



Submitted electronically via regulations.gov

December 4, 2020

The Honorable Alex Azar
Secretary of Health and Human Services
c/o James Lawrence
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 (Nov. 4, 2020), Docket No. HHS-OS- 2020-0012.

Dear Secretary Azar,

SNAC International 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" (hereinafter "Proposed Rule"). ^{1/} SNAC International is the international trade association of the snack food industry representing snack manufacturers, marketers and suppliers. Founded in 1937, SNAC International represents over 400 companies worldwide including but not limited to, manufacturers of potato chips, tortilla chips, cereal snacks, pretzels, popcorn, kettle corn, cheese snacks, snack crackers, meat snacks, pork rinds, snack nuts, party mix, corn snacks, fruit snacks, snack bars, granola, cookies, and various other snacks. As such, our members will undoubtedly be affected by the Proposed Rule and are uniquely positioned to offer valuable feedback to HHS about the impact of existing U.S. Food and Drug Administration (FDA) regulations on businesses of varying sizes and our potential perspective regarding to the Proposed Rule.

SNAC International supports regulatory reform and values opportunities to review and modernize regulations to ensure they are no more burdensome than necessary, especially for small businesses. We applaud HHS's efforts to take another look at the regulatory review process and consider ways to improve it. However, we have significant concerns about the expansive and accelerated approach taken in the Proposed Rule. In general, SNAC is concerned that the suggested approach would require intense work from FDA that would not only take critical agency resources and experience away from managing the COVID-19

^{1/} 85 Fed. Reg. 70096 – 70124 (Nov. 4, 2020).

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 are concerned that there is potential that the Proposed Rule could lead to the inadvertent sunseting of regulations that have been in place for many years and are essential to maintaining consumer confidence in our nation's food supply, as well as a level playing field within the industry. The food industry in particular relies on the durable public standards that have been codified in the Code of Federal Regulations (CFR), such as those around Food Safety; Nutrition and Food Labeling; Food Ingredients; and Food Standards of Identity and Quality. These standards are essential to maintaining relationships of trust between all members of the supply chain and especially consumers. This approach has the potential to cause confusion and distrust that could harm regulated industry and the benefitting public alike.

A preliminary review of the Proposed Rule raises the following issues with the Department's proposed approach:

- The Proposed Rule should provide greater clarity as to how the sunset exceptions will function;
- The Proposed Rule does not sufficiently outline how agencies will consider the factors for and how the Review process for regulations will be conducted;
- The timeline for review in the Proposed Rule is unrealistic and could lead to inadvertent sunseting of regulations which would cause unnecessary chaos and harm to the industry and consumers alike;
- The proposed public review website shifts responsibility from the Department to the public, is unduly burdensome, and does not guarantee the necessary regulations will be reviewed in a timely manner;
- The Proposed Rule would disproportionately impact the food industry because many companies are small businesses; and,
- The use of machine learning in regulatory reform is a novel approach and affected members of the public have been afforded no opportunity to comment on the methodology.

Procedurally we also have the following concerns:

- The Proposed Rule was published on November 4, 2020, with a comment deadline of 30 days. The APA requires agencies to provide adequate notice of a proposed rule followed by a meaningful opportunity to comment on the rule's content. 2/ This short time frame is not adequate to do so.
- The Proposed Rule is extremely broad, both in theoretical and projected reach. It would cover regulations spanning the 11 operating divisions of HHS – including the FDA, which itself is made up of six centers that oversee food safety and applied nutrition, drug evaluation and research, devices and radiological health, biologics evaluation and research, veterinary medicine, and tobacco products. For the food industry, the scope of

2/ 5 U.S.C. § 553(b)-(c).

regulations that would be impacted by the Proposed Rule affect nearly every aspect our industry from the way products are manufactured and produced to ensure safety, the labeling of products, the claims that can be made, the lawful use of certain ingredients, and adherence to standards of identity and quality. Thirty days is an insufficient amount of time for a rule of this scope.

Effective regulatory reform is important to our industry and to all our members. The food industry in particular, which is comprised of so many small business members, supports the need for a measured approach to regulatory reform. Nonetheless, in light of the concerns outlined above and the short comment period, at a minimum we ask for an extension of the comment period. More importantly, we support HHS publishing a subsequent Proposed Rule to address the issues we raise, so that we can provide more meaningful comment on the Department's proposal.

Sincerely,

A handwritten signature in black ink that reads "Elizabeth Avery". The signature is written in a cursive, flowing style.

Elizabeth Avery
President & CEO
SNAC International
703.836.4500 ext. 204
1560 Wilson Blvd, Suite 440, Arlington, VA 22209
www.snacintl.org