



November 13, 2020

Submitted electronically via regulations.gov

Docket Clerk
U.S. Department of Agriculture
Food Safety and Inspection Service
1400 Independence Avenue SW
Mailstop 3758, Room 6065
Washington, DC 20250–3700

**Re: FMI- The Food Industry Association Comments on the Food Safety and Inspection Service Proposed Rule on Prior Label Approval System:
Expansion of Generic Label Approval; Docket No. FSIS–2019–0019**

Dear Sir or Madam:

FMI- The Food Industry Association (FMI) appreciates the opportunity to provide comments on the Food Safety and Inspection Service (FSIS or the Agency) Proposed Rule on Prior Label Approval System: Expansion of Generic Label Approval.¹ FMI supports FSIS’s proposal to amend its labeling regulations to expand the circumstances under which FSIS will generically approve the labels of meat, poultry, and egg products. FMI further encourages the Agency to consider additional areas where generic approval may be appropriate or where the label approval process can be streamlined.

As the food industry association, FMI works with and on behalf of the entire industry to advance a safer, healthier and more efficient consumer food supply chain. FMI brings together a wide range of members across the value chain — from retailers that sell to consumers, to producers that supply food and other products, as well as the wide variety of companies providing critical services — to amplify the collective work of the industry. www.FMI.org

FMI Supports the Proposed Rule

In brief, FSIS’s Proposed Rule seeks to expand the circumstances under which FSIS will generically approve the labels of meat, poultry, and egg products, avoiding the need

¹ 85 Fed. Reg. 56538 (September 14, 2020), Proposed Rule on Prior Label Approval System: Expansion of Generic Label Approval; Docket No. FSIS–2019–0019, hereinafter “Proposed Rule.”



to submit these labels to FSIS sketch approval and freeing Agency resources to pursue other regulatory priorities. In the Proposed Rule, FSIS explains that, drawing on its experience with expanded generic label approval since 2013, “the Agency has concluded that the current label regulations continue to require industry to submit for approval a significant number of labels that could successfully be generically approved.”² Subjecting these labels to sketch approval imposes unnecessary cost on food companies and consumes Agency resources that could be used “to better focus on other consumer protection and food safety activities.”³ FMI agrees and believes the Proposed Rule is an important step in streamlining label approval requirements and continuing to modernize FSIS’s regulatory framework.

FMI supports the key elements of the Proposed Rule that would expand generic approval to cover a number of additional circumstances, including:

- Labels on products for export that deviate from FSIS requirements but meet the requirements of the foreign country.
- Claims in a label’s ingredients statement that designate ingredients as certified “organic” under the Agricultural Marketing Service (AMS) National Organic Program (NOP).
- Geographic landmarks or symbols.
- Negative claims highlighting the absence of a specific ingredient when the ingredient is not listed in the ingredient statement, e.g., “No Milk,” “Preservative Free.”
- Labels produced under voluntary FSIS inspection that otherwise meet FSIS’s criteria for generic approval of meat and poultry product labels.

FMI supports FSIS’s expansion of the categories of labels that are eligible for generic approval. FMI agrees that companies are well-suited to develop these types of claims in a way that complies with FSIS regulations and results in truthful and non-misleading labels. FSIS has well-established policies regarding these claims, and food companies have shown they can consistently implement these claims in compliance with FSIS requirements. Many of our members routinely make use of the generic approval process as an efficient way to bring compliant labels to market, and the Proposed Rule will help continue to streamline the label review process. Expanding generic approval as proposed will remove barriers to bringing new products to market and free up scarce Agency resources. The Proposed Rule is both appropriate and consistent with the Agency’s long-standing mission to ensure the commercial supply of meat, poultry, and

² Proposed Rule at 56541.

³ *Id.*



egg products is correctly labeled and packaged while streamlining and modernizing FSIS's regulatory programs.

Generic Label Approval Should Be Expanded to Additional Label Categories

FMI recommends that FSIS expand the Proposed Rule to include additional categories of labels eligible for generic approval. Fundamentally, generic approval, as reflected in the Proposed Rule, is based on the premise that the industry is readily capable of complying with well-established Agency policies for certain types of label claims, rendering sketch approval unnecessary. However, generic label approval currently does not extend to Organic claims for the product or Temporary approvals. As with other categories of generic approval, Organic claims and certain types of Temporary approvals can be readily implemented by industry, and extending generic approval to them would save significant Agency and industry resources.

- As noted above, FSIS proposes to expand generic label approval to include ingredients in the ingredient statement that are certified as "organic" under the NOP. We recommend that generic approval be expanded to also include Organic certification claims for the entire product (e.g., a USDA "Organic" claim on the front panel). Organic labeling is applied under a detailed program overseen by AMS and recognized certifying agents. The requirements for certification are clearly defined in extensive AMS regulations and guidance, and certifying agents ensure that Organic producers and processors are operating in compliance with those regulations, issuing certifications to demonstrate a company's compliance. Further, AMS has extensive enforcement mechanisms to ensure that USDA Organic claims are made in compliance with NOP requirements. If a company has already received Organic certification for a product, there is little additional value in having that company submit the same certification to FSIS as part of a sketch approval merely to verify the existence of the certification. FMI therefore recommends that FSIS extend generic label to include Organic claims made in compliance with a USDA Organic certification under the NOP.
- Within the proposed rule, there are distinctions between certified and non-certified claims relevant to the requirement to submit for pre-approval rather than generic approval. FMI recommends that certified claims, such as Non-GMO and gluten free, should be eligible for generic approval as they will have been preapproved by the respective certifying body. If it is not possible to include all certified claims within the generic guidelines, FMI recommends FSIS pre-select the certifying bodies that meet their standards, such that if a company uses one of these FSIS pre-selected certifiers, the label would be eligible for generic approval. In contrast, any certified claims by a certifying body that has not been pre-selected by FSIS would continue to require pre-approval submission. A list of



pre-selected certifying bodies could be included within the FSIS Compliance Guideline for Label Approval with its corresponding claim type.

- We encourage FSIS to allow a generically approved Temporary approval for extensions of time sensitive claims (e.g., “New,” “Now,” “Improved”). Currently, the FSIS Food Standards and Labeling Policy Book allows these claims to be used for a period of six months from the date of initial approval.⁴ However, extensions to the “New and Similar Terms” six-month period are allowed if certain conditions are met. We recommend FSIS expand the regulations to allow for generic approval of time extensions based on this documented policy. Substantiation supporting eligibility for a 6-month extension would be included with the generic temporary approval paperwork and available to inspectors.
- To decrease the number of repetitive submissions and reviews, we propose that FSIS allow a Temporary and a sketch approval submission to be submitted simultaneously. Occasionally, a company may need to submit for a Temporary label approval to account for an alternate ingredient substitution that requires a change to the ingredient statement, after which the labels are updated or the company reverts to the original ingredient. If the ingredient substitution is made permanent and the label bears a special statement or claim potentially affected by the ingredient change, the company must again submit the same label to obtain sketch approval for the special statement or claim affected by the ingredient substitution. The result is that the company must submit—and FSIS must review—the same label with the same formulation two separate times. FSIS could streamline this process by allowing establishments to submit in this type of situation a combined Temporary and sketch approval—the temporary approval to cover the noncompliant ingredient statement, and the sketch approval to cover the use of the alternate ingredient in the updated label bearing the special statement or claim. This process would further streamline FSIS label review and reduce Agency burdens while still ensuring that FSIS reviews both the initial temporary approval request and the continued use of the special statement or claim with the alternate ingredient.

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FMI supports FSIS’s Proposed Rule to expand the scope of generic approval, and we encourage FSIS to continue efforts to identify additional areas for expansion.

Should you have questions about these comments, please feel free to contact me at sbharris@fmi.org.

⁴ See “New and Similar Terms,” FSIS Food Standards and Labeling Policy Book (Rev. August 2005).



Sincerely,

Stephanie Harris

Stephanie Harris
Chief Regulatory Officer & General Counsel

