



Council for Responsible Nutrition

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

December 21, 2015

Via e-filing on www.regulations.gov

U.S. Environmental Protection Agency
EPA Docket Center
Mailcode 2822IT
Attention: Docket ID No. EPA- HQ-RCRA-2007-0932
12000 Pennsylvania Avenue, NW
Washington, DC 20460

Re: Comments of the Council for Responsible Nutrition to EPA’s Proposed Management Standards For Hazardous Waste Pharmaceuticals - (Docket HQ-RCRA-2007-0932)

Dear Sir or Madam:

The Council for Responsible Nutrition (CRN)¹ respectfully submits the following comments to the U.S. Environmental Protection Agency’s (EPA) proposed rule under the Resource Conservation and Recovery Act (“RCRA”) – “Management Standards for Hazardous Waste Pharmaceuticals,” 80 Fed. Reg. 58,014 (Sept. 25, 2015) (“Proposal”). CRN encourages EPA to develop regulations for the management of hazardous waste dietary supplements that are appropriate, efficient and practicable, but are not unduly burdensome as to unnecessarily increase the cost of dietary supplements for the over 150 million Americans that use these important products to maintain their health. CRN has reviewed comments submitted by the Consumer Healthcare Products Association (“CHPA”) on the EPA’s Proposal and fully agrees with CHPA regarding the issues related to dietary supplements.

Dietary supplements are regulated as a category of food and contain ingredients that can be safely consumed by humans. Products that are safe to eat, including dietary supplements, should not be treated as hazardous wastes under RCRA when discarded; however, if they are determined wastes, certain additional adjustments would be appropriate to further reconcile the Proposal with how unsold or unused dietary supplements are currently managed. The

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.

adjustments will help EPA more fully realize its goals to develop “a tailored, sector-specific regulatory framework” that still ensures proper management of wastes. 80 Fed. Reg. 58015. Burdensome disposal rules would increase the resources needed to manage dietary supplements, and that in turn leads to higher prices as retailers are forced to share the burden up and down the supply chain. It is important to recognize that current industry practices involve the use of “reverse logistics” providers to process unsold or unused dietary supplements; in order to increase efficiency in the management of dietary supplements, these “reverse logistics” providers should be able to determine if unsold or unused dietary supplements are to be discarded so that waste determination could be centralized.

CRN supports the recommendations regarding dietary supplements outlined in CHPA’s comments to the Proposal. Specifically, CRN agrees that: (a) EPA should maintain its historic interpretation that unsold or unused dietary supplements are not a “solid wastes” until a final determination is made to discard them; (b) EPA should recognize and account for the well-established “reverse logistics” process for managing unsold or unused dietary supplements; (c) EPA should recognize that dietary supplements sent to a “reverse logistics” provider for further processing, including those destined for donation, recycling or reclamation, are not “solid wastes” subject to RCRA; (d) and EPA should permit the waste determination to be made at the “reverse logistics” provider if dietary supplements are to be discarded.

In summary, CRN encourages EPA to adjust the Proposal to align with established processes used to manage unsold or unused dietary supplements. CRN urges EPA to fully consider the detailed comments submitted by CHPA that support the aforementioned recommendations. We thank you for the opportunity to comment and are available to provide further information or answer any questions.

Sincerely,

A handwritten signature in black ink, appearing to read "D. MacKay", with a checkmark-like flourish at the end.

Douglas MacKay, N.D.
Senior Vice President, Scientific and Regulatory Affairs