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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.

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" (hereinafter "Proposed Rule"). 2/ CRN is the leading trade association representing dietary supplement and functional food manufacturers and ingredient suppliers. 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 perspective regarding the Proposed Rule.

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 and ingredient suppliers. CRN companies produce a large portion of the 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 180 companies that manufacture dietary ingredients and/or dietary supplements, 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 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).

CRN supports regulatory reform and values opportunities to review and modernize regulations to ensure they are no more burdensome than necessary. 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, CRN 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 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 a genuine potential that the Proposed Rule could lead to the inadvertent sunsetting of regulations that have been in place for many years and are essential to maintaining consumer confidence in our nation's food supply, including dietary supplements, as well as a level playing field within the industry. Abandoning these rules of law has the potential to breed chaos, confusion, and distrust that could irreparably harm regulated industry and the benefitting public alike.

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

1. The Proposed Rule should provide greater clarity as to how the sunset exceptions will function;

2. The Proposed Rule does not sufficiently outline how agencies will consider the factors for and how the Review process for regulations will be conducted;

3. The timeline for Review in the Proposed Rule is unrealistic and could lead to inadvertent sunsetting of regulations which would cause unnecessary chaos and harm to the industry and consumers alike;

4. 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;

5. 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.

We discuss these and other issues in more detail below. In light of these concerns, we recommend the Department revise and issue a subsequent Proposed Rule for comment.

We also note for the record that due to the very short comment period of 30 days, we were not able to provide comments that are as thorough as necessary for a Proposed Rule of this scope. Our comments below offer our initial feedback on HHS's proposal to Assess and Review the vast majority of regulations affecting our industry. We respectfully request for an extension to the Proposed Rule comment period. At the end of these comments we outline the basis for our request.

Background

The Proposed Rule would set expiration dates for HHS regulations (subject to certain exceptions), unless the Department periodically "assesses" (Assess) the regulations to determine if they are subject to the Regulatory Flexibility Act (RFA), and if they are, performs a "review" (Review) that satisfies the criteria in the RFA. The dietary supplement industry in particular relies on the durable public standards that have been codified in the Code of Federal Regulations (CFR). These standards are essential to maintaining relationships of trust between all members of the supply chain and especially consumers. The Proposed Rule would require FDA to analyze and justify, as warranted, virtually all regulations pertaining to:

- **Food/Dietary Supplement Safety** (e.g., Food Safety Modernization Act (FSMA), Good Manufacturing Practices (GMPs), import/export requirements, among others);

- **Nutrition and Food/Dietary Supplement Labeling** (e.g., nutrition labeling, claims, and ingredient labeling, among others);

- **Food/Dietary Supplement Ingredients** (e.g., food and color additive regulations, Generally Recognized as Safe (GRAS) regulations, and procedural regulations governing the agency's premarket review functions, among others); and

These regulations have been in place for many years, some for many decades, and have become the standard for assuring the safety and labeling for all food and dietary supplement products regulated by the FDA. They are, in many cases necessary, for industry to ensure compliance with statutory obligations and they help maintain consumer confidence in the food supply and ensure a level playing field.

Substantive Comments

1. The Proposed Rule should provide greater clarity as to how the sunset exceptions will function

HHS identifies six categories of regulations that would be excepted from the sunset requirements of the Proposed Rule (but not the Assessment or Review requirements). HHS should provide more information regarding the meaning of these exceptions and to which regulations they would apply.

Among other things, the Proposed Rule would not apply to, "Regulations whose expiration pursuant to this section would violate any other Federal law." HHS explains that this means regulations that are "prescribed by Federal law, such that the Department exercises no discretion as to whether to promulgate the Regulation and as to what is prescribed by the Regulation." 3/ The Proposed Rule suggests that such exceptions would be "rare" and that regulations will not be excepted "simply because the statutory authority for the Regulation provides that the Secretary "shall" prescribe regulations." 4/ The Proposed Rule provides examples of regulations that would not be excepted; however it does not provide examples of any regulations that would be excepted. We understand this exception to be very narrowly drawn, but the Proposed Rule could be made clearer by providing at least one example of a regulation that would fall under this exception so that affected entities can better estimate which, if any, regulations would be excepted and thus comment on the proposed approach.

Further, the Proposed Rule would not apply to regulations that "were issued in consultation with other agencies because of a legal requirement to consult with that other agency." 5/ We seek to better understand this exception and how it would apply to those food and dietary supplement regulations issued by FDA. For example, it is unclear whether it applies when FDA is required to "coordinate" with other agencies by law. Examples of those regulations relevant to our industry that would fall under this exception also are needed for us to provide meaningful comment on the Proposed Rule.

2. The Proposed Rule does not sufficiently outline how agencies will consider the factors for and how the Review will be conducted

Under the Proposed Rule, regulations that are Assessed and determined to have a significant economic impact upon a substantial number of small entities (SEISNOSE), would then be subject to Review to determine whether the regulation should be amended or rescinded. This Review process would consider seven factors, including the five factors set out in the Regulatory Flexibility Act. 6/ CRN agrees that these are important factors to consider in Reviewing

3/ 85 Fed. Reg. at 70109.
4/ *Id*.
5/ *Id*.; 85 Fed. Reg. at 70110.
6/ The factors set out in 5 USC § 610(b) are: (1) the continued need for the rule; (2) the nature of complaints or comments received concerning the rule from the public; (3) the complexity of the rule; (4) the extent to which the rule overlaps, duplicates or conflicts with other Federal rules, and, to the extent feasible, with State and local governmental rules; and (5) the length of time since the rule has been evaluated or the degree to which

regulations and appreciates the Department providing the transparency into the Review process that is so essential to reasoned regulatory reform. We have concerns, however, that without additional clarity and transparency regarding the proposed Review process, the Department's decision-making could be considered arbitrary or capricious. We suggest that HHS provide further clarity into the agency's decision-making process as to when a regulation would be identified as requiring rescission or amendment based on the factors. For example, if HHS were to identify overlap or duplication between a regulation under review and other Federal regulations, HHS should identify which factors would guide its decision to rescind versus amend the regulation and/or how the Department would identify which regulation is duplicative. Similarly, HHS should clarify whether there are numerical or content benchmarks that HHS will use to guide its decision-making with regard to complaints received about the regulation. Further, HHS should explain how the two additional factors beyond the RFA would come into play. HHS should outline this information in a subsequent Proposed Rule.

3. <u>The timeline for review in the Proposed Rule is unrealistic and could lead to inadvertent sunsetting of regulations, which would cause unnecessary chaos and harm to the industry and consumers alike</u>

The Proposed Rule would require the Assessment and Review of several thousand regulations in the first two years following the finalization of the rule (and thousands of regulations on a continuing basis thereafter). 7/ HHS estimates there are at least 273 rulemakings that will need to be Reviewed in the first two years, which it estimates will take 9,160 to 22,900 hours to perform (40 to 100 hours per Review). 8/ Additionally, HHS estimates that it will have to "Assess" an additional 2,207 rulemakings to determine whether they require Review. The Assessment phase is estimated to take 6,621 to 22,070 hours. Some of those assessed rulemakings will also require Review.

CRN appreciates the Department's ambition and willingness to prioritize badly needed regulatory review. But, these figures are highly unrealistic and committing to this review timeframe could lead to inadvertent sunsetting of regulations, which would cause unnecessary chaos and harm to the industry and consumers alike. In justifying the accelerated timeline, the Proposed Rule points to past efforts to conduct regulatory reviews. As an example, the Proposed Rule notes that for the time period July 2016 to April 2017, HHS planned to conduct up to 40 retrospective analyses

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technology, economic conditions, or other factors have changed in the area affected by the rule. The Proposed Rule would also consider two additional factors: "(6) whether the regulation complies with applicable law; and (7) "other considerations as required by relevant executive orders and laws."

7/ 85 Fed. Reg. at 70112. Roughly 12,400 HHS regulations are over 10 years old and the "vast majority" would need to be Assessed within the first two years.

8/ The Department generated cost estimates based on the time needed to Assess or Review a "rulemaking," which it defined as consisting of on average five regulations.

but only managed to complete 19. 9/ Although we support regulatory reform, we consider the quality of the review to be as important as the quantity of the reviews. We would encourage HHS to set review expectations that provide a timeframe more realistic to what is required for a thoughtful and substantive process.

Additionally, the two-year review period seems unrealistic and inappropriate for this particular administrative department in the context of the COVID-19 pandemic. We are concerned that the accelerated timeline has the potential to deter the agency from focusing on the critical issues of managing the COVID-19 pandemic and the Department's equally vital day-to-day responsibilities relevant to our industry, such as food and dietary supplement safety and ensuring products are properly labeled.

4. 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

HHS acknowledges several times in the Proposed Rule the risk that regulations could expire/sunset because the Department failed to Assess or Review them. To mitigate that risk, HHS proposes to establish a website tracking the status of the reviews, which HHS suggests will provide members of the public the opportunity to remind HHS if a deadline is nearing and request that HHS Review the regulation. 10/

We appreciate that this process may be intended to provide transparency and accountability as to the Department's progress, which are important pillars of regulatory reform. However, we are concerned that this system would shift the responsibility of timely review and avoiding inadvertent sunsetting from HHS onto the industry, which has the potential to be quite burdensome. We agree with the Department that small entity trade associations would likely be closely monitoring the website and would speak up if needed. 11/ The role of trade associations is especially important for the many small entity members of our industry. It is inappropriate, however, to purposely design a system dependent on our oversight for effectiveness.

9/ 85 Fed. Reg. at 70099.

10/ *See e.g.,* 85 Fed. Reg. at 70111 ("the Department recognizes that there is a risk that a Regulation whose benefits outweigh its costs could expire because the Department failed to Assess or Review it. The Department believes that risk may be lowered by members of the public reminding the Department if the Assessment or Review deadline is nearing and the Department has not commenced the Assessment or Review of a Regulation.").

11/ 85 Fed. Reg. at 70117 n144 (While the Department does not anticipate that every small entity will closely monitor the Department-managed website, the Department believes that for Regulations that have a truly significant impact on small entities, at least one affected small entity, or small entity trade association(s), would.")

5. 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

The Proposed Rule is supported by an HHS regulatory reform project, which piloted an approach to incorporate AI-driven data analytics (i.e., machine learning) into expert policy insights and reform. CRN applauds HHS for applying new technologies in creative ways that have the potential to streamline regulatory review and maximize review efficiency. Nonetheless, we are concerned that the details of this novel approach have not been made available for public review. For example, we understand that one analytical approach used in the pilot was to identify regulations that contained "old-fashioned terms" and recommend that those regulations be flagged for review. It is unclear whether this method would be used to identify the regulations requiring review. If machine learning is used to identify regulations for review, we would encourage HHS to be open and transparent about the technology it is using and the parameters. HHS should provide additional information regarding the methodology used in a subsequent Proposed Rule.

Procedural Comments

The Proposed Rule was published on November 4, 2020, with a comment deadline of 30 days. This short time frame is particularly concerning because HHS provided no advance notice or foreshadowing of a rulemaking of this type. In promulgating regulations, HHS is bound by the rulemaking procedures of the Administrative Procedures Act (APA), 5 U.S.C. § 553. The APA requires agencies to provide adequate notice of a proposed rule followed by a meaningful opportunity to comment on the rule's content. 12/ While we recognize that there is no established minimum comment period prescribed by the APA, Executive Order 12866 states that the public's opportunity to comment, "in most cases should include a comment period of not less than 60 days." 13/ Similarly, Executive Order 12889 states that for publication of proposed rules regarding technical regulations and sanitary measures, service of notice for such regulations shall not be less than 75 days before the comment due date (subject to some exceptions not relevant here). 14/ Shorter comment periods have been upheld only in the face of exigent circumstances. 15/ Here, no exigency exists. HHS has not issued the Proposed Rule to respond to a pressing public health or safety concern, nor is HHS under any court-ordered or statutory deadline to issue a final rule by a prescribed date. Further, certain affected parties (i.e., entities regulated by Centers for Medicare & Medicaid Services ("CMS")) have been provided 60 days to comment,

12/ 5 U.S.C. § 553(b)-(c).

13/ Exec. Order No. 12866, § 6(a)(1), 58 Fed. Reg. 51735, 51740 (October 4, 1993).

14/ Exec. Order No. 12889 § 6, 58 Fed. Reg. 69681 (Dec. 30, 1993). Many of the FDA regulations that will be within the scope of the review include technical and sanitary regulations.

15 *See, e.g., Omnipoint Corp. v. FCC,* 78 F.3d 620, 629–30 (D.C.Cir.1996) (upholding 15–day comment period given the "urgent necessity for rapid administrative action" evidenced by "congressional mandate [to act] without administrative or judicial delays" (citation omitted)).

suggesting that holding some affected parties to a 30 day comment window is not essential to HHS's rulemaking objectives (and further raises potential due process conflicts by allowing some regulated industry more time to respond to HHS).

The comment timeframe also raises concerns because many businesses were closed or employees on leave for the days surrounding Thanksgiving. This year, we also are navigating the challenges of the COVID-19 pandemic, which necessitates increased attention to worker safety, supply chain logistics, interfacing with local and public health departments, responding to consumer inquiries, and much more.

Moreover, HHS's public meeting on the proposed rule was a mere 10 calendar days (over the holidays) before the comment deadline. Public meetings are an important forum for affected parties to better understand proposed rules and an agency's interpretation of them. The short comment period effectively precludes us from taking the public meeting into account when considering our feedback on the Proposed Rule.

Further, 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 and dietary supplement safety and applied nutrition, drug evaluation and research, devices and radiological health, biologics evaluation and research, veterinary medicine, and tobacco products. The Proposed Rule spans 29 pages in the Federal Register (including 5 pages of proposed regulations) and encompasses 16 different topic areas upon which comments are requested. For the dietary supplement industry, the scope of 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 quality. Thirty days is an insufficient amount of time for a rule of this scope.

As we understand it, the Regulatory Streaming Analysis provided as supplemental information to the Proposed Rule (which is itself 170 pages, precluding meaningful review and assessment in 30 days) estimated that as many as 3,200 FDA regulations would fall into the category of unedited rules that are more than 10 years old. 16/ FDA appears to have the second-highest number of sections with outdated words per regulatory entity, only incrementally outpaced by CMS. CMS-regulated parties have until January 4, 2021 to review and provide comment, 30 additional days. 17/ As noted, there is a fundamental due process issue by allowing certain entities additional time to provide comments, especially when the impacts to the industries are similar. As such, the 30-day comment period is insufficient and should be extended.

16 Regulatory Streaming Analysis, Doc. No. HHS-OS-2020-0012-003 at 13.
17 *Id*. at 16.

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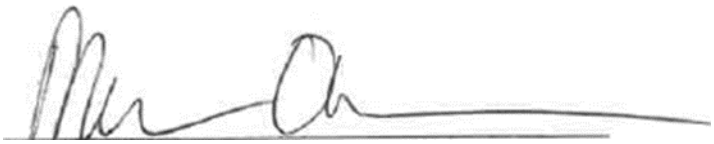
Effective regulatory reform is important to our industry and to all our members. The dietary supplement industry in particular supports the need for a measured approach to regulatory reform. Nonetheless, in light of the concerns outlined above and the short comment period, HHS should issue a subsequent Proposed Rule to address the issues we raise, so that we can provide meaningful comment on the Department's proposal.

Sincerely,



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