INDIAN DRUG MANUFACTURERS' ASSOCIATION

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INDIAN PHARMACEUTICALS FOR GLOBAL HEALTH

25th May 2015

Mr. B. P. Sharma, IAS
Health Secretary
MINISTRY OF HEALTH & FAMILY WELFARE
Government of India,
Nirman Bhawan; C-Wing
New Delhi 110 011

22/06

Subject: FSSAI – Recall of Health Supplements not given Product Approval / NOC or files closed

Dear Sir,

Greetings from Indian Drug Manufacturers' Association.

It was indeed courteous to meet us on 19thMay 2015 with urgent and pressing matters pertaining to Food Safety and Standards Authority of India (FSSAI) recent order and actions leading to / intending to make age-old Health Supplements removal from shelves.

As you are aware, the FSSAI has recently banned near 200 products and closed files of over 800 products applied for permitting for manufacturing and marketing. The list was put up on website and most manufacturers have not even received their individual communication with respect to the changed status of their product, previously allowed or being marketed. Further, the FSSAI's enforcement cell has issued a circular dated 21st April 2015 (but pasted on their website on 14th May 2015) Ref No: File No. 1(2)2011/States/FSSAI/Vol.I instructing Food Safety Commissioners of various states to take necessary action against all banned / files closed products and their manufacturers whose stocks are yet available on shelves.

O/C

Such a drastic action can lead to utter chaos with regards to availability of Health Supplements – many of which are internationally available to in the same avatar by multinationals, and being consumed by the Indians for decades, albeit safely.

1. The products whose permission to manufacture and market has not been granted are containing known ingredients and hence harmless.
2. The products banned (or their files closed) have already been re-applied by most Food Business Operators (FBOs) with necessary corrections in their composition and awaiting final positive nod from the FSSAI (some for even a couple of years). Hence, the most of the currently available products are already modified in compliance and hence safe.

3. All the concerned products are in market place for years (and even decades) and no apparent adverse reactions to any specific has yet been reported.
4. Even the FSS Act provides for smooth transition of ALL already permitted / marketed products under the erstwhile Prevention of Food Adulteration (PFA) Act to the new FSSAI licensing. This is based on implied evidence that already being safely consumed do not require scrutiny for their safety.
5. None of the product rejected or files closed product has any ingredient or quantity contrary to what is available as Over-The-Counter (OTC) globally. Hence, there is never a real scare of any safety concern in their continuing to be marketed and consumed.

The matter regarding Product Approval being arbitrary and outside the purview of the Act, is yet to be decided upon in the Supreme Court and hence for such under consideration delicate subject, such hasty steps by FSSAI was not required.

Also as per your information the new regulations pertaining to Section 22 covering Health Supplements, Nutraceuticals, etc. is scheduled to be hosted on the web within 2 weeks. When such a draft is already available, we are unable to comprehend why FSSAI develop their own yardstick to gauge product safety and efficacy by imposing the arbitrary and outside the FSS Act purview Product Approval System.

Further, by putting up brand names of products rejected on the open web site the FSSAI has irreparably damaged even age-old trusted brands leading to loss of brand value and irrecoverable potential future losses in sales for FBOs.

We earnestly plead that the FSSAI's recent move to instruct Food Commissioners of various states to take appropriate steps against products rejected / files closed is put on hold. There is an urgent need to force no coercive action in this matter pending the Supreme Court outcome or gazette of the New Regulations pertaining to Section 22 of the FSS Act.

Thanking you,

S V VEERAMANI
President

DR R K SANGHAVI
Chairman, Medical Subcommittee