

March 5, 2025

**By Electronic Submission**

U.S. Department of Agriculture,  
Food Safety and Inspection Service  
1400 Independence Avenue SW  
Mailstop 3758  
Washington, DC 20250–3700

**Re: Food Date Labeling. Request for Information. Food Safety and Inspection Service (FSIS), U.S. Department of Agriculture (USDA); Food and Drug Administration (FDA), U.S. Department of Health and Human Services (HHS). Docket No. FSIS-2024-0021.**

The Council for Responsible Nutrition (CRN)<sup>1</sup> appreciates the opportunity to provide comments to the request for information by the Food Safety and Inspection Service (FSIS) and the Food and Drug Administration (FDA) as part of ongoing work to support the National Strategy for Reducing Food Loss and Waste and Recycling Organics. Dietary supplements are regulated by FDA as a category of food. The dietary supplement and functional food industry’s practices and preferences related to date labeling are relevant to the agencies’ request. We provide responses to select questions the agencies posed for commenters below.

**Industry Practices and Preferences for Date Labeling**

1. Which products contain date labels, and which do not? Why do some products contain date labels and others do not?

CRN Response

Although FDA regulations, including Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements (21 CFR Part 111), do not require date labeling

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<sup>1</sup>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](http://www.crnusa.org).

for dietary supplements,<sup>2</sup> many manufacturers voluntarily use shelf-life dating (also called expiration dating). Manufacturers use date labels to provide shelf-life information, which can indicate how long a product can be expected to maintain its quality, for the benefit of consumers and retailers. Because date labeling has been used on consumer products for many years, such as on food packages and over-the-counter drug products, consumers and retailers have become accustomed to date labels and may even expect them. Moreover, some global markets require shelf-life dating for dietary supplements. For example, Health Canada requires natural health product labeling to include an expiry date, which “should come after a term that the general public will clearly understand, for example “Expiration,” “Expiry date” or “EXP”. ”<sup>3</sup>

2. What standards or criteria do manufacturers and producers consider when deciding which food date label phrase to use? Are different phrases used for different products or categories of products, and if so, why? Are there legal or trade requirements or marketing standards that impact which phrases are used (i.e., local or state requirements, industry best practice standards, etc.)? If so, please describe.

CRN Response:

The dietary supplement cGMPs do not require shelf-life labeling but require that any shelf-life date used must be supported by data.<sup>4</sup> Data may pertain to quality attributes, such as strength of dietary ingredients in the dietary supplement. The cGMPs do not specify or provide guidance on phrases that may be used to indicate shelf-life; thus, manufacturers determine date label phrases for their products based on a variety of considerations. Commonly used phrases for dietary supplements include “Expiration” (abbreviated as “Exp”), “Best if Used by” (shortened as “Best By”) or “Use By.”

Manufacturers consider the specific product, the intended use of the product, and the space available on the packaging when determining which shelf-life phrase to use. For example, the phrase “Use By” may be necessary not only for food safety considerations but may also be more appropriate for certain specialty nutrition products whereby the product is intended for use by consumers or patients to supplement a substantial portion of the diet, or even as the sole source of the diet. In such cases, manufacturers may determine the firm “Use By” phrase as most appropriate.

Manufacturers also consider space available on packaging when determining the label phrase to use. For example, date coding on the package itself may have limited character spacing availability, and in these circumstances, manufacturers may apply the date label phrase that indicates where the date itself is located or coded. For example, the phrases “Use by date on bottom of container” or “Best if used by date on bottom of container,” may be used and the date itself is ink jetted or coded on-line during

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<sup>2</sup>Food and Drug Administration. Final Rule: Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements. 72 FR 34752 (Jun. 25, 2007).

<https://www.federalregister.gov/documents/2007/06/25/07-3039/current-good-manufacturing-practice-in-manufacturing-packaging-labeling-or-holding-operations-for>.

<sup>3</sup>Health Canada. Guidance document: Labelling of natural health products. <https://www.canada.ca/en/health-canada/services/drugs-health-products/natural-non-prescription/legislation-guidelines/guidance-documents/labelling.html#a1>

<sup>4</sup>72 Fed. Reg. 34752, 34856 (Jun. 25, 2007). <https://www.federalregister.gov/d/07-3039/p-1695>.

manufacturing. This approach ensures flexibility for on-line manufacturing, package sizing, and labeling considerations. Finally, manufacturers have various capitalization preferences. For example, “EXP” and “Exp” are interchangeable because they would not be expected to be interpreted differently by a consumer.

Regarding state standards, California’s Assembly Bill, AB 660, requires specific phrases for a food manufacturer, processor, or retailer responsible for the labeling of food items for human consumption that chooses, or is otherwise required by law, to display a date label to communicate a quality or safety date on a food item manufactured on or after July 1, 2026. For instance, “BEST if Used by” or “BEST if Used or Frozen by” must be used to indicate the quality date of the food item.<sup>5</sup> The specified phrases for a quality date under this bill do not include “expiration,” which is a common phrase used by the dietary supplement industry.

3. What standards or criteria do manufacturers and producers consider when deciding what date to use?

CRN Response:

As stated in the preamble of the dietary supplement cGMPs, FDA requires shelf-life dating to be supported by data, if used. As shelf-life dating is not a requirement, FDA declined to provide guidance on the types of data that should be used to support a shelf-life date. However, many manufacturers have testing programs designed to assess the stability characteristics of their dietary supplements and use testing results to support shelf-life dates. Further, FDA labeling regulations require that dietary supplements meet the label claim through their shelf-life.<sup>6</sup> Thus, stability testing is often relied upon to establish a product’s shelf life and inform any shelf-life dating used.

4. Would a particular product have a different date depending on the phrase used (e.g., would the date be the same or different if the phrase were “Best if Used By” versus “Use By” or “Freeze By”)? If so, please explain.

CRN Response:

The phrases “Expiration” and “Best if Used by” or their shortened forms are used interchangeably in the dietary supplement industry to indicate a product’s shelf-life, that is, the length of time that a product can be expected to maintain its quality. Manufacturers may also use the phrase “Use By” as opposed to “Expiration” or “Best if Used By” (see our response to Question 2).

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<sup>5</sup>AB 660 Food and beverage products; labeling; quality dates, safety dates, and sell-by dates.

[https://leginfo.legislature.ca.gov/faces/billNavClient.xhtml?bill\\_id=202320240AB660](https://leginfo.legislature.ca.gov/faces/billNavClient.xhtml?bill_id=202320240AB660).

<sup>6</sup>21 CFR 101.9(g)(3) and (g)(4); 21 CFR 101.36(f)(1).

5. What challenges or limitations do food manufacturers have when establishing or changing food date labels?

CRN Response:

When establishing the final rule for current good manufacturing for dietary supplements, FDA declined to require shelf-life dating, expiration dating, or best if used by dating for dietary supplements because of methodology and data limitations. Dietary supplements may contain a wide range of dietary ingredients from vitamins and minerals to amino acids to herbals and botanicals. Although testing methodologies exist for analyzing the strength of some ingredients in finished products, such as vitamin C, they are lacking for other ingredients, such as many botanicals. It remains a challenge, if not impractical, to require shelf-life dating supported by data for all dietary supplements.

For those manufacturers that can establish a shelf-life date, the challenges to changing date labels, such as changing the phrase used, are consistent with that of making any label change and/or making a change to on-line coding capabilities. For example, additional time and resources are needed to create and implement new labels. More time may be needed by smaller companies as compared to larger companies. The typical amount of time necessary to make a label change range from 18 – 24 months and could be longer if date coding during on-line manufacturing would need to be modified. In addition, packaging sizing, character space count limitations (for coding), must be considered. For this reason, some manufacturers may code the date on-line during manufacture and use the labeling to point to where the date is located (for example, the label would state “Use by date on bottom of container” and the date would be coded on-line during manufacture). Due to character spacing, some manufacturers use the shortened form “Best By” as a shortened form of “Best if used by.” Further, manufacturers typically desire to use up inventory to reduce waste, and the time to run through existing stock varies greatly.

6. Are there costs associated with changing the date label phrase or date used in addition to the costs associated with any label change? If so, please explain what those are. What data are available on the use of certain food date label phrases and cost to manufacturers, retailers, or consumers?

CRN Response:

As previously described, shelf-life dating is not currently required by federal regulation of dietary supplements; however, many manufacturers choose to establish product shelf-life based on data, which also support “Expiration” or “Best if Used by” dates used. If shelf-life dating becomes mandatory, then there would be significant costs related to generating data to support shelf-life dating for those not already doing so as part of manufacturing. Further, it may not be practical to generate data due to methodology limitations as previously described.

7. How do grocery retailers determine that a food item is no longer sellable? Do the considerations differ depending on the food item? Do the considerations take into account the phrase and/or date on the label, and if so, how?

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CRN Response:

Grocery retailers take varying approaches to determining when a food item is no longer sellable. Like many packaged foods, it is difficult to visually determine if a dietary supplement, typically sold in sealed, non-transparent packaging, has declined in quality. Therefore, retailers may rely on “Expiration,” “Best if Used By,” or “Use by” date to help determine when a product should be removed from store shelves. We believe retailers interpret the phrases “Expiration,” “Best if Used By,” and “Use by” to mean the same for the purposes of removing products from store shelves.

Summary

Dietary supplement and functional food manufacturers voluntarily use food date labeling (shelf-life labeling) and determine the appropriate date label phrase to use by considering the specific product, the product’s intended use, packaging limitations, and date coding capabilities. Therefore, a variety of date label phrases are commonly used, including, “Expiration,” “Best if used by,” and “Use by.” Shelf-life dating is often used to indicate the length of time that a product can be expected to maintain its quality. The dietary supplement cGMPs do not require shelf-life dating but expect that any shelf-life dating used to be based on data, such as stability data. Due to methodology and data limitations, it may not be possible for all dietary supplements to include a shelf-life date.

Thank you for considering our responses.

Sincerely,

A handwritten signature in cursive script, appearing to read 'Haiuyen Nguyen', with a long horizontal flourish extending to the right.

Haiuyen Nguyen

Vice President, Regulatory & Nutrition Policy