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FSSAI clarifies regulations on Methylcobalamin usage in health supplements



New Delhi, Jan 11 (UNI) The Food Safety and Standards Authority of India (FSSAI) has provided clarity on the regulatory framework surrounding the use of methylcobalamin, a form of Vitamin B12, in health supplements, medical purpose and nutraceutical products.

The Union Health Ministry's decision to lift the ban on methylcobalamin, a critical vitamin B12 derivative, is yet to be formalized, leaving its regulatory status in limbo despite scientific backing and growing demand for its use in treating conditions such as diabetic neuropathy.

While the Government of India's Scientific Committee approved the molecule's safety in 2019, the necessary gazette notification to officially lift the ban is still pending, raising concerns among health professionals and industry stakeholders.

Dr Sanjay Agrawal ,Scientific Advisor of ALKOMEX GBN U.S.A. and Leading Pharmaceutical Consultant and Inventor Ahmedabad , emphasized, "As per the Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, and Prebiotic and Probiotic Food) Regulations, 2022, the permitted forms of Vitamin B12 currently include cyanocobalamin and hydroxocobalamin. However, methylcobalamin may also be permitted under certain conditions, provided that food business operators notify the Food Authority and submit any additional safety data requested."

The regulations also stipulate that the level of Vitamin B12 in products must not exceed one Recommended Dietary Allowance (RDA) except in specific categories such as Food for Special Medical Purposes (FSMP) and Food for Special Dietary Use (FSDU). In such cases, prior approval from the Food Authority is required for levels exceeding the RDA.

Most of Indian population is deficient of methylcobalamin due to a number of factors, most important is vegetarian population is more in Indian than non veg.

Methylcobalamin is frequently available in non veg. than veg sources . Best source is milk and milk products states, Dr Sanjay Agrawal said.

Vitamin B12, a crucial water-soluble vitamin, is integral to DNA synthesis, red blood cell production, and neurological function. It is predominantly found in animal-based foods like meat, fish, and dairy products, with plant-based foods providing little to none. Deficiency in this vitamin can lead to serious health consequences, often requiring supplementation.

"Methylcobalamin, an active form of vitamin B12, is the most bioavailable and therapeutically effective form. Unlike cyanocobalamin, which requires biotransformation, methylcobalamin is readily absorbed and utilized by the body, making it a preferred choice for supplementation," says Dr Agrawal.

Dr. Agrawal added, "This development highlights Government's focus on balancing innovation in the nutraceutical sector with consumer safety. It is crucial for food business operators to remain compliant and ensure transparency in the use of derivatives and salts of vitamins in their formulations."

The statement comes in response to an official letter issued by the Secretariat of FSSAI's Expert Committee on Nutraceuticals, addressing industry concerns about the inclusion of methylcobalamin under the regulations.

This clarification is likely to guide manufacturers and stakeholders in aligning their products with regulatory standards while addressing the growing demand for diverse forms of Vitamin B12 in health supplements.

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