



# HEALTHCARE NUTRITION COUNCIL

Improving outcomes through awareness and action

*Submitted via Regulations.gov*

July 14, 2023

JonnaLynn Capezzuto  
Office of Operations  
Food and Drug Administration  
Three White Flint North  
11601 Landsdown St.  
North Bethesda, MD 20852

## **RE: Docket No. FDA-2023-N-0155 Quantitative Research on Front of Package Labeling on Packaged Foods – Comments to OMB**

Dear Division of Dockets Management,

The Healthcare Nutrition Council (HNC) is commenting on the U.S. Food and Drug Administration's (FDA or agency) information collection associated with a study entitled "Quantitative Research on Front of Package (FOP) Labeling on Packaged Foods" (FDA-2023-N-0155), which was published in the *Federal Register* on June 15, 2023 and submitted to the Office of Management and Budget (OMB). HNC is an association representing manufacturers<sup>1</sup> of enteral nutrition (EN) formulas and oral nutrition supplements (ONS), including those categorized as medical foods, and parenteral nutrition (PN). Our mission is to improve patient outcomes by advancing nutrition policies and actions that raise awareness and optimize access of essential nutrition support therapies across the continuum of care.

HNC would like to emphasize [our comments](#) that were submitted to the docket in March. Consistent with current nutrition labeling exemptions that apply to specialized nutrition products classified as medical foods,<sup>2</sup> HNC believes these products should also be exempt from FOP labeling. Additionally, HNC believes ONS, often categorized as foods for special dietary use (FSDU), should be exempt from these requirements. These specialized nutrition products are high quality, scientifically based and nutrient dense foods which are intended to provide supplemental or sole source nutrition for individuals who are at risk of malnutrition or cannot achieve adequate nutritional intake from a normal diet. In the case of some FSDU, for example, calories are intentionally high to help a patient meet their higher nutrition needs while they undergo chemotherapy or hemodialysis. These higher caloric density products are formulated for a specific purpose to help individuals achieve their personal nutrition goals. Since they are used by a unique population, these specialized nutrition products should not be categorized the same as conventional foods that would undergo front of package labeling requirements. These products are often recommended or prescribed under the direction of a physician, registered

---

<sup>1</sup> HNC members are Abbott Nutrition, Nestle Health Science, and Nutricia North America.

<sup>2</sup> [21 CFR 101.9\(i\)\(8\)](#).



# HEALTHCARE NUTRITION COUNCIL

Improving outcomes through awareness and action

dietitian nutritionist, or other health care professional (HCP). For these reasons, HNC requests the agency include this product category along with health care provider input when conducting quantitative research. Furthermore, patients who are using these products as a result of an HCP recommendations could also be invited to participate in the research process to better understand how they may react to front of package labeling.

We would appreciate the opportunity to meet with FDA to discuss these considerations. Please let me know if there are any questions.

Sincerely,

A handwritten signature in black ink that reads "Robert Rankin". The signature is written in a cursive, flowing style.

Robert Rankin  
Executive Director

FDA-2023-N-0155 | 2