

F. No. RCD-02004/7/2025-Regulatory-FSSAI [Comp. No. 15748]
Food Safety and Standards Authority of India
(A Statutory Authority established under the Food Safety & Standards Act, 2006)
(Regulatory Compliance Division)
FDA Bhawan, Kotla Road, New Delhi-110 002

Dated, the 15th October, 2026

Advisory

Subject: Mandatory Compliance with Labelling Requirements and Warning Statements for plant and botanical ingredients and their extracts - reg.

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, constitute a comprehensive regulatory framework designed to regulate the manufacture, sale and distribution of non-conventional food categories viz., Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, food with added prebiotic and probiotic ingredients, Functional Food and Novel Food in India.

2. These regulations stipulate compliance standards concerning the permissible limit *inter alia* of plant and botanical ingredients and their extracts either alone or in combination of ingredients. Furthermore, the regulation imposes rigorous labelling requirements, prohibiting any medicinal claims or suggestions of disease cure, and strictly limits the use of ingredients to those explicitly categorized under the designated schedules to ensure consumer safety and product efficacy within the ambit of the FSS Act, 2006.

3. It has been observed that several Food Business Operators (FBOs) engaged in the manufacture and sale of Nutraceuticals, Health Supplements, or food for special dietary use or food for special medical purpose etc., are not adhering to the mandatory labelling requirements and warning statements as prescribed under Schedule IV (List of plant or botanical ingredients) of the aforesaid regulations.

4. The Schedule IV of the said Regulations covers a vast array of botanical ingredients, many of which require specific cautionary labelling due to their physiological effects. Under these regulations, FSSAI mandates that warning statements must be prominent, legible, and clear to prevent misuse, especially by vulnerable populations. The regulations specify certain warnings for individual plants or extracts based on their known side effects or contraindications. For example, few disclaimers prescribed for individual botanical ingredients are illustrated below:

Botanical name	Common name/Plant Part name	Permitted range of usage for Adults per day (given in terms of raw herb/material) and Disclaimer/caution statement
Azadirachta indica A. Juss.	Nimba / Neem / Margosa -Leaf tree	1-3 g (as powder) (Not recommended for males and females planning to conceive)
Coleus forskohlii / C. aromaticus / C. barbatus (syn)	Gandiva / Pathachoor / Parn-yavani	3-5 g (as powder) (Not recommended for children below 5 years)

Euphorbia neriifolia/ E. pilosa / E. royalana / E. dracunculoides	Snuhi /Thuhar/ Sehund- Leaf	3-5 g (as fresh) (Not recommended for children below 5 years and pregnant women)
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5. A consolidated list of all such plant and botanical ingredients/extracts where mandatory declaration/cautionary statement required to be displayed when such plant/botanical ingredients or extracts are used has been prepared in consultation with Ministry of Ayush. The same is enclosed as Annexure I.

6. In view of the above, considering consumer safety and the prevention of misleading claims, manufacturers of health supplements, nutraceuticals, FSDU, FSMP are hereby directed to ensure mandatory labelling indicating plant part used and immediate compliance with the specific disclaimer/cautionary statement or warnings based on the nature of the ingredient as provided in respect of several individual plant/botanical ingredients as kept at Annexure I here under, and in compliance to provision under the Schedule IV [see regulations 3.(13), 4.(2), 6.(2)(i), 7.(2)(i), 7.(3)(v), 8.(2)(i), 9.(2)(i), 12.(1)(i), 12.(2), 12.(3)(i), 12.(3)(ii) and 12.(3)(iii)] of the aforesaid regulations.

Non-compliance to the statutory requirement as above constitutes violation of provision under section 23 of the FSS Act 2006 and shall attract stringent action under Section 52 of the FSS Act, 2006.

7. In furtherance, Food Business Operators are directed to review their labels and formulations to ensure that the products are in compliance with the provisions laid down under the FSS Act 2006 and the aforesaid regulations as amended from time to time. Failure to comply with these labelling mandates shall render the FBO liable for regulatory action, including suspension or cancellation of licenses and imposition of penalties under the provisions of the Food Safety and Standards Act, 2006.

This issues with the approval of Competent Authority.



Dr. Amit Sharma
Executive Director (Compliance Strategy)

Encl: As above

To:

1. All concerned Food Business Operators.
2. Commissioners of Food Safety of all States/UTs
3. ED (TICD) - for implementation on imported food products
4. Directors of all Regionals Offices, FSSAI
5. CTO, FSSAI - with a request for uploading on the FSSAI website

Copy for information to:

1. PPS to Chairperson, FSSAI
2. PS to CEO, FSSAI.
3. All Divisional Heads, FSSAI.

Annexure-I

List of plant or botanical ingredients and mandatory caution statement

Sr No.	Botanical name and part used	Official and common names	Permitted range of usage for adults per day (given in terms of raw herb/material)
1	Azadirachta indica A. Juss.		
	Leaf	Nimba / Neem / Margosa tree	1-3 g (as powder) (Not recommended for males and females planning to conceive)
	Fruit	Neem	1-2 g (as pulp) (Not recommended for males and females planning to conceive) (Not recommended for children below 5 years)
2	Carica papaya L.		
	Unripe fruit	Papita	30 -50 g (Not recommended during pregnancy)
	Leaf/Juice	Papita	5 – 10 g/ml (for decoction) (Not recommended during pregnancy)
3	Coccinia grandis (L.) Voigt. / C. indica / C. cardifolia (syn)		
	Leaf	Bimbi/Kundru phal / Kuntru shak	5-10 g (Not recommended for children below 5 years)
4	Coffea arabica / C. robusta		
	Seed (Dry/Green)	Kaaphi / Kahava / Coffee	3-5 g (Not recommended for children below 5 years)
5	Coleus forskohlii / C. aromaticus / C. barbatus (syn)		
	Root / Leaf / Whole plant	Gandiva / Pathachoor / Parn-yavani	3-5 g (as powder) (Not recommended for children below 5 years)
6	Daucus carota L.		
	Seed	Gajar	1-2 g (as powder) (Not recommended during pregnancy)
7	Euphorbia neriifolia/ E. pilosa / E. royalana / E. dracunculoides		
	Leaf	Snuhi / Thuhar / Sehund	3-5 g (as fresh) (Not recommended for children below 5 years and pregnant women)
8	Hibiscus rosasinensis L.		
	Flower	Japakusum/ Gudahal	1-3 g (as powder) (Not recommended during pregnancy)
9	Ipomia nil Linn. / Convolvulus nil Linn. / Convolvulus biobatus (syn)		
	Seed	Shankhini / Krishanbeej / Kaaladana	3-5 g (Not recommended in children below 5 years and pregnant women)
10	Lepidium sativum L.		
	Seed	Chandershoola / Chansur / Halon / Garden cress	3-6 g (as powder) (Not recommended during pregnancy)
11	Operculina turpethum / Ipomea turpethum (syn)		

	Root/Seed	Trivrat / Nishoth	1-3 g (Not recommended for children below 5 years)
12	Piper betle L.		
	Leaf	Tambula / Pana-patta / Paan	2-5 g (Not recommended for children below 5 years)
13	Plumbago zeylanica Linn. / P. indica		
	Root	Chitraka / Chitra-sfed / Lalpushp	1-2 g (as powder) after purification (Not recommended for children below 5 years and pregnant women)
14	Putranjiva roxburghii		
	Fruit seed kernel	Putrajivak / Jiya-pota	3-6 g (Not recommended for children below 5 years)
15	Rumex vesicarius L. / R. nepalensis / R. maritimus / R. acetosella		
	Leaf	Ambat chukka / Chukra	10-20 g (Not recommended for children below 5 years)
16	Trichosanthes bracteata Lam. / T. palmata Roxb. (syn)		
	Root / Fruit	Inder Vaaruni / Vishaalaa	0.5-1 g (as powder) (Not recommended for children below 5 years and pregnant women)