



Council for Responsible Nutrition

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May 12, 2016

VIA ELECTRONIC SUBMISSION

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

**RE: Docket No. FDA-2015-N-1260; Fixed-Combination and Co-Packaged Drugs:
Applications for Approval and Combinations of Active Ingredients Under
Consideration for Over-the-Counter Monograph.**

Dear Sir or Madam:

The Council for Responsible Nutrition¹ (CRN) appreciates the opportunity to comment on the U.S. Food and Drug Administration's (FDA) Proposed Rule for Fixed-Combination and Co-Packaged Drugs (Proposed Rule) as it relates to dietary supplements.

In the Proposed Rule, FDA states that the purpose of this regulatory action is to “harmonize the requirements for prescription and nonprescription products and make them consistent with long-standing Agency policy.” The Proposed Rule further states that FDA considers dietary supplements that are combined into a single dosage form with or co-packaged with a drug to meet the definition of “drug” under section 201(g) of the Federal Food, Drug, and Cosmetic Act,

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.

thereby subjecting dietary supplements to the specific evidentiary requirements for approval outlined in the rule.

CRN disagrees that dietary supplements should be included within the scope of the Proposed Rule. As written, the Proposed Rule is overly broad and imposes an inflexible, blanket rule on all dietary supplements without regard to the labeling and specific directions for use that may accompany a particular dietary supplement product. Therefore, we recommend that FDA remove all references and discussion of dietary supplements within the Proposed Rule. The Agency should limit the scope of any final rule to drug products and address its concerns related to dietary supplements outside of this regulatory action on a case-by-case basis.

Should FDA have questions or require additional information regarding our comments, please feel free to contact me directly at 202-204-7672 or ral-mondhiry@crnusa.org.

Respectfully Submitted,

A handwritten signature in black ink, appearing to read "Rend Al-Mondhiry". The signature is fluid and cursive, with a long horizontal stroke at the end.

Rend Al-Mondhiry
Associate General Counsel
Council for Responsible Nutrition