INDIAN DRUG MANUFACTURERS' ASSOCIATION

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PARTNERS IN GLOBAL HEALTHCARE

October 30, 2013

The Chief Executive Officer
Food Safety and Standards Authority of India
Food and Drug Administration Bhawan
Kotla Road, Near Bal Bhawan
New Delhi 110002

Dear Sir,

Sub: Suggestions on draft Food Safety and Standards (Licensing and Registration of Food Business) amendment Regulations, 2013 Dated: 10-10-2013.

Ref: Notification No. 2-15015 /30/2012 dated 12th August, 2013

We, the Nutraceutical Subcommittee of Indian Drug Manufacturers' Association (IDMA), are dedicated to the growth of the healthcare industry in India. IDMA represents a large number of Indian companies operating in the healthcare space and our member companies are, inter alia, engaged in the manufacture and marketing of pharmaceuticals, cosmetics, foods for special dietary uses, nutraceuticals, functional foods, dietary supplements, etc.

Although the Food Safety and Standards Act, 2006, was brought into force in August, 2010, the Licensing Regulations came into force effective 05th August, 2011. The Licensing Regulations vide first proviso to Regulation 2.1.2 provided for one year time period for conversion of existing licenses under the Prevention of Food Adulteration (PFA) Act to Food Safety Standards Authority (FSSA) license or apply for licenses under FSSA by the food business operators (FBOs).

We, on behalf of our member food business operators, sincerely thank you for considering to issue a formal valid notification for the extension of time limit to convert PFA licenses into FSSA licenses by 30 months i.e. upto 04th February, 2014. However, the time limit of 30 months is insufficient and in the current scenario the FBOs will require at least 48 months i.e. upto 04th August, 2015 for seeking conversion of licenses for all their products for the following reasons:

A. Many of the manufacturers of the foods for special dietary uses, nutraceuticals, functional foods, dietary supplements, etc. had applied for licenses in accordance with

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the Licensing Regulations from August 2011 onwards, by paying the prescribed fees. However, due to ambiguous and uncertain procedural requirements introduced from time to time, many of the applications were kept pending or not even accepted for processing by the Food Safety Standards Authority of India (FSSAI). Due to this scenario, many of the FBOs have been operating under the existing licenses and still awaiting clarity on the approach followed by FSSAI in processing their applications.

B. Since the introduction of the FSSAI Licensing Regulations, there have been various changes to the procedures (including release of more than 8 advisories at periodical intervals), issuance of Indian food code and even certain directions issued to the Licensing Authorities, which has resulted in uncertainty and lack of uniform and inconsistent approach in processing the applications filed by the FBOs.

C. Unfortunately, due to these uncertainties, growth of the dietary supplement & nutraceutical industry has significantly been impacted. We strongly apprehend that a large number of applications cannot be processed in next 3 months and this would cripple the operations of the FBOs and to the extent that many of them closing down their well established businesses for no fault of theirs. Further, essential health supplements, dietary supplements etc will be out of shelves resulting in serious nutritional deficiencies and health concerns in consumers dependant on these products.

It is thus desired that the time period specified for conversion of licenses in the first proviso to Regulation 2.1.2 be increased to at least 48 months (instead of 30 months) and facilitate industry working in this difficult period.

Thanking you

MANISH DOSHI
President

DR R K SANGHAVI
Chairman, Nutraceutical Subcommittee