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Apex court ruling on FSSAI order brings some relief to food, drug firms

OUR BUREAU

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A recent Supreme Court ruling has brought some relief to food and nutraceutical companies that were unable to sell their products due to a "product approval process" introduced by the food safety regulator.

Last week, the apex court quashed a product approval advisory from the Food Safety and Standards Authority of India (FSSAI) that required food companies to seek approval on a broad spectrum of products, including those already available/being consumed.

With the court rendering the product approval system (of May 2013) "defunct" (except on new products) companies will be able to bring products that had been held up due to delays in the approval process back into the market indicated RK Sanghavi, Chairman, Indian Drug Manufacturers' Association's nutraceuticals sub-panel.

Several products, including

Ranbaxy's Revital (now owned by Sun Pharma), 'had been caught in this net and are now back in the market. Packaged food manufacturers are however, wary, preferring to wait for more clarity before bringing their products back.

The Supreme Court had upheld the judgment of the Bombay High Court (about a year ago) that had disposed of a Special Leave Petition filed by the FSSAL

The Bombay High Court, in its August order, had said that the advisory had no force of law and that the FSSAI had no power to issue an advisory without it being ratified by Parliament. The issue had been brought to the court by Vital Neutraceuticals.

The industry had been knocking on FSSAI's doors for about two years, said IDMA's Daara Patel. The apex court's order will allow health supplements, nutraceuticals and so on to enter the market in line with globally prevalent practices, he said. Industry representatives, however, said that a recently issued draft of the FSS Act (2006) would bring in more clarity as it defined the different product categories and the claims they can make.

Products outlined in the guidelines issued late last month indicate that the product cannot claim medicinal properties. In fact, the guidelines list several ingredients, allowing firms easy access to the market if they contain them in combinations and quantities outlined in the rules. Only new products not mentioned here will require formal product approval.

This was a globally-accepted system, IDMA representatives said, adding that the consumer was protected by provisions already available in the law. Besides, safety has nothing to do with product approvals on paper, they said, adding that it depended on the FSSAI lifting samples from the market and testing them for their quality and safety.

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