

OUR PRACTICE

Medical Foods

Baker Donelson has significant experience in the growing field of medical foods, identifying for our clients important commercial opportunities targeting consumers already under medical supervision.

Medical foods are a distinct category of United States Food and Drug Administration (FDA) regulated products. They do not require a prescription and do not require premarket review or approval by the FDA. Medical foods are also exempt from nutrition labeling and health and nutrient content claim requirements that are applicable to most other food products, including dietary supplements.

Baker Donelson's food and drug attorneys are experienced in assessing the regulatory status and compliance of medical food products, including reviewing permissible marketing and labeling claims, compliance with good manufacturing practices, analyzing and reviewing product substantiation, and advising clients on the distinctive nutritional requirements necessary for medical food positioning. Baker Donelson's attorneys are also actively engaged with key players in the medical foods space, including industry stakeholders, the FDA, consumer and advocacy groups, Congress, and the United States Federal Trade Commission.

No matter the issue, Baker Donelson's experienced food and drug attorneys stand ready to assist at each step of the product life cycle – from development to distribution.