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Developing and marketing botanical drugs in the United States

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United States has the largest pharmaceutical market in the world, as well as strong demand for the use of botanicals as medicine. However, only two botanical drugs are currently approved for use in the USA, Veregen® (sinecatechins) and Mytesi™ (crofelemer). Why is there such a discord? United States historical use of plants as drugs is unique. The cultivation of tobacco to the growth of the new nation during the era of mislabeling, adulteration and unintended addiction have all contributed to shaping its regulatory policies and perceptions of botanicals far differently than other countries. Unlike other countries, the United States has no separate regulatory category for traditional or herbal medicines. Instead, these products are considered crude drugs which may be developed as either a food (includes dietary supplements), a drug, medical device or cosmetic. This cross-cultural confusion is worthy of exploration for those wishing to enter the US marketplace. The presentation helps understanding of the culture and history of the American market to understand hidden barriers for product approval of botanicals as drugs as well as consumer expectations and demands of botanicals. Furthermore, helps in understanding the regulatory paths for development of a botanical product based on the four US guiding principles for classification: Intention of use, route of administration, formulation and risk. Graphs will assist to quickly differentiate characteristics of regulatory categories emphasizing dietary supplements, standard single chemical entity drugs and heterogeneous botanical drugs. Unique chemistry and manufacturing controls of each classification will be discussed, focusing on those required of heterogeneous drug products under the guidance for industry botanical drugs issued by the FDA in 2004 and revised in 2016.

Biography

Christina Marrongelli holds her Bachelor's degree from University of Mississippi, School of Pharmacy in Pharmaceutical Sciences and Doctor of Pharmacy. She has expertise in botanical discovery and development, business, regulatory affairs and clinical services. She achieved advanced training in Dietary Supplement Quality Control and conducted research in drug discovery to drug development of natural products leading to a patent position in conjunction with the National Center for Natural Product Research. She is also the Adjunct Professor at the University of South Carolina School of Medicine, Department of Drug Discovery and Biomedical Sciences, serves as Chair for the Naturopathic Doctors Formulary Council for the Maryland Board of Physicians and is an Advisory Member of several laboratory and public health working groups. She is the CEO of ECHealthcare™ and Integrative Pharmacy Solutions located in Washington DC. Her organization provides representation and expert advisement in business development, regulatory affairs, legislation and education to assist academic, healthcare, research and government agencies in the field of natural product development and Cannabis research.

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