

F. No. 43/Std/PA/FSSAI/2018
Food Safety and Standards Authority of India
(A Statutory Authority established under Food Safety and Standards Act, 2006)
(Standards Division)
FDA Bhawan, Kotla Road, New Delhi- 110002

Dated, the 5th November, 2019

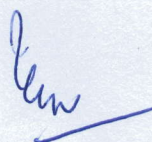
FORM-II

Subject: Appeal for the approval of 'Hintonia latiflora, multivitamins and minerals capsule' under Food Safety and Standards (Approval for Non-Specified Food and Food Ingredients) Regulations, 2017 - reg.

Application No:	F. No. 43/Std/PA/FSSAI/2018		
Date of application:	18.05.2018		
Name of organization:	M/s Ishaana Nutraceuticals Pvt. Ltd.		
Name of the applicant:	M/s Ishaana Nutraceuticals Pvt. Ltd.		
Registered office address:	M/s Ishaana Nutraceuticals Pvt. Ltd., G 47, 86 UPSIDC Industrial area, Selaqui, Dehradun - 248 011.		
Authorized person:	Sh. K. Devasenapathi		
Name of the product:	<i>Hintonia latiflora</i> , multivitamins and minerals capsule		
Product category:	13.5 (Dietetic foods)		
Composition:			
Ingredients	Food Additives		
<i>Hintonia latiflora</i> bark extract (standardized to polyphenol content 6-10% calculated as coutareagenin), Vitamin C, Vitamin E (as tocopherol acetate), Vitamin B1, Vitamin B2, Vitamin B6, Folic acid, Vitamin B12, Biotin, Zinc (Zinc sulphate), Chromium (Chromium picolinate)	Name	INS No	Limits (mg/Kg)
	Microcrystalline cellulose	460 (i)	-
	Hydroxypropyl methyl cellulose	464	-
	Starches, enzyme treated	1405	-
	Magnesium stearate	470 (iii)	-
	Talc	553(iii)	-
	Silicon dioxide, amorphous	551	-
	Carmoisine	122	-
	Titanium dioxide	171	-
	Tartrazine	102	-
	Brilliant blue FCF	133	-
Application status:	Approved		

1. Conditions for approval:

- (i) The appeal was examined and the product is approved under category of food for special dietary use to be taken under medical advise for dietary management of



impaired glucose tolerance. The target consumer group shall be restricted to Type II diabetes only. These information's shall be clearly depicted on the label.

(ii) The usage level of 'Hintonia latiflora bark extract' shall be 100 - 300 mg per day. The vitamins and minerals content shall comply with the relevant provision of the Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Food and Novel Food) Regulations, 2016 (herein after referred as Nutraceuticals regulations).

(iii) The label of the product shall comply with the relevant provisions applicable to the category of food for special dietary use specified under the Nutraceuticals regulations in addition to Food Safety and Standards (Packaging and labelling) Regulations, 2011.

(iv) The Food Business Operator shall, after grant of approval apply for license as per the procedure specified in the Food Safety and Standards (Licensing and Registration of Food Businesses) Regulations, 2011 and amendments thereof.

(v) If a Food Business Operator has reason to believe that the food for which the approval has been granted poses any risk to health, he shall immediately suspend the manufacture, import, sale, or distribution of such article of food and take steps to recall the same under intimation to Food Authority in accordance with the provisions of the Food Safety and Standards (Food Recall) Regulations, 2017.

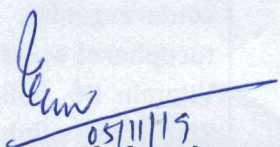
(vi) The Food Business Operator shall comply all the rules and regulations made under the Food Safety and Standards Act, 2006 and as amended from time to time.

(vii) The Food Authority may, for reasons to be recorded in writing, suspend or revoke approval granted as per regulation 4 (8) of Food Safety and Standards (Approval for Non-Specified Food and Food Ingredients) Regulations, 2017.

(viii) The Form II (Rejection letter) issued to this product vide letter dated 13.10.2018 (copy enclosed) stands withdrawn.

2. Reasons for rejection, if any: NA

This issues with the approval of the Competent Authority.


(Dr. Rubeeena Shaheen)
Director (Standards)
FSSAI, New Delhi.

डॉ. रूबीना शाहीन/Dr. RUBEENA SHAHEEN
निदेशक / Director
भारतीय खाद्य संरक्षा एवं मानक प्राधिकरण
Food Safety and Standards Authority of India
(स्वास्थ्य एवं परिवार कल्याण मंत्रालय)
(Ministry of Health & Family Welfare)
भारत सरकार/Government of India
एफ. डी. ए. भवन, कोटला रोड, नई दिल्ली-110002
FDA Bhavan, Kotla Road, New Delhi-110002

Copy to:

1. PPS to CP, FSSAI, FDA Bhavan, Kotla Road, New Delhi - 110002.
2. Sr. PS to CEO, FSSAI, FDA Bhavan, Kotla Road, New Delhi - 110002.
3. Director (Imports), FSSAI, FDA Bhavan, Kotla Road, New Delhi -110002.
4. Head (Regulatory Compliance), FSSAI, FDA Bhavan, Kotla Road, New Delhi -110002.
5. Commissioner of Food Safety, 4-Subhash Road, Secretariat, Dehradun, Uttarakhand - 248001.
6. Designated Officer, Food Safety and Standards Authority of India, 1st Floor, NBCC Place, Bismah Pitamah Marg, Pragati Vihar, New Delhi-110003.