Office Order

Dated, the 23rd May, 2017

Subject: Constitution of Working Group to draft GMP requirements for factory premises where manufacture of plant extracts/ nutraceuticals/ ingredients to be used in the supplements / nutraceuticals categories indigenously within India - reg.

With the approval of Competent Authority a Working Group has been constituted to draft GMP requirements for factory premises where manufacture of plant extracts/nutraceuticals/ ingredients to be used in the supplements/ nutraceuticals categories indigenously within India.

2. Currently Schedule IV of the Food Safety and Standards (Licensing and Registration of Food Businesses) Regulations, 2011 has broad requirements for hygienic manufacturing procedure for foods. The Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Food and Novel Food) Regulations, 2016 notified on 23.12.2016. In light of the above, there is need for developing and prescribing appropriate GMP under FSS Act and Rules for categories covered under Nutraceutical Regulations. To draft this Working Group has been constituted.

3. The Working Group will comprise of the following members:

   i. Dr. Surinder Kumar Sharma, Advisor Ayurveda (Retd.), Ministry of Aayush, Ayush Bhawan, B Block, GPO Complex, INA, New Delhi - 110023.

   ii. Dr. Suman Kapur, Dean, Research and Consultancy, Birla Institute of Technology and Science, Room No. A- 101, Department of Biological Sciences, Jawahar Nagar, Sharmirpet, RR Mandal-311403.

   iii. Dr. Virender K. Batis, Emeritus Scientist, Molecular Biology Unit, Dairy Microbiology Division, National Dairy Research Institute, Karnal-132001.

   iv. Dr. Ramchandra V. Gadre, Chief Scientist, Biochemical and Biological Engineering Group, Chemical Engineering and Process Development Division, CSIR-National Chemical Laboratory, Dr Homi Bhabha Road, Pune-411008.
v. Sh. Malay Mitra, Dy. Drugs Controller (Retd.), CDSCO, 8/308, Rajender Nagar, Sector 3, Sahibabad (UP) – 201105 (external expert)

4. Terms of reference for Working Group as follows:

   i. To draft the GMP guidelines for factory premises where manufacture of plant extracts / nutraceuticals / ingredients to be used in the supplements / nutraceuticals categories indigenously within India.

(Sunil Bakshi)
Advisor (Regulations/Codex)

To:

1. Dr. Surinder Kumar Sharma, Advisor Ayurveda (Retd.), Ministry of Aayush, Ayush Bhawan, B Block, GPO Complex, INA, New Delhi – 110023.
2. Dr. Suman Kapur, Dean, Research and Consultancy, Birla Institute of Technology and Science, Room No. A-101, Department of Biological Sciences, Jawahar Nagar, Sharmirpet, RR Mandir- 311403.
3. Dr. Virender K. Batish, Emeritus Scientist, Molecular Biology Unit, Dairy Microbiology Division, National Dairy Research Institute, Karnal- 132001.
4. Dr. Ramchandra V. Gadre, Chief Scientist, Biochemical and Biological Engineering Group, Chemical Engineering and Process Development Division, CSIR-National Chemical Laboratory, Dr Homi Bhabha Road, Pune- 411008.
5. Sh. Malay Mitra, Dy. Drugs Controller (Retd.), CDSCO, 8/308, Rajender Nagar, Sector 3, Sahibabad (UP) – 201105 (as external expert)

Copy To:
1. Advisor (Standards), FSSAI
2. Joint Director (Standards), FSSAI
3. AD (GA), FSSAI
4. Dr. A. K. Sharma (Consultant and Panel Coordinator), FSSAI