

QualPharma

FSSAI SPEECHLESS

Lack of clarity on upper tolerable limit (TUL) and recommended dietary allowance (RDA) standards

India : Design (Amendment) Rules, 2021

*Why filtration is
critical process?*

Inflammation

**DNA Fingerprinting
Technology Helpful in
Tracking Rapists**

*International
Yoga Day
June 21*

S.K. SINGH

**Managing Director
Cachet Pharmaceuticals Private Limited**

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FSSAI SPEECHLESS

Lack of clarity on upper tolerable limit (TUL) and recommended dietary allowance (RDA) standards

Food Safety and Standards Authority of India (FSSAI), the only regulatory Indian authority to regulate food and nutraceuticals, has banned methylcobalamin through the Gazette passed in 2016 vide **F.No 1-4/Nutraceuticals/FSSAI-2003** with Subject- **Direction under section 16[5] of Food Safety and Standards Act 2006 regarding operationalisation of standards of Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Food and Novel food. Methylcobalamin, commonly known as Vitamin B12**, is an essential nutrient to regulate certain vital bodily functions like cell multiplication, blood formation, and protein synthesis. Most of the manufacturers are continuously manufacturing the said product which proves the inefficiency of FSSAI. Some of the widely sold

brands approved by FSSAI and available in the drug retail supply chain are **Health Aid's** vitamin B12 (methylcobalamin) 1500 micro gram (mcg), **Nature Made's** vitamin B12-1000 mcg, B-12 dots by **Twinlab-500 mcg**, **Jarrow Formula's** methyl B-12-1000 mcg, **Nature bounty's** vitamin B-12 1000 mcg, **Source natural's** methylcobalamin vitamin B12-5000 mcg, **Solgar sublingual's** methylcobalamin supplement-1000 mcg, **Cobaforte CD3** plus tablet-1500 mcg, **Nocob** methylcobalamin 1500 mcg among others.

The easy availability of methylcobalamin far beyond the RDA which is continuously referred by FSSAI in its mail leads the experts in dilemma to conclude whether Methylcobalamin is approved or not and if the RDA is applicable to methylcobalamin or not. Considering Methylcobalamin is

banned, how thousands of brands of methylcobalamin are available in market? And if considering methylcobalmin is not banned the question arises, why approval status is not mentioned in the gazette.

When QualPharma experts have asked FSSAI ex-CEO Mr Pawan Agarwal in 2019, he committed that Methylcobalamin will be included in the gazette within due course of time. It has been almost one and a half year but the process has not been initiated yet. During this time the FSSAI has been drawing flak from the industry and experts over laxity in enforcement of compliances due to poor regulatory oversight, lack of clarity on upper tolerable limit (TUL) and recommended dietary allowance (RDA) standards. This has prompted manufacturers to produce methylcobalamin above permissible limits.



Dr Sanjay Agrawal

Dr Sanjay Agrawal founded PHARMA CONSULTANTS and INVENTOR in 2005 to assist pharmaceutical companies around the globe. He has actively worked in pharmaceutical and related industries for more than 28 years. He is Editor-in-Chief of renowned IJM Today and honorable member of the editorial board of QualPharma and The Antiseptic. Dr Sanjay Agrawal is also the illustrious member of the National Geographic Society and ex- member of scientific committee of IDMA. His prestigious articles are published in various magazines and websites for example—The Antiseptic, NuFFoods Spectrum, Pharmabiz

Dr. Agrawal had received various awards for his valuable support and contributions in healthcare and pharmaceutical sector .Dr. Agrawal obtained his postgraduation in Biochemistry from prestigious institution, completed MBBS and MBA from IMT. He has

worked with many international and national Pharmaceutical company. Dr. Sanjay Agrawal is the patent holder of many research formulations which are successfully commercialized.

Currently besides his core jobs, Dr Agrawal devotes his time for the benefit of pharma fraternity. He has raised his voice against the ban imposed on methylcobalamin manufacturing. He has been asking to the regulators from more than a year about

- Why Methylcobalamin is not added in the gazette yet when promised by the former CEO Mr Pawan Agrawal Ji?
- Why cyanocobalamin is promoted even though there is a cyanide group attached to it?
- Why 1 mcg RDA is imposed on nutraceutical manufacturer?
- Technical aspect of damage caused when 500 mcg is taken as prophylactic use?
- Why should we have faith in FSSAI when every time we have to go to ICMR for clarification?

The industry has also alerted the Centre towards streamlining the drug regulatory regime related to regulating nutraceuticals as several brands containing ingredients above permissible limits have entered the drug retail supply chain evading Indian Council of Medical Research (ICMR) prescribed RDA values. These brands have been evading the RDA values of ICMR and despite being approved under the FSSAI license are being used as drugs for therapy purposes.

Amidst the grave scenario, regulatory experts have therefore written to the Centre that nutraceuticals which are meant for the prevention of disease must be brought under the ambit of the Drugs Controller General of India (DCGI). They recommend DCGI as being more technically sound as compared to the FSSAI. Methylcobalamin is widely marketed in the country as a drug for chronic neurological disorders with a recommended dietary allowance of 2000 microgram (mcg) intramuscular but as per the FSSAI, it is detrimental for patients when

used above 1 mcg for prevention and disease management.

But industry experts rue that still FSSAI talks about adhering to ICMR stipulated RDA values. Pharmaceutical industry had earlier written to the union ministry of chemicals and fertilisers seeking clarity on methylcobalamin ban while giving reference about FSSAI approving brands having methylcobalamin for therapeutic use despite a ban.

According to the letter, "Even if we consider methylcobalamin is banned but we have been continuously communicated in mails by the officials of FSSAI that RDA value of methylcobalamin is 1 mcg. It has to be noted that researchers have claimed that the source of vitamin B12 is mostly non - vegetarian food. Globally, the RDA value is 2.4 mcg. In India where the population is mostly vegetarian, on the contrary, RDA is defined as 1 mcg. We have the full right to know from the regulators where this scientific value has come from. Since, me-

thylcobalamin has not been included in the gazette notification, why FSSAI is talking about RDA value. However, FSSAI has asked us to question the ICMR about this concern. We have been recommending that FSSAI must discuss with ICMR and explain to us the reason for keeping RDA value at 1 mcg."

In a recent letter issued to the Union ministry of chemicals and fertilisers, the industry has drawn the attention to the industry's consistent efforts to seek clarity of the ban on methylcobalamin and about defining its arbitrary RDA values by ICMR and approved by FSSAI, as mentioned in correspondences or emails shared with the concerned divisions of ICMR and FSSAI dated December 17, 2020, dated November 2, 2020, dated October 7, 2020, dated September 26, 2020, and dated September 16, 2020.

The FSSAI is Speechless.

~By Dr. Sanjay Agrawal

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Innovation is truth of Science

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