Drug industry cheers FSSAI's removal of the ban on Methylcobalamin.

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Methylcobalamin is an essential nutrient to regulate vital bodily functions like cell multiplication, blood formation, and protein synthesis.
Despite the ban, products containing Methylcobalamin were available on the market.

Taking serious note of this, Dr. Sanjay Agrawal, a leading pharmaceutical consultant, had written to FSSAI time and again seeking clarification from it on the easy availability of Methylcobalamin in the absence of the authority's gazette notification on the removal of
ban on the product.

In replying to his grievance, FSSAI had earlier this week clarified that all vitamin B12 derivatives, including Methylcobalamin, are allowed for products falling under FSS Regulations, 2016, through amendments three months back.

The authority stated that, however, the usage level should not exceed one recommended dietary value (RDA) (except in the case of Food for Special Medical Purpose (FSMP) and Foods for Special Dietary Uses (FSDU), where beyond RDA requires prior approval of the authority).

Hailing the FSSAI's notification lifting the ban on Methylcobalamin, Dr. Agrawal said, "This has brought much-needed respite to drug makers engaged in manufacturing Methylcobalamin. Since 2019, we have been waiting for the updated gazette." However, the authority's approved RDA for Methylcobalamin (1mcg) has drawn flak from healthcare experts.

Dr. Agrawal, stated that "Source of vitamin B12 is primarily non -vegetarian food. In the whole world, the RDA is 2.4 mcg. In India, where the population is predominantly vegetarian, RDA is defined as one mcg.

Studies on Methylcobalamin for therapy and prophylactic use in neurological disorders contradict FSSAI's RDA value of Methylcobalamin. Scientific studies have observed that Methylcobalamin should be taken at the dose of 500 mcg per day for an individual to lead an everyday life.

In acute cases of neuropathy, a dose of 1,500 mcg per day can be safely taken. A dose of 1 mg per day is required to be taken for age-related brain decay."

He demanded that FSSAI send a notification approving RDA of Methylcobalamin up to 500 mcg for prophylactic use. He also took exception to FSSAI's approval of high doses of Methylcobalamin surpassing its RDA of 1 mcg. He cited a product on the market named Nezexa tablet, including Methylcobalamin 1500 mcg, which FSSAI duly approves.

The pharmaceutical consultant has dashed a letter to FSSAI expressing concern over products containing

Methylcobalamin being approved by it exceeding its RDA value. The concerned division in FSSAI is looking into the issue, stated the authorities in communication with him.