
Healthcare Nutrition Council

529 14th Street, NW • Suite 750 • Washington, DC 20045

December 3, 2018

Division of Dockets Management
HFA-305
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

RE: Docket No. FDA-2014-N-1721 for “Agency Information Collection Activities; Proposed Collection; Comment Request; Investigational New Drug Applications.”

Dear Dockets Management Staff,

The Healthcare Nutrition Council (HNC)* submits these comments in response to the U.S. Food and Drug Administration’s (FDA) Notice “Agency Information Collection Activities; Proposed Collection; Comment Request; Investigational New Drug Applications” (Docket No. FDA-2014-N-1721).

Enclosed with this comment submission are previously submitted HNC comments, which were sent to the Center for Food Safety and Applied Nutrition and the Center for Drug Evaluation and Research on February 5, 2018 through FDA’s open docket. The detailed comments attached (point B specifically) outline HNC’s recommendations for repealing portions of the “Guidance for Clinical Investigators, Sponsors, and IRBs: Investigational New Drug Applications (INDs)”, in particular all portions related to foods including the section that indicates an investigation intended to evaluate the effects of a Medical Food on a disease would require an IND. HNC would like to highlight a few specific aspects of our comments below.

As the Agency solicits comments on information collection activities related to the clinical investigation of unapproved new drugs and biological products, HNC believes it is imperative to also address the significant regulatory burden that would be introduced for both industry and academia, as well as the overt conflict in statutory intent of the IND process, should nutrition research be required to follow the IND process. Moreover, An IND is by its very name intended only for an investigational new drug. Requiring an IND for conducting a study that involves nutritional research using food is unprecedented and unsupported by the Federal Food, Drug and Cosmetic Act. This is particularly true for research on the effect of Medical Foods on diseases, as Medical Foods are required by statute to be intended for the dietary management of a disease or condition. Investigation of a Medical Food’s effects on a disease does not inherently make that Medical Food a drug; rather, it comports with the intended use of Medical Foods set forth by statute.

Furthermore, it fails to address a legitimate public health need, significantly discourages both research and innovation, and incrementally and unnecessarily increases regulatory burden on industry, academic researchers and FDA. Requiring an IND significantly delays nutrition research timelines by requiring the upfront completion of an IND application from nutrition researchers who likely have no experience with the investigational drug process. The current IND guidance has created unnecessary obstacles for nutrition research in the area of Medical Foods and we feel it is important to note this concern as FDA collects information related to IND applications.

HNC previously recommended FDA repeal portions of the IND Guidance, specifically all portions related to foods including section VI(D) which indicates an investigation intended to evaluate the effects of a Medical Food on a disease (including the dietary management of a disease) would require an IND. We still strongly support that recommendation and encourage FDA to consider these aspects when collecting IND-related information for this open docket notice.

Thank you for the opportunity to provide comments on FDA’s Agency Information Collection. Please do not hesitate to contact me with any questions you may have.

Sincerely,



Nadia Cayce, PhD
Executive Director
Healthcare Nutrition Council

***About HNC:** *The Healthcare Nutrition Council (HNC) is an organization representing the manufacturers of enteral nutrition formulas, parenteral nutrition solutions, supplies and equipment. HNC member companies are Abbott Nutrition, B. Braun Medical, Nestlé Health Science and Nutricia North America. We are committed to improving health by advancing policies that address and raise awareness of nutrition and its impact on patient outcomes and healthcare costs. This includes promoting nutritional screenings, diagnoses, assessments and appropriate and timely nutrition clinical interventions while protecting patients' access to specialized nutrition support products and services throughout the continuum of care. For more information on HNC, please visit <https://healthcarenutrition.org>.*