
October 15, 2026

FSSAI

FSSAI lists 16 botanicals that need caution statements on labels

An FSSAI advisory of October 15, 2026 directs makers of health supplements and nutraceuticals to label the plant part used and the listed caution statements.

THE FOOD SAFETY AND Standards Authority of India (FSSAI), Regulatory Compliance Division, FDA Bhawan, Kotla Road, New Delhi, issued an advisory dated October 15, 2026 under F. No. RCD-02004/7/2025-Regulatory-FSSAI [Comp. No. 15748]. Its subject is mandatory compliance with labeling

requirements and warning statements for plant and botanical ingredients and their extracts. It concerns 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.

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Advisory, F. No. RCD-02004/7/2025-Regulatory-FSSAI [Comp. No. 15748]

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The Food Safety and Standards Authority of India (FSSAI), Regulatory Compliance Division, FDA Bhawan, Kotla Road, New Delhi, issued an advisory dated October 15, 2026 under F. No. RCD-02004/7/2025-Regulatory-FSSAI [Comp. No. 15748]. Its subject is mandatory compliance with labeling requirements and warning statements for plant and botanical ingredients and their extracts. It concerns 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.

FSSAI states that it has observed several Food Business Operators (FBOs) making and selling nutraceuticals, health supplements, food for special dietary use or food for special medical purpose not adhering to the mandatory labeling requirements and warning statements prescribed under Schedule IV (List of plant or botanical ingredients) of those regulations. It says warning statements must be prominent, legible and clear to prevent misuse, especially by vulnerable populations. A consolidated list of the plant and botanical ingredients and extracts for which a declaration or cautionary statement must be displayed when they are used has been prepared in consultation with the Ministry of Ayush and is enclosed as Annexure I.

Manufacturers of health supplements, nutraceuticals, FSDU and FSMP are directed to ensure mandatory labeling indicating the plant part used, and immediate compliance with the specific disclaimer, cautionary statement or warnings set out in Annexure I, in compliance with 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)]. Annexure I lists 16 ingredients, from *Azadirachta indica* (neem) to *Trichosanthes bracteata*, each with the part used, official and common names, the permitted range of usage for adults per day in terms of raw herb or material, and a caution statement. The caution statements say an ingredient is not recommended for children below 5 years, during pregnancy or for pregnant women, or for males and females planning to conceive.

The advisory states that non-compliance violates section 23 of the Food Safety and Standards Act, 2006 and attracts stringent action under section 52. FBOs are directed to review their labels and formulations, and failure to comply makes them liable to regulatory action, including suspension or cancellation of licences and penalties under the Act. It is issued with the approval of the Competent Authority, signed by Dr. Amit Sharma, Executive Director (Compliance Strategy), and addressed to all concerned FBOs, the Commissioners of Food Safety of all States and UTs, ED (TICD) for implementation on imported food products, the Directors of all FSSAI Regional Offices, and the CTO, FSSAI, with a request to upload it on the FSSAI website.

The advisory asks for immediate compliance and gives no other date. It does not set a transition period, and it does not say how products already on sale or labels already printed are to be treated.

Issued by	Food Safety and Standards Authority of India (FSSAI), Regulatory Compliance Division
Document	Advisory, F. No. RCD-02004/7/2025-Regulatory-FSSAI [Comp. No. 15748]
Dated	October 15, 2026
Applies to	Manufacturers of health supplements, nutraceuticals, food for special dietary use (FSDU) and food for special medical purpose (FSMP)
Regulations	Schedule IV 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
Labels must show	The plant part used, and the caution statement given for the ingredient in Annexure I
Ingredients listed	16, in Annexure I, prepared in consultation with the Ministry of Ayush
Takes effect	Immediate compliance; no other date or transition period stated
Imported food	Addressed to ED (TICD) for implementation on imported food products
Non-compliance	Violation of section 23 and action under section 52, Food Safety and Standards Act, 2006; suspension or cancellation of licences and penalties
Signed by	Dr. Amit Sharma, Executive Director (Compliance Strategy)

Annexure I: plant or botanical ingredients and mandatory caution statement

Sr. No.	Botanical name (part used)	Official and common names	Permitted range for adults per day (raw herb/material)	Caution statement
1	Azadirachta indica A. Juss. (Leaf)	Nimba / Neem / Margosa tree	1-3 g (as powder)	Not recommended for males and females planning to conceive
1	Azadirachta indica A. Juss. (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

2	<i>Carica papaya</i> L. (Leaf/Juice)	Papita	5-10 g/ml (for decoction)	Not recommended during pregnancy
3	<i>Coccinia grandis</i> (L.) Voigt. / <i>C. indica</i> / <i>C. cardifolia</i> (syn) (Leaf)	Bimbi / Kundru phal / Kuntru shak	5-10 g	Not recommended for children below 5 years
4	<i>Coffea arabica</i> / <i>C. robusta</i> (Seed, dry/green)	Kaaphi / Kahava / Coffee	3-5 g	Not recommended for children below 5 years
5	<i>Coleus forskohlii</i> / <i>C. aromaticus</i> / <i>C. barbatus</i> (syn) (Root / Leaf / Whole plant)	Gandiva / Pathachoor / Parn-yavani	3-5 g (as powder)	Not recommended for children below 5 years
6	<i>Daucus carota</i> L (Seed)	Gajar	1-2 g (as powder)	Not recommended during pregnancy
7	<i>Euphorbia neriifolia</i> / <i>E. pilosa</i> / <i>E. royalana</i> / <i>E. dracunculoides</i> (Leaf)	Snuhi / Thuhar / Sehund	3-5 g (as fresh)	Not recommended for children below 5 years and pregnant women
8	<i>Hibiscus rosasinensis</i> L. (Flower)	Japakusum / Gudahal	1-3 g (as powder)	Not recommended during pregnancy
9	<i>Ipomia nil</i> Linn. / <i>Convolvulus nil</i> Linn. / <i>Convolvulus biobatus</i> (syn) (Seed)	Shankhini / Krishanbeej / Kaaladana	3-5 g	Not recommended in children below 5 years and pregnant women
10	<i>Lepidium sativum</i> L. (Seed)	Chandershoola / Chansur / Halon / Garden cress	3-6 g (as powder)	Not recommended during pregnancy
11	<i>Operculina turpethum</i> / <i>Ipomea turpethum</i> (syn) (Root/Seed)	Trivrat / Nishoth	1-3 g	Not recommended for children below 5 years
12	<i>Piper betle</i> L. (Leaf)	Tambula / Panapatta / Paan	2-5 g	Not recommended for children below 5 years
13	<i>Plumbago zeylanica</i> Linn. / <i>P. indica</i> (Root)	Chitraka / Chitrasfed / Lalpushp	1-2 g (as powder) after purification	Not recommended for children below 5 years and pregnant women
14	<i>Putranjiva roxburghii</i> (Fruit seed kernel)	Putrajivak / Jiya-pota	3-6 g	Not recommended for children below 5 years
15	<i>Rumex vesicarius</i> L. / <i>R. nepalensis</i> / <i>R. maritimus</i> / <i>R. acetosella</i> (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
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[The advisory](#) (PDF, 1.7 MB)

Source: [FSSAI's own copy](#).

Checked against the official copy on October 22, 2026.

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