Regulatory requirements for registration of Nutritional supplements and Herbal products in India: A case study

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US-FDA regulates finished dietary supplement products and dietary ingredients under the Dietary Supplement Health and Education Act of 1994 (DSHEA). The Directive 2002/46/EC of the European Parliament and Council of 10th June 2002 established harmonized rules for the labeling of food supplements and introduced specific rules on vitamins and minerals in food supplements. The aim was to harmonize the legislation and to ensure that these products are safe and appropriately labeled so that consumers can make informed choices. In India, the Food Safety and Standards Act, 2006 and Rules, 2011 regulate manufacture, storage, distribution, sale and import of food articles to ensure their safe and wholesome availability for human consumption. There are no separate guidelines for nutritional supplements in India. The labeling requirements for nutritional supplements are also same as for food products. There is no control over imported food products. In US, regulatory management of botanical drug products is the same as non-botanical drug products (under the Federal Food, Drugs & Cosmetics Act, 1938). For new botanical drug, FDA regulations require NDA for marketing submitted under Section 505(b). There is no separate regulation for herbal products in U.S. In EU, there are three regulatory routes for herbal remedies by which medicines can reach the consumer namely as Unlicensed herbal remedies, Products registered under the Traditional Herbal Medicines Registration Scheme (THMRS) and Licensed herbal medicines. In India, Drugs & Cosmetics Act, 1940 and corresponding Rules, 1945 regulate herbal and Ayurvedic products. In this presentation, based on the compilation and comparative studies of regulations governing Nutritional Supplements and Herbal Products in USA and EU/ EU and in India, a gap analysis would be presented and finally what should be the befitting appropriate regulations in Indian perspective would be arrived at.

Biography

Professor Dr. B.P. Nagori is presently working as Professor and Director at Lachoo Memorial College of Science & Technology, Jodhpur, India. Dr. Nagori has a blend of 29 years of experience in teaching, research, development & administration. He is the founder Dean of Faculty of Pharmacy, Rajasthan University of Health Sciences, Jaipur. He has designed a new branch in M. Pharm. (Pharmaceutical Management & Regulatory Affairs) for the first time in the country with his background knowledge of pharmacy, management and law. His areas of interest include Pharmaceutical Management, Regulatory Affairs, IPR, Quality Assurance, Pharmaceutical Chemistry, Medicinal & Pharmaceutical Applications of various Gums, Institutional Management and Total Quality Management. He has been guiding 12 Ph.D. scholars and 2 have been awarded Ph.D. degree under his guidance. He has attended and presented 23 papers in Scientific Conferences and has published 38 papers in International and National Journals of repute. He has also authored two books. He is recipient of the Principal of the Year 2010 Award conferred by Association of Pharmaceutical Teachers of India.