suspension, powders and solution/liquid preparations. Children 6-11 years, Adolescents 12-17 years, and Adults 18 years and older: The acceptable dosage forms for this age category and specified route of administration are indicated in the Compendium of Monographs Guidance Document.	Maximum doses should not result in excess of maximum daily values of substances listed in other annexures (e.g. vitamins, minerals). *Daily doses for symptoms associated with seasonal and environmental allergens:* Children: 2-4 years: 0,3 g to 1 g 5-9 years: 0,5 g to 2 g 10-14 years: 1 g to 4 g Adolescents: 15 to 17 years: 2 g to 8g Adults: 18 years and older: 2 g to 8 g *Daily doses as algal protein:* Children: 2-4 years: 0, 6 g to 1 g 5-9 years: 0,9 g to 2 g 10-11 years: 1,5 g to 4 g Adolescents: 12 to 14 years: 1,5 g - 4g 15 to 17 years: 2,6 g - 8g Adults: 18 years and older: 2,6 g to 8 g

Ingredient	Health Supplement Claim	Specified Warning(s)	Dosage
	synthesis.		*Maximum dose of Spirulina as a source of beta-carotene:* Children: 2 to 4 years: 1 g 5 to 9 years: 2 g 10 to 14 years: 4 g Adolescents: 15 – 17 years: 8 g Adults: 18 years and older: 8 g *Maximum dose of Spirulina as a source of iron:* Children: 2 to 4 years: 1 g 5 to 9 years: 2 g 10 to 14 years: 4 g Adolescents: 15 – 17 years: 8 g Adults: 18 years and older: 8 g

Annexure B applications required

The following substances have been found to have insufficient information available as to their effectiveness or safety. The specific areas of concern are stated relative to each substance but any substance would require a separate, complete Annexure B application to motivate for their inclusion.

Ingredient	Area(s) of concern
Apple cider vinegar	The specified claims to be used are to be justified by studies demonstrating effectiveness. Specified warning(s) and identified applicable minimum/maximum dosages that provide for the safe use of the substance require identification.
Bee pollen	As this product may be associated with severe allergic reactions evidence of effectiveness of the chosen health supplement claim is required. Specified warning(s) and identified applicable minimum/maximum dosages that provide for the safe use of the substance require identification.
Co-enzyme A	No potential health supplement claim is known to be relevant to this substance. Specified warning(s) and identified applicable minimum/maximum dosages that provide for the safe use of the substance require identification.
Hydroxycitric acid	Annexure B submission required in order to substantiate the use of this substance with reference to the possible adverse events (most notably hepatotoxicity) noted with its inclusion in products internationally.
Inosine	At this time there is not enough scientific information to determine an appropriate range of doses for inosine.
Phosphatidyl choline **Phosphatidyl inositol** **Phosphatidyl serine**	At this time there is not enough scientific information to determine an appropriate use and range of doses for these substances.

PROPOSED AMENDMENTS TO ANNEXURES C, F, H, J and M

Text indicated by ~~red strikethrough~~ is proposed for deletion.
Text indicated by blue underline is proposed for insertion.

ANNEXURE C

Allowable levels and claims: Probiotics

Various requests have been received for the addition of specified bacteria to Annexure C: Probiotics. In review of most data submitted the vast majority of bacterial strains do not support the standardised probiotic health claim as stated in the current annexure C.

Other claims or adjusted clams, that are in line with a health supplement, may however be relevant to these bacterial species and SAHPRA is considering that a separate sub-section of another Annexure be created for “live cultures”. In order to facilitate the generation of such a list that would permit listing of any bacterium as a “live culture” **comment is requested** that identifies the bacterial species and strains and provides all supportive information as indicated on page 4 of this document. Those bacterial strains already proposed by way of Annexure B application on the SAHPRA CM portal will be considered for inclusion.

ANNEXURE F

Allowable levels and claims: Minerals

The inclusion of the following notice regarding the use of amino acid chelates:

Amino acid chelates as acceptable sources of minerals:

Due to the non-specific description of the ligand in the amino acid chelate, it is theoretically possible that an amino acid chelate may contain amino acids which are separately listed as health supplements in Annexure G of Guideline 7.04, with specified dosage ranges and may contribute to the total values of more than one substance per dosage unit. Different amino acids may be used in different chelation formulations (e.g. Glycine, Methionine, Lysine, Aspartate) already identified as source materials for various minerals. Not only should these be specifically identified but the amount of amino acid delivered from the source materials identified must therefore be identified as these may constitute active ingredients to a product formulation and should not exceed or contribute to exceeding the maximum daily value identified in Annexure G of Guideline 7.04.

The inclusion of the following new mineral entry:

Minerals	Health Supplement Claim (Single Substance Formulations)	Health Supplement Claim (Multiple Substance Formulations)	Children		Adults	
			Minimum	Maximum	Minimum	Maximum
Silicon ***Sources:*** *Calcium silicate;* *Choline-stabilised orthosilicic acid;* *Orthosilicic acid;* *Silicic acid;* *Silicon dioxide;* *Silicon hydrolyzed animal protein (HAP) chelate;* *Silicon hydrolyzed vegetable protein (HVP) chelate,* *Sodium metasilicate*	Helps to maintain healthy hair, nails and/or skin.	Mineral supplement.	*Not permitted.*	*Not permitted.*	**10 mg**	**84 mg**

The inclusion of the following new mineral entry for electrolytes noting that only those electrolytes not already stated in Annexure F: Minerals will be stated. Further, substances such as sodium, chloride and phosphate do not contribute to the maintenance of good health since there is likely to be excess of such substances (particularly sodium) from the diet, not a deficiency. Comment is therefore sought on the intention to provide for

Minerals	Health Supplement Claim (Single Substance Formulations)	Health Supplement Claim (Multiple Substance Formulations)	Children		Adults	
			Minimum	Maximum	Minimum	Maximum
Electrolytes ***Including:*** *Sodium* *Chloride* *Phosphate*	*Not permitted.*	Contributes to normal electrolyte balance.	*Not permitted.*	*Not permitted.*	**Comment required.**	**Comment required.**

The following Annexure F entries are proposed to be amended:

Minerals	Health Supplement Claim (Single Substance Formulations)	Health Supplement Claim (Multiple Substance Formulations)	Children		Adults	
			Minimum	Maximum	Minimum	Maximum
Magnesium	Contributes to normal electrolyte balance.	Contributes to normal electrolyte balance.	Daily dose levels unchanged and remain as provided.			
Potassium	Contributes to normal electrolyte balance.	Contributes to normal electrolyte balance.	**98 mg***	**600 mg***	**98 mg***	**600 mg***

**specific to the claim stated*

ANNEXURE H

Allowable levels and claims: Animal Extracts, Products and Derivatives

The inclusion of the following new entries:

Ingredient	Health Supplement Claim	Specified Warning(s)	Dosage
Coturnix coturnix Quail egg	Contributes to maintaining normal immune responses to seasonal and environmental allergens.	Consult a relevant health care provider prior to use if: • you are pregnant or breastfeeding, or • your symptoms persist or worsen. Do not use if you have a (quail) egg allergy.	Minimum: 26,88 mg dried powder Maximum: 134,4 mg dried powder in 5 divided doses
Royal jelly ***Sources:*** *Apis mellifera - secretion* *(Dry, Powder, Non-Standardised Extracts (Dry extract, Tincture, Fluid extract, Decoction, Infusion)*	Antioxidant. Nutritive tonic.	Consult a relevant health care provider prior to use if you are- • pregnant or breastfeeding; or • allergic to bee products, poplar tree products, or balsam of Peru. *Contraindication(s):* Do not use this product if you have a history of asthma or allergies. *Known adverse reaction(s)* Stop use immediately if hypersensitivity/allergy occurs or if you experience irritation or swelling of the mouth or throat occurs.	*Antioxidant:* Not to exceed 6 g fresh royal jelly or the equivalent thereof per day. *Nutritive tonic:* 0,8 to 6 g fresh royal jelly, or the equivalent thereof per day.

ANNEXURE J

Allowable levels and claims: Carotenoids

The amendment of the following new entries:

Carotenoid	Health Supplement Claim	SPECIFIED WARNING(S)	Dosage	
			Minimum	Maximum
B. Carotenoids mainly used as Anti-oxidants				
Lutein *(3R,3'R,6'R)-beta,epsilon-Carotene-3,3'-diol* *(3R,3'R,6-R)-beta,epsilon-Carotene-3,3'-diol* *CI 75125* *E161(b)* *Mixed carotenoids (comprising xanthophylls and zeaxanthin)* *Vegetable lutein* *Vegetable luteol* *Xanthophylls*	Antioxidant for the maintenance of good health/eye health. Antioxidant that helps fight/protect (cell) against/reduce (the oxidative effect of/the oxidative damage caused by/cell damage caused by) free radicals.		*Annexure B submission required.*	~~6 mg~~ 20 mg
	For products providing at least 6 mg per day: Helps to maintain/support eyesight in certain conditions (associated with sunlight damage). Helps to improve macular pigment optical density.		6 mg	
Sources: *Oleoresin from the flower of marigold (Tagetes erecta L.(Asteraceae)); Arnica montana (Flower); Capsicum annuum (Fruit); Cucurbita pepo (Flower); Fucus vesiculosus (Whole); Oryza sativa (Whole plant); Pisum sativum (Whole plant); Solanum lycopersicum (Fruit); Tagetes erecta (Flower); Tagetes erecta (Herb flowering oleoresin); Tagetes erecta (Petal); Taraxacum officinale (Flower); Tussilago farfara (Flower); Viscum album (Leaf)*				
Lutein Esters ***Sources:*** *Oleoresin from the flower of marigold* *(Tagetes erecta L.(Asteraceae))*	~~*As for Lutein.*~~ Antioxidant for the maintenance of good health/eye health. Antioxidant that helps fight/protect (cell) against/reduce (the oxidative effect of/the oxidative damage caused by/cell damage caused by) free radicals.	~~*As for Lutein.*~~	~~*As for Lutein.*~~ *Annexure B submission required.*	40 mg
	For products providing at least 12 mg per day: Helps to maintain/support eyesight in certain conditions (associated with sunlight damage). Helps to improve macular pigment optical density.		12 mg	

ANNEXURE M

Allowable levels and claims: Saccharides

The inclusion of the following new entries:

Ingredient	Health Supplement Claim	Specified Warning(s)	Dosage
Glucomannan *(1-6)-alpha-D-gluco-D-mannan* *konjac* *manna* *mannoglucan* ***Sources:*** *Amorphophallus bulbifer* *Amorphophallus konjac* *Amorphophallus muelleri* Other sources: *Aloe species*	Promote(s) bowel movements by increasing bulk volume and water content. Provide(s) gentle relief of irregular bowel movements.	Not to be taken immediately before bedtime. Take with meals 2 hours before or after taking other medications Taking this product with insufficient liquid may result in choking and/or esophageal blockage/obstruction of the throat, esophagus or intestine. *Weight loss:* Do not use continuously for more than two (2) months without consulting your relevant health care provider. As a boxed warning: This product is not intended to prevent or treat obesity.	0,5 to 5 g 3 times per day The dosage form must not be a solid dosage form such as a capsule, pill or tablet.
	Contributes to the maintenance of normal blood cholesterol levels		Daily intake of 4 g of glucomannan. The claim may be used only for food which provides a daily intake of 4 g of glucomannan. In order to bear the claim information shall be given to the consumer that the beneficial effect is obtained with a daily intake of 4 g of glucomannan.
	May assist with weight loss when used with increased physical activity and an energy-reduced diet in healthy individuals.		Daily intake of 3 g of glucomannan in three doses of 1 g each, together with 1-2 glasses of water, before meals and in the context of an energy-restricted diet. The claim may be used only for food which contains 1 g of glucomannan per quantified portion. In order to bear the claim information shall be given to the consumer that the beneficial effect is obtained with a daily intake of

			3 g of glucomannan in three doses of 1 g each, together with 1-2 glasses of water, before meals and in the context of an energy-restricted diet.
Pectin/s *Citrus fruit/peel* ***Sources:*** May be derived from *Citrus aurantiifolia, Citrus limon, Citrus maxima, Citrus paradisi, Citrus reticulata, Citrus sinensis, Malus domestica.*	Demulcent. For the protection of irritated area in throat.	Stop use and ask / consult a relevant health care provider if sore throat symptoms worsen or persist for more than 2 days. Taking this product with insufficient liquid may result in choking and/or esophageal blockage/obstruction of the throat, esophagus or intestine.	Permitted in lozenges only.