

FSSAI lifts ban on Methycobalamin

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By Rajendra Diwe :

The Vitamin B12 was banned since 2016

After a long debate of over five years on the use of Methycobalamin, commonly known as Vitamin B12, the Food Safety and Standard Authority of India (FSSAI) has removed the ban on it. FSSAI has recently mentioned that it has listed all Vitamin B12 derivatives, including Methycobalamin, under Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Foods and Novel Foods) Regulations, 2016 through amendments gazette notified on September 16, 2021. According to e-pharmail, FSSAI had banned Methycobalamin through the gazette passed in 2016. The product was later approved by the scientific committee of FSSAI in December 2019 based on scientific evidence of its safe use, but the amended gazette was not issued in this regard thus putting drug-makers in a bind.

Methycobalamin is an essential nutrient to regulate certain vital bodily functions like cell multiplication, blood formation and protein synthesis. Despite the ban, the products containing Methycobalamin were available in the market. Taking a serious note of this, Dr Sanjay Agrawal, a leading pharmaceutical consultant, had written to FSSAI time and again seeking clarification from it on easy availability of Methycobalamin in absence of the authority's gazette notification on removal of ban on the product. Replying to his grievance, FSSAI had earlier this week clarified that all Vitamin B12 derivatives, including Methycobalamin, are allowed for products falling under FSS Regulations, 2016 through amendments three months back. Later, the pharmaceutical industry has sought intervention of Union minister of health and family welfare Mansukh Mandaviya in notifying removal of ban on Methycobalamin, commonly known as vitamin B12.

What are types of Vitamin B12 Four common chemical forms of Vitamin B12: Methycobalamin ; Adenosylcobalamin; Cyanocobalamin; Hydroxocobalamin are the four common chemical forms of Vitamin B12. Methycobalamin and Adenosylcobalamin are both naturally occurring co-enzymes which are found in food sources. They work synergistically in slightly different ways to cover most of Vitamin B12 needs. Cyanocobalamin is a synthetic form of Vitamin B12 which the body converts into Adenosylcobalamin and Methycobalamin before it can be used. The most common and cost-effective form of Vitamin B12, Cyanocobalamin is most often found in supplements and some fortified foods. Hydroxocobalamin is a highly bioavailable form of Vitamin B12 that is used to treat people with a serious deficiency. It's only available on prescription and is usually administered by intramuscular shot or in an IV drip. On the issue of recommended dietary allowance, FSSAI had banned methycobalamin in 2016.