



# INDIAN DRUG MANUFACTURERS' ASSOCIATION

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## **PARTNERS IN GLOBAL HEALTHCARE**

10<sup>th</sup> December, 2013

**Shri Keshav Desiraju, IAS,**

Secretary to the Government of India,  
Ministry of Health & Family Welfare,  
Nirman Bhavan,  
New Delhi.

Dear Sir,

We thank you for giving us an audience and patiently understanding the difficulties faced by manufacturers of nutraceuticals when the undersigned visited your office on 2nd Dec 2013. The FSSAI encompasses regulations for foods and allied products as well. Unfortunately nutraceuticals have been regulated with same yardstick as normal foods although these are strictly health supplements.

Under the Canadian law, nutraceutical refers to 'a product isolated or purified from foods that are generally sold in medicinal forms not usually associated with foods. A **Nutraceutical is demonstrated to have a physiological benefit or provide protections against chronic diseases.**' In US the new nutraceutical bill establishes these products as a separate category falling in between drugs and dietary supplements like vitamins and minerals. Unfortunately, the FSSAI has not recognized the nature and function of nutraceuticals and through advisories attempted to put restrictions on the amounts vitamins / minerals, at levels which are applicable for ordinary foods, without appropriate regulations being in place. Besides FSSAI is insisting on individual product approval even for nutraceutical products manufactured & sold in India for a number of years. Moreover, the Product Approval system per se is beyond the current purview of the Act

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and yet being insisted upon. Also uncalled for advisories are being issued which actually dictate new standards / changes in formula etc without any legal sanctity.

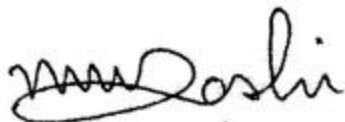
The whole scenario currently prevailing is of total confusion and the frustrated nutraceutical manufacturers are totally driven to the fence and fear closure of their businesses primarily because of arbitrariness in the functioning of FSSAI and ill-knowledge of nutraceuticals. Even the huge amounts collected for Product Approval and (also) Scientific Panel evaluation besides by Zonal licensing centers (per product) are not been provided for in the Act!

We had been thus left with no choice but to seek your assistance and intervention.

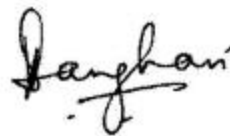
This is to intimate your good office that after making several representations at various levels of FSSAI without any success or interest for harmony between FSSAI & Food Industry, we in the meantime, the members of the association, fearing threat to their livelihood, in view of fast approaching timeline of Feb 2014 have enforced upon the association to join the Writ Petition for quashing the advisories which are unlawful when dictating changes in product, etc and also a plea for maintaining status quo till new regulations are in place for nutraceuticals.

We hope, you understand the grave situation which has lead to legal recourse.

Thanking you,



Manish U Doshi  
*President*



Dr R K Sanghavi  
*Chairman, Nutraceutical Subcommittee*