



INDIAN DRUG MANUFACTURERS' ASSOCIATION

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PARTNERS IN GLOBAL HEALTHCARE 29th April 2013

The Director,
FOOD SAFETY AND STANDARDS AUTHORITY OF INDIA,
FDA Bhawan; Near Bal Bhavan,
Kotla Road, New Delhi - 110 002

Subject: Health Food Supplements / Dietary Supplements / Proprietary
Health Supplements / Nutraceutical Supplements under Food
Safety and Standard Act 2006, Rules & Regulation 2011 -
Licensing of FBOs

Dear Sir,

The registration of Dietary/Health Food/Proprietary Health/Nutraceutical Supplements product-wise was initiated vide the new Food Safety and Standards Rules, 2011 (gazetted on 5th May 2011 & effective from 5th August 2011). We were happy to note that a new act is being put in place of the erstwhile PFA (Prevention of Food Adulteration) Act with an intend to streamline licensing and permissions for the benefit of the rapidly growing nutraceutical sector.

In this regard we would request you not to insist on product approval prior to grant of manufacturing site licensing. This is because most current Food Business Operators (FBOs) are in business since years and it has hampered the smooth conduct of their operations besides having hindered smooth transition from PFA to FSSAI regime. The FBOs already in operations should be immediately granted FSSAI license pending submission of necessary documents required to clear their manufacturing sites considering the strong pre-existence/history of such products which itself provide the evidence of safe consumption.

We look forward to your favorable intervention in this regard and hope to provide a sigh of relief to the countless FBOs who are suppliers of nutritionals and nutraceuticals to a large consume segment and benefitting their health.

Thanking you

DR R K SANGHAVI
Chairman, Nutraceutical Subcommittee

Mr MANISH DOSHI
President

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