



HEALTHCARE NUTRITION COUNCIL

Improving outcomes through awareness and action

Submitted via Regulations.gov

March 24, 2023

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, Maryland 20852

RE: Quantitative Research on Front of Package Labeling on Packaged Foods (FDA-2023-N-0155)

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 proposed study entitled "Quantitative Research on Front of Package Labeling on Packaged Foods" (FDA-2023-N-0155), which was published in the *Federal Register* on January 26, 2023. HNC is an association representing manufacturers¹ 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.

We applaud FDA's efforts to improve public health by exploring the development of a front of package (FOP) labeling system to complement the Nutrition Facts label and help consumers interpret nutrient information and make informed dietary choices. Consistent with current nutrition labeling exemptions that apply to specialized nutrition products classified as medical foods,² 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. ONS are high quality, scientifically formulated 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. As a result, the populations who use ONS products often have nutritional goals which are vastly different from the general, healthy population and often do so under the direction of a physician, registered dietitian, or other health care professional. Further labeling intended to help ONS consumers interpret nutrition information would be unnecessary and could cause confusion regarding the nutritional benefits of these products. Medical foods, FSDU, and ONS can be used as sole source nutrition and often provide higher amounts of calories, fats, added sugar, or sodium by design. FOP labeling designed for the general population could inadvertently discourage the use of such essential nutrition intended for specific patient populations. For these reasons, HNC respectfully requests that ONS, FSDU, and medical foods be exempt from FOP labeling schemes.

We appreciate the opportunity to provide comments on this impactful proposed regulation. 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

¹ HNC members are Abbott Nutrition, Nestle Health Science, and Nutricia North America.

² [21 CFR 101.9\(i\)\(8\)](#).