POLICY FOR NUTRACEUTICALS TO BE OUT BY DECEMBER, 2009

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The Food Safety and Standards Authority of India (**"FSSAI"**) plans to introduce the policy on Nutraceuticals in India by December 2009. Nutraceuticals are dietary supplements meant to fill nutritional deficiencies in food and are divided into functional foods, functional beverages and mineral supplements. Currently, nutraceuticals and food supplements are neither classified as food nor as drug for licensing purposes in India .

PSA view – Though nutraceuticals have been in the market for almost a decade in India , there was no regulatory system or monitoring process in place for them. Lack of effective regulations resulted in unsubstantiated medical and legal claims and confusion in the minds of stakeholders. With the introduction of the Nutraceutical policy, the hitherto unregulated area will certainly benefit the pharma companies, the nutraceutical market, and most of all the consumers.

Legal barrier to centralization of WHO certification *(In continuation of August Flash item)*

The DCGI's initiation to centralize WHO certification has ran into legal roadblocks. As many as five stay orders have been passed by the High Court of Chennai and Karnataka. DCGI's move has been held to be detrimental by manufacturers on the ground it will involve inspection of over 5,000 drug manufacturing units spread across India by approximately 20 central drug inspectors. Their argument is DCGI is the authority for approval of new drugs and clinical trials and, as such, can not extend its authority to licensing drugs manufacture.

PSA view – Since the WHO-GMP requirements demands issuance of certification from a competent national authority, the plea taken by exporters is not sustainable. Further, as the WHO has refused to recognize the certification granted by state licensing authorities, it is in the interest of drug manufacturers/exporters to accept the change. The DCGI has planned to increase its staff strength to over 200 by end of 2010 and take other necessary actions. Certainly, steps will be and should be taken by the DCGI to assure manufacturers/exporters of its ability to undertake this task efficiently without causing difficulty to them.

Implementation of Food Safety and Standards Act

FSSAI has announced that the Food and Safety Standards Act, 2006 (**"Act"**) shall come into effect in entirety from January 2010. Certain sections of the Act were already in force (*See September Flash*). The Act was enacted to consolidate laws relating to food and to establish a statutory regulator to regulate manufacture, storage, distribution, sale, and import of food, and to ensure availability of safe and wholesome

food for human consumption.

PSA view – Since its establishment in September 2008, FSSAI has taken several measures to ensure transition from Prevention of Food Adulteration Act, 1954 and Rules 1955 to the new regulatory regime. According to the paper by Public Health Foundation of India, 80% of all deaths in India are attributable to food and water. As food safety had never been the primary area of attention of the authorities, FSSAI is committed to address this issue at the grass-root level. Moreover, with nutraceuticals, proprietary foods, and genetically modified foods entering the Indian market, a system to regulate such new range of food becomes vital which FSSAI will do.

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