



May 29, 2015

Via electronic submission

Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Request for Extension of the Comment Period

Early Clinical Trials With Live Biotherapeutic Products: Chemistry, Manufacturing, and Control Information; Guidance for Industry; Request for Comments. 80 *Fed. Reg.* 17050-17051 (March 31, 2015). Docket No. FDA–2010–D–0500.

Dear Sir or Madam:

The Council for Responsible Nutrition¹ (CRN) is the leading trade association that represents dietary supplement and functional food manufacturers as well as marketers and ingredient suppliers. Overall, CRN supports modification to the February 2012 guidance titled “Early Clinical Trials with Live Biotherapeutic Products: Chemistry, Manufacturing, and Control Information; Guidance for Industry” that addresses when the label on commercially available foods or dietary supplements containing live biotherapeutic products (LBPs) would be adequate

¹ The Council for Responsible Nutrition (CRN), founded in 1973 and based in Washington, D.C., is the leading trade association representing dietary supplement and functional food manufacturers, marketers and ingredient suppliers. CRN companies produce a large portion of the functional food ingredients and dietary supplements marketed in the United States and globally. Our member companies manufacture popular national brands as well as the store brands marketed by major supermarkets, drug stores and discount chains. These products also include those marketed through natural food stores and mainstream direct selling companies. CRN represents more than 150 companies that manufacture dietary ingredients, dietary supplements and/or functional foods, or supply services to those suppliers and manufacturers. Our member companies are expected to comply with a host of federal and state regulations governing dietary supplements and food in the areas of manufacturing, marketing, quality control and safety. Our supplier and manufacturer member companies also agree to adhere to additional voluntary guidelines as well as to CRN’s Code of Ethics. Learn more about us at www.crnusa.org.

to satisfy the requirements for information on the chemistry, manufacturing, and control (CMC) in an investigational new drug application (IND) when these products are used as investigational new drugs in early phase clinical trials. The 2012 guidance introduces several burdensome obstacles to researchers investigating the health impact of commercially available foods and dietary supplements containing LBPs, including yogurt and probiotic dietary supplements, which are already being safely consumed by many Americans. The proposed modification would facilitate additional clinical trial research involving foods and dietary supplements containing LBPs. By allowing sponsors of INDs to use the product label to satisfy the requirements for CMC information under the four conditions FDA stated in the March 31, 2015 Federal Register notice, the agency enables the IND process to be more efficient as sponsors using commercially available foods and dietary supplements containing LBPs would not have to spend additional resources to contact product manufacturers and obtain the detailed manufacturing and quality control data that are required for sponsors investigating other LBP containing products intended to be developed into drugs or vaccines. Commercially available foods and dietary supplements containing LBPs have a high safety profile and information on the product label should provide adequate CMC information, under the conditions FDA provided, for early phase clinical trials.

CRN appreciates the opportunity to provide these initial comments to FDA; however, we respectfully request for a 30-day extension of the comment period in order to provide more in-depth comments that would assist FDA in the modification of the February 2012 guidance for industry.

Thank you for considering our request.

Sincerely,

A handwritten signature in black ink, appearing to read "D. MacKay", with a checkmark-like flourish at the end.

Douglas MacKay, N.D.

Senior Vice President, Scientific & Regulatory Affairs