U.S. Food and Drug Administration's India Office

presents

Regulatory Expectations for Ayurvedic Products

in collaboration with India's **Ministry of Ayush**

आयुष मंत्रालय
MINISTRY OF
AYUSH

Online Zoom Webinar

January 23, 2023

4:00 – 7:00 p.m. IST (5:30 – 8:30 a.m. EST)

Click HERE to register

AGENDA

- Session 1 – Is my Ayurvedic product a food or drug?
- Session 2 – My Ayurvedic product is a food, now what?
- Session 3 – My Ayurvedic product is a drug, now what?
- Live Session of Q & A

OPENING REMARKS

Dr. Sarah McMullen, Director, FDA India Office
Vaidya Rajesh Kotecha, Secretary, Ministry of Ayush

FDA SPEAKERS

Dr. Charles Wu, FDA CDER, Botanical Review Team
Dr. Haijing Hu, FDA CFSAN, Office of Dietary Supplement Programs

Dr. Charles Wu is a master pharmacology/pharmacognosy reviewer, and the lead for the Botanical Review Team within the Office of Pharmaceutical Quality, part of the FDA's Center for Drug Evaluation and Research (CDER). Dr. Wu trained in clinical medicine — including Traditional Chinese Medicine — and earned his Ph.D. from the University of Amsterdam. Dr. Wu began his career at the FDA in 2001 at the Center for Biologics, Evaluation, and Research. Since 2013, Dr. Wu has been a part of the CDER's Botanical Review Team, becoming the lead in 2017. He has served as the FDA's focal information contact to the WHO's International Regulatory Corporation for Herbal Medicine, and now as the Steering Group Member and Vice-Chair through 2023 — as well as an expert for regional consultation of traditional medicine for COVID-19 response in the African Region. During his tenure at the FDA, Dr. Wu has gained extensive regulatory experience and scientific knowledge regarding a variety of therapeutic products, including chemical, biological, and botanical drugs; he has published over 30 peer-reviewed journal articles and scientific book chapters.

Dr. Haijing Hu joined the FDA in 2010 and has served in several roles and positions. In 2019 she became the chief of the Regulations Implementation Branch within the Office of Dietary Supplement Programs, part of the Center for Food Safety and Applied Nutrition (CFSAN). Dr. Hu leads a multi-disciplinary team to review industry submissions and inspectional findings on labeling and CGMP compliance. She also collaborates across FDA offices to develop compliance actions and compliance policies. Prior to this position, Dr. Hu was in the Office of Compliance, within the FDA's Center for Drug Evaluation and Research (CDER), as a senior microbiologist with a focus on pharmacy compounding. She also conducted microbiological assessments for sterile drug manufacturing (for CDER) and sterilization and disinfection assessments for medical devices (for the FDA's Center for Devices and Radiological Health). Dr. Hu obtained her Ph.D. in 2003 as a food microbiologist and has more than 10 years of experience in microbiological research prior to joining the FDA.