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Update and challenges to the medical food category

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Medical foods (MFs) existed for five decades as FDA-approved drugs in the United States until 1988 when the Orphan Drug Act was passed establishing them separate from drugs. In the early 1990s, MFs were codified under the Nutrition Labeling and Education Act, but exempted from common nutrient labeling. One regulation was passed [21 CFR101.9(j)(8)], which required MFs to be specially formulated (purified); for patients with chronic medical needs; intended to provide nutritional support for unique nutrient needs in the management of a specific disease or condition and intended to be administered under medical supervision in patients receiving active, ongoing care to assure instructions on use. In 1996, the FDA proposed regulations which further defined the MF category but withdrew these without comment in 2003. Since that time, the FDA has written frequently asked question guidance on MFs which it finalized in May 2016. This guidance did nothing to clarify the definition of MFs, the distribution channel for MFs other than restating medical supervision and provided no guidance on clinical substantiation. The drug division at FDA also issued guidance to institutional review boards in 2013 requiring that MF trials be performed under an investigational new drug application whereas guidance from the Orphan category exempts them from this requirement. The lack of FDA action on MFs has led to confusion amongst physicians, pharmacists and payers as well as restriction of patient access to these essential therapies. Industry is proposing best practice guidelines.

Biography

Bruce P Burnett is an expert in the field of Nutritional Product Development. He is a Vice President of Compliance, Regulatory and Medical Affairs at Entera Health, Inc. He has received his BS degrees in Biology and Chemistry from Eastern Washington University and his Master's and PhD in Biochemistry and Biophysics from Yale University. He has also received several NIH and SBIR grants, served on the ad hoc study section for review of SBIR awards and acts as a Reviewer for several journals around the world. He has 50 peer-reviewed publications, 2 book chapters and over 30 peer-reviewed published abstracts.

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