Council for Responsible Nutrition
1828 L Street, NW, Suite 510 • Washington, DC 20036-5114
(202) 204-7700 • fax (202) 204-7701 • www.crnusa.org

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VIA ELECTRONIC SUBMISSION

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

RE: Food Labeling; Gluten-Free Labeling of Fermented or Hydrolyzed Foods. 80 *Fed. Reg.* 71990-72006 (November 18, 2015). Docket No. FDA-2014-N-1021.

The Council for Responsible Nutrition[1] (CRN) appreciates the opportunity to comment on the U.S. Food and Drug Administration's (FDA) Proposed Rule for Gluten-free Labeling of Fermented or Hydrolyzed Foods (Proposed Rule) as it relates to enzyme dietary supplements and ingredients, which are products that assist in the digestion of dietary sugars, fats and proteins.

Enzyme dietary supplements and ingredients should not be classified as fermented or hydrolyzed foods. The enzymes are typically produced from bacteria or fungi, or extracted from plants. Microbial-sourced enzymes are not themselves fermented or hydrolyzed, but are released by microbes as part of their life cycle. In the production of certain enzymes, the microbial food

[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.

sources include wheat, which is broken down by the microbes through fermentation. In the specific case of protease enzymes with the intended use of assisting with gluten digestion, wheat must be one of the ingredients used in the fermentation media to promote release of protease enzymes that break down gluten by the microbes. By the end of fermentation, most of the wheat is consumed by the microbes. Subsequent enzyme extraction and purification processes remove microbial matrix components such as proteins and protein fragments, resulting in enzyme products that do not contain consequential amounts of gluten proteins or gluten protein peptides. However, verification, by scientifically validated methods, that the final enzyme product contains less than 20 ppm gluten is needed for those products that bear the "gluten-free" claim as required by 21 CFR 101.91. We recommend that FDA clarify that enzymes are not fermented or hydrolyzed foods or ingredients for the purposes of labeling "gluten-free" and would not be subject to proposed § 101.91(c)(2), (c)(3), or (c)(4), if these sections are to be included in the final rule. Instead, enzyme products that bear the "gluten-free" claim under 21 CFR 101.91 would be subject to proposed § 101.91(c)(1) like other foods that are not fermented or hydrolyzed.

In the Proposed Rule, FDA states that it is challenging to quantify gluten in food matrices in which gluten proteins have been hydrolyzed into peptides. Further, the agency is not aware of any scientifically validated methods to quantify intact gluten from detection and quantification of gluten protein peptides. While CRN understands there is a lack of scientifically valid methods, it is important to note that a method based on the R5 competitive ELISA test protocol with inactivated protease enzyme is in progress, to quantify gluten in products containing protease enzymes. More detail is provided in comments submitted by Deerland Enzymes, Inc. of Kennesaw, GA. CRN encourages FDA to follow the work being done to validate a method to verify presence of less than 20 ppm gluten in enzyme products that comply with 21 CFR 101.91.

Respectfully Submitted,

Haiuyen Nguyen

Director, Scientific & Regulatory Affairs
Council for Responsible Nutrition