American Society for Nutrition
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May 12, 2026

Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket No. FDA-2026-N-1736 Agency Information Collection Activities; Proposed Collection; Comment Request; Investigational New Drug Application Requirements

The American Society for Nutrition (ASN) appreciates the opportunity to provide comments to the U.S. Food and Drug Administration (FDA) on the estimated burden and methodology used for Investigational New Drug (IND) efforts, ways to enhance clarity on the information being collected, and ways to minimize the burden of the collection of information on respondents. ASN would like to use this opportunity to reiterate our past comments to FDA expressing concerns with the current IND proposed rule and current process. Established in 1928, ASN is a not-for-profit organization dedicated to the mission of advancing the science, education, and practice of nutrition. ASN has more than 8,000 members around the world, working throughout government, clinical practice, academia, and industry, to conduct research to achieve the ASN vision of "A Healthier World Through Evidence-Based Nutrition."

As ASN has shared in the past, IND processes should not apply to food and nutrition research efforts. ASN has long communicated[1] that the current IND application and review processes are not appropriate for human research on food, nutrients, and dietary supplements since a drug development model cannot accurately be applied to foods or their components, and that INDs should not be necessary for food studies that will not result (nor are intended to result) in the development of new drugs or drug claims. ASN supports the Agency's efforts to allow IND exemptions for clinical studies evaluating health benefits of a food product or dietary supplement for human consumption, provided those studies meet the safety and exemption criteria set forth by FDA.

Exemptions from INDs for clinical investigations of lawfully marketed food products that are not intended for drug development will alleviate limitations on human nutrition research and remove burdens to investigators, such as the need for significant human and financial resources and delayed research projects, allowing for more human nutrition research, clinical trials, and product innovation. These exemptions will more readily allow for nutrition research in the U.S. to support the Administration's goals related to food and health, including development of food labeling claims designed to help consumers make healthier food choices and for nutrition research to support federal dietary recommendations and policies, such as the Dietary Guidelines

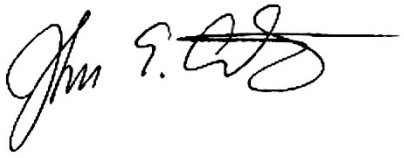
[1] https://nutrition.org/wp-content/uploads/2023/03/ASN-Comments-on-IND-Exemptions.2023.pdf; https://nutrition.org/wp-content/uploads/2023/03/Nutrition-Org-Sign-on-Letter-re-IND-Proposed-Rule.2023.pdf; https://asn-cdn-remembers.s3.amazonaws.com/3a359c2a938d59152137205370bff49a.pdf; https://asn-cdn-remembers.s3.amazonaws.com/7ae4fa5a6772968856c8cb8e9466a228.pdf

for Americans and Dietary Reference Intakes. We appreciate the Administration and FDA's efforts to advance the role of nutrition in health and disease prevention, yet current FDA rulemaking such as this are specifically at odds with promoting research on the role of food and nutrition in chronic disease prevention.

As it is currently written, the proposed rule, "Investigational New Drug (IND) Applications; Exemptions for Clinical Investigations to Evaluate a Drug Use of a Product Lawfully Marketed as a Conventional Food, Dietary Supplement, or Cosmetic," has set forth a complicated framework that has introduced significant confusion into the food and nutrition research space, increased the cost of critical research, and decreased the ability to actually conduct such research. ASN requests that FDA clarify many issues within the proposed rule, such as clarifying that clinical investigations assessing lawfully marketed foods and supplements are not studies of "drug uses" when the product will continue to be intended for consumption as food, not as a drug, and should be exempted from needing to submit an IND application. FDA should also provide exemptions for foods and supplements that are not yet "lawfully marketed" (i.e., products under development or products being reformulated) as well. ASN further urges that the Center for Food Safety and Applied Nutrition (CFSAN) is the most appropriate FDA Center related to food and nutrition research exemptions, rather than Center for Biologics Evaluation and Research (CBER) or the Center for Drug Evaluation and Research (CDER).

Thank you for your attention to this important research issue. ASN appreciates FDA's efforts to allow IND application exemptions for clinical investigations to evaluate products lawfully marketed as conventional food or dietary supplements since it has a significant impact on the advancement of food and nutrition research. Please contact Sarah Ohlhorst, MS, RD, ASN Chief Science Policy Officer (240-428-3647; sohlhorst@nutrition.org) if ASN may provide additional information.

Sincerely,



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