



December 27, 2021

Daniel J. Barry
Acting General Counsel
U.S. Department of Health and Human Services
200 Independence Ave SW
Washington, DC 20201
Docket HHS-OS-2020-0012 / RIN 0991-AC24

Re: Securing Updated and Necessary Statutory Evaluations Timely; Proposal To Withdraw or Repeal (October 29, 2021), Docket No. HHS-OS-2020-0012.

The Council for Responsible Nutrition (CRN)¹ appreciates the opportunity to provide comments on the Department of Health and Human Services' ("HHS" or "the Department") Proposed Rule "Securing Updated and Necessary Statutory Evaluations Timely; Proposal to Withdraw or Repeal" ("Proposed Rule"). Although we applauded HHS's efforts to modernize its regulatory review process, CRN had significant concerns with the expansive and accelerated approach taken in the November 4, 2020 proposed rule,² as well as with the final rule ("Sunset final rule") issued on January 19, 2021 that mostly mirrored the proposed rule. In brief, CRN previously voiced³ concerns that the suggested approach would not only require the Food and Drug Administration (FDA) to reallocate critical agency resources from public health priorities such as managing the COVID-19 pandemic and routine agency activities, but also would not allow for the kind of targeted and reasoned regulatory reform that is necessary and appropriate. Further, we were concerned that there would be potential for the inadvertent sunset of regulations that have been in place for many years and are essential to FDA regulated industries including the food and dietary supplements industries.

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.

² 85 Fed. Reg. 70096 – 70124 (Nov. 4, 2020).

³ CRN Comment on FR Doc # 2020-23888. Available at <https://www.regulations.gov/comment/HHS-OS-2020-0012-0273>.

CRN also noted that the comment period of 30 days for the November 4, 2020 proposed rule was insufficient given its expansive scope and only allowed us (and many other stakeholders) to provide preliminary comments to HHS. Thus, we welcomed the Department's March 23, 2021 decision to delay the effective date of the Sunset final rule issued on January 19, 2021, as well as the recent proposal to withdraw this final rule in its entirety after thorough review. We align with HHS's current belief that implementing the Sunset final rule would "impede the Department's routine operations and hamper its ability to carry out other key priorities and goals, particularly during an ongoing public health emergency."⁴ We look forward to hearing about future plans for regulatory review that balances regulatory impact with public health priorities.

Thank you for considering our comments.

Sincerely,



Haiuyen Nguyen
Senior Director, Scientific & Regulatory
Affairs

⁴ 86 Fed. Reg. 59906-59931 (October 29, 2021).