DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Parts 352, 354, 362, and 412

[Docket No. FSIS–2019–0019]

RIN 0583–AD78

Prior Label Approval System: Expansion of Generic Label Approval

AGENCY: Food Safety and Inspection Service (FSIS), U.S. Department of Agriculture (USDA).

ACTION: Final rule.

SUMMARY: FSIS is amending its regulations to expand the circumstances under which it will generically approve the labels of meat, poultry, and egg products. Also, as of the effective date of this final rule, FSIS will no longer evaluate generically approved labels that establishments and egg products plants voluntarily submit for FSIS review. FSIS is also announcing the availability of revised guidelines on the types of labels that must be submitted to FSIS for approval.

DATES: This rule is effective March 20, 2023. Submit comments on the revised FSIS Guideline for Label Approval on or before February 17, 2023.

ADDRESSES: A downloadable version of the revised FSIS Guideline for Label Approval is available to view and print at *https://www.fsis.usda.gov/inspection/compliance-guidance.* No hard copies of the guideline have been published.

FSIS invites interested persons to submit comment on the revised FSIS Guideline for Label Approval. Comments may be submitted by one of the following methods.

- *Federal eRulemaking Portal:* This website provides the ability to type short comments directly into the comment field on this web page or attach a file for lengthier comments. Go to *https://www.regulations.gov.* Follow the on-line instructions at that site for submitting comments.
- *Mail:* Send to Docket Clerk, U.S. Department of Agriculture, Food Safety and Inspection Service, 1400 Independence Avenue SW, Mailstop 3758, Washington, DC 20250–3700.
- *Hand- or Courier-Delivered Submittals:* Deliver to 1400 Independence Avenue SW, Jamie L. Whitten Building, Room 350–E, Washington, DC 20250–3700.

Instructions: All items submitted by mail or electronic mail must include the Agency name and docket number FSIS–2019–0019. Comments received in response to this docket will be made available for public inspection and posted without change, including any personal information, to *https://www.regulations.gov.*

Docket: For access to background documents or comments received, call (202) 720–5627 to schedule a time to visit the FSIS Docket Room at 1400 Independence Avenue SW, Washington, DC 20250–3700.

FOR FURTHER INFORMATION CONTACT: Rachel Edelstein, Assistant Administrator, Office of Policy and Program Development, by telephone at (202) 205–0495.

SUPPLEMENTARY INFORMATION:

Executive Summary

FSIS is finalizing its September 14, 2020, proposal to expand the circumstances in which FSIS will generically approve the labels of meat, poultry, and egg products (85 FR 56538). This final rule will expand generic approval to products only intended for export that deviate from domestic labeling requirements and permit generic approval of the labels of products that receive voluntary FSIS inspection. This final rule will also expand generic approval to: (1) ''Organic'' claims that appear in a product label's ingredients statement; (2) ''Geographic landmarks'' displayed on a product label; (3) ''Negative'' claims made on product labels that identify the absence of certain ingredients or types of ingredients. Furthermore, as of the effective date of this final rule, FSIS will no longer evaluate generically approved labels voluntarily submitted to the Agency for review. FSIS will, however, continue to provide industry with relevant resources, including updated generic labeling guidance, and timely answers to generic labeling questions via phone, askFSIS, and the Small Plant Help Desk.

Considering these changes, FSIS has revised and reissued the FSIS Guideline for Label Approval [1] to provide the public with updated information on the types of labels that must be submitted to FSIS for approval consistent with this final rule.

As is shown in Table 1, this final rule has net benefits of $799,507, annualized at the 7 percent discount rate over 10 years. Of which, industry will experience cost savings of $517,888, annualized at the 7 percent discount rate over 10 years, from the reduction in preparing and submitting certain labels for FSIS evaluation. FSIS will experience cost savings of $281,619, annualized at the 7 percent discount rate over 10 years, from the reduction in label evaluations. This final rule does not create any new cost burden for industry or FSIS.

TABLE 1—NET BENEFITS
[Cost savings]

	Annualized net benefit (7% discount rate, 10 years)
Industry	$517,888
Agency	281,619
Total	799,507

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I. Background

The Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 *et seq.*), Poultry Products Inspection Act (PPIA) (21 U.S.C. 451 *et seq.*), and Egg Products Inspection Act (EPIA) (21 U.S.C. 1031 *et seq.*) (hereinafter, ''the Acts'') direct the Secretary of Agriculture to maintain inspection programs designed to ensure that meat, poultry, and egg products are safe, wholesome, not adulterated, and properly marked, labeled, and packaged. These laws prohibit the sale of products under any false or misleading name, marking, or labeling and require the Secretary to approve product marking and labeling (21 U.S.C. 457(c), 607(d), and 1036(b)). The Department's longstanding interpretation [2] of these provisions is that they require the Secretary or his or her representative to

[1] The latest revision of the FSIS Guideline for Label Approval is available at: *https://www.fsis.usda.gov/inspection/compliance-guidance.*

[2] See, *e.g.,* 60 FR 67444, December 29, 1995; 76 FR 75809, 75810, December 5, 2011; 78 FR 66826, November 7, 2013; 85 FR 56538, 56539, September 14, 2020.

approve all labels to be used on federally inspected and passed, domestic and imported, meat, poultry and egg products, before the products may be distributed in commerce. To implement these provisions, FSIS uses a prior approval program for labels on federally inspected meat, poultry, and egg products (9 CFR part 412). Without approved labels, meat, poultry, and egg products may not be sold, offered for sale, or otherwise distributed in commerce.

To receive FSIS approval, meat, poultry, and egg product labels must comply with the Acts and the labeling regulations implemented thereunder. As discussed in the proposed rule (85 FR 56538, 56539), the regulations contain provisions to ensure that no statement, word, picture, design, or device that is false or misleading in any particular, or that conveys any false impression, or that gives any false indication of origin, identity, or quality, appears in any marking or other labeling (9 CFR 317.8, 381.129, and 590.411(f)(1)). Also, as discussed in the proposed rule, FSIS regulations require that meat, poultry, and egg product labels display up to eight features, to ensure that consumers have the information necessary to make informed purchasing decisions (85 FR 56538, 56539). The required features include: (1) The standardized, common or usual, or descriptive name, of the product (9 CFR 317.2(c)(1) and (e), 381.117, and 590.411(c)(1)); (2) an ingredients statement containing the common or usual name of each ingredient of the product listed in descending order of predominance (9 CFR 317.2(c)(2) and (f), 381.118, and 590.411(c)(1)); (3) the name and place of business of the manufacturer, packer, or distributor (9 CFR 317.2(c)(3) and (g), 381.122, and 590.411(c)(2)); (4) an accurate statement of the net quantity of contents (9 CFR 317.2(c)(4) and (h), 381.121, and 590.411(c)(4)); (5) the inspection legend, including the number of the official establishment [3] (9 CFR 312.2(b), 317.2(c)(5) and (i), 381.96, 381.123, and 590.411(c)(5)); (6) a handling statement if the product is perishable, *e.g.,* ''Keep Frozen'' or ''Keep Refrigerated'' (9 CFR 317.2(k), 381.125(a), and 590.410(a)(1)–(2)); (7) nutrition labeling for applicable meat and poultry products (9 CFR part 317, subpart B; part 381, subpart Y; and 590.411(e)); [4] and (8) safe handling instructions if the meat or poultry component of the product is not ready-to-eat (9 CFR 317.2(l) and 381.125(b)). In addition, imported meat, poultry, and egg products must bear the country of origin under the product name (9 CFR 327.14(b)(1), 381.205(a), and 590.950(a)(2)).

Under the prior label approval program, certain categories of labels receive ''sketch approval,'' meaning they must be submitted to FSIS for review and approval before use. However, FSIS regulations allow some product labels that bear all required labeling features and comply with the Agency's labeling regulations to be ''generically approved'' (9 CFR 412.2(a)(1)), meaning they may be used in commerce without prior FSIS review. Establishments, therefore, do not need to submit generically approved labels to FSIS' Labeling and Program Delivery Staff (LPDS) for evaluation. Instead, as discussed in the proposed rule, Inspection Program Personnel (IPP) perform surveillance and enforcement tasks in the field to verify that generically approved labels comply with labeling requirements (85 FR 56538, 56543).

Generic label approval has been in place in some form since 1983 (48 FR 11410, March 18, 1983). FSIS previously expanded the categories of labeling claims eligible for generic approval in 1995 (60 FR 67444, December 29, 1995). FSIS completed an assessment of the modified system in 1998 (76 FR 75809, December 5, 2011) and concluded that the great majority of establishments effectively used generically approved labels and that the gradual implementation of generic label provisions under the 1995 final rule was effective. FSIS expanded generic approval again in 2013 (78 FR 66826, November 7, 2013) and, in 2016, conducted a limited assessment of generic labels under the modified system, which found a high level of compliance with the requirements.

In June 2020, the USDA Office of Inspector General (OIG) concluded an audit of FSIS product labeling oversight (OIG audit #24601–0002–23, ''Controls Over Meat, Poultry, and Egg Product Labels'').[5] In response to the audit recommendations concerning FSIS oversight of generic labeling, the Agency agreed that it would continue to enhance its outreach efforts to ensure establishments are aware of applicable mandatory labeling features for generic labels. FSIS also agreed to update its internal policies to improve IPP label verification activities. FSIS took subsequent action to satisfy OIG's audit recommendations and, based on such action, the USDA Office of the Chief Financial Officer (OCFO) closed the audit on June 29, 2021.

Since the 2013 rulemaking (78 FR 66826), FSIS has gained significant, additional experience evaluating labels required to be submitted and approved. From that experience, FSIS has observed through its prior label approval system that most labels in the categories discussed in this final rule are compliant and do not require changes. Therefore, the Agency 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. Therefore, on September 14, 2020, FSIS published a proposed rule to amend the meat and poultry products inspection regulations to expand the circumstances under which labels of meat and poultry products would be deemed to be generically approved by the Agency (85 FR 56538). FSIS also proposed to cease evaluating generically approved labels submitted to FSIS for review (85 FR 56538, 56542). FSIS proposed these changes to its regulations to reduce the number of labels submitted for evaluation by FSIS and to lessen the paperwork burden on official establishments (85 FR 56538, 56541). As stated in the proposed rule, the reduction in staff time spent approving these labels will allow the Agency to better focus on other consumer protection and food safety activities, such as developing guidance materials, answering labeling policy questions, providing outreach to stakeholders, and ensuring IPP effectively verify that establishments meet labeling requirements (85 FR 56538, 56541). FSIS is now finalizing the proposed rule with minor changes to clarify label approval requirements with respect to voluntarily inspected poultry.

II. Final Rule

This final rule is consistent with the proposed rule. First, the final rule will extend generic label approval to products only intended for export that deviate from domestic labeling requirements, by removing 9 CFR 412.1(c)(2). As explained in the proposed rule, FSIS maintains an Export Library that lists requirements for exported products that foreign authorities have officially communicated to FSIS, including

[3] For purposes of this document, the term ''establishment'' includes official meat and poultry establishments and egg products plants, unless otherwise indicated.

[4] Nutrition labeling for egg products must comply with the provisions of 21 CFR part 101, promogulated under the Federal Food, Drug, and Cosmetic Act and the Fair Packaging and Labeling Act [9 CFR 590.411(e)].

[5] OIG's audit report is available at: *https://www.usda.gov/sites/default/files/audit-reports/24601-0002-23.pdf.*

labeling requirements.[6] At times, foreign country labeling requirements conflict with domestic requirements. FSIS regulations (9 CFR 317.7 and 381.128) permit export product labels to deviate from FSIS' domestic labeling requirements in order to comply with foreign country requirements or to be marketed more easily in a foreign country.[7] FSIS IPP verify whether product for export meets requirements listed in the Export Library, including labeling, when certifying products for export. Verification of foreign requirements is ultimately determined by each foreign country's competent authority.

Second, the final rule will revise the types of ''special statements and claims'' requiring label submission by providing for generic approval of three additional types of claims. As explained in the proposed rule, FSIS has, through its prior label approval system, routinely evaluated these types of claims for several years. From that experience, FSIS has observed that errors, omissions, and misrepresentations are rare on these types of labels. FSIS has, therefore, decided to expand generic approval to such claims. As with all generically approved labels, IPP will continue to conduct routine verification tasks in establishments to verify ongoing compliance with labeling requirements. FSIS is amending 9 CFR 412.1(e) and 412.2(b) to make these changes.

Under this final rule, the following types of claims will be generically approved:

a. ''Organic'' claims that appear in a product label's ingredients statement, which designate an ingredient as certified ''organic'' under the Agricultural Marketing Service's (AMS's) National Organic Program. The ingredients statement on these product labels designates specific ingredients as ''organic'' (*e.g.,* ''organic garlic''). Under this rule, FSIS will no longer require the submission and evaluation of supporting documentation to verify that such ingredients are indeed certified as ''organic'' by an AMS-recognized third-party certifier. However, FSIS will continue to require establishments to submit labels certifying a total product as organic to FSIS for evaluation.

b. ''Geographic landmarks'' displayed on a product label, such as a foreign country's flag, monument, or map. For example, the following claims displayed on a product label will no longer require FSIS review prior to entering commerce: a Polish flag depicted on a Polish sausage product label, or an outline of the State of Nevada depicted on a product label for beef produced in Nevada.

c. ''Negative'' claims made on product labels that identify the absence of certain ingredients or types of ingredients. For example, statements such as ''No MSG Added,'' ''Preservative Free,'' ''No Milk,'' ''No Pork,'' or ''Made Without Soy,'' on product labels that do not list these ingredients in the ingredients statement will no longer have to be evaluated by FSIS before use. However, FSIS evaluation of labels that bear negative claims relating to the raising of the animal from which the product is derived (*e.g.,* ''no antibiotics administered'') or negative claims relating to the use of genetically modified ingredients will continue to be required.

Third, the final rule will permit generic approval of the labels of products that receive voluntary FSIS inspection. FSIS provides several types of voluntary inspection services under the authority of the Agricultural Marketing Act (AMA) (7 U.S.C. 1621 *et seq.*), including inspection for: rabbits (9 CFR part 354), certain non-amenable species of livestock and poultry, such as elk, bison, and migratory waterfowl (9 CFR part 352, subpart A, and 9 CFR part 362); and products that contain meat or poultry but are not under FSIS jurisdiction, *e.g.,* closed-faced sandwiches (9 CFR 350.3(c)and 362.2(a)). Before this final rule, labels for some products produced under these voluntary inspection programs were not covered under the Agency's generic approval regulations at 9 CFR part 412. This final rule will permit generic approval for them on the same basis as amenable meat, poultry, and egg products by amending the relevant regulations where needed to include references to 9 CFR part 412.[8] For clarity, the final rule will also modify 9 CFR 352.1 to update the section heading and remove unnecessary language.

Finally, under the final rule, FSIS will no longer evaluate generically approved labels submitted voluntarily for FSIS review. Over the years, producers have become more familiar with FSIS' generic labeling requirements, and FSIS has provided additional guidance to assist them in designing compliant labels. Because voluntarily submitted labels receive a lower review priority than other labels, industry can receive more timely labeling assistance by utilizing Agency resources or contacting FSIS for help. Therefore, FSIS' evaluation of otherwise generic labels no longer represents an efficient use of Agency resources.

FSIS will, however, continue to provide industry with generic labeling resources and assistance to help them comply with requirements. For example, FSIS has revised and reissued the FSIS Guideline for Label Approval [9] to provide updated information on the types of labels that must be submitted to FSIS for approval consistent with this final rule. FSIS will also continue to assist industry with generic labeling issues via phone, askFSIS, and the Small Plant Help Desk.

II. Summary of Comments and Responses

FSIS received 33 comments on the proposed rule from individuals, trade associations, private businesses, non-profit organizations, a consultant, a software company, the European Union (EU), and OIG. Fourteen commenters supported the proposed rule; though, some commenters requested revisions to or clarification on specific provisions of the rule. Most of these commenters stated that they supported the proposed rule because it will streamline the prior label approval system, reduce the label approval backlog, result in a cost savings for industry and government, and allow FSIS to utilize its resources more effectively.

Four commenters opposed the proposed rule, generally citing concerns over reduced oversight of meat, poultry, and egg product labeling claims. Twelve comments expressed concerns regarding specific provisions or language in the proposed rule but did not otherwise express opposition or support for the remainder of the rule. The remaining comments were outside the scope of the rule. A summary of the relevant issues raised by commenters and the Agency's responses follows.

[6] The Export Library is available at: *https://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/exporting-products/export-library-requirements-by-country.*

[7] Although there is no specific equivalent regulation for egg products, FSIS follows the same policy because such products, intended exclusively for export, must comply with foreign countries' requirements and are therefore not considered misbranded.

[8] Under existing regulations, non-FSIS-jurisdiction products that contain meat or poultry (9 CFR 350.3(c)) and products containing non-amenable species of poultry (9 CFR part 362), which are voluntarily inspected, are already subject to the label approval provisions of 9 CFR part 412. Nonetheless, this final rule adds additional regulatory language to 9 CFR part 362 to further clarify label approval requirements with respect to voluntarily inspected poultry.

[9] The latest revision of the FSIS Guideline for Label Approval is available at: *https://www.fsis.usda.gov/inspection/compliance-guidance.*

A. Industry Compliance and Agency Oversight

Comment: OIG questioned FSIS' conclusion that its previous generic labeling assessments found a high level of industry compliance with requirements and its assertion in the proposed rule (85 FR 56538, 56543) that OIG's audit of FSIS' product labeling oversight (OIG audit #24601–0002–23) does not affect the proposed expansion of generic labeling eligibility. Unlike FSIS, OIG does not believe that the assessments or the audit found a high level of industry compliance with generic labeling requirements. As part of its audit, OIG reviewed 878 generic labels that industry voluntarily submitted to FSIS for review and found that FSIS requested changes to 74 percent of these labels. OIG also noted that three establishments OIG visited during its audit did not make required modifications to their generic labeling records. For these reasons, OIG recommended that FSIS consider performing a statistically valid assessment, before publishing this final rule, to ensure establishments have achieved a high level of compliance with generic label requirements. OIG also asked FSIS to consider ensuring that IPP select generic labels when performing General Labeling Tasks.

Response: As discussed in the proposed rule (85 FR 56538, 56541), FSIS completed an assessment of its generic labeling system in 1998 (76 FR 75809, December 5, 2011). Of the 1,513 labels that FSIS reviewed during its assessment, 1,434 (approximately 95 percent) were either in complete compliance or had only minor labeling errors (*e.g.,* insufficient spacing around the declaration of net weight or an error in the name of the manufacturer, packer, or distributor) that were not of public health or economic significance (76 FR 75813). As discussed in the proposed rule (85 FR 56538, 56541), FSIS also conducted a limited assessment in 2016, with similar results. Thus, FSIS maintains its view that its previous assessments found a high level of compliance from the labels reviewed.

In June 2020, OIG concluded an audit of FSIS' oversight of generically approved and sketch approved labeling.[10] In response to the official draft of the audit, FSIS expressed concerns that the audit was flawed in several areas, and that OIG misinterpreted specific labeling regulations and how they are applied to the labeling review process. FSIS also expressed concerns that OIG evaluated the label approval program on a rigid set of standards that did not accurately reflect FSIS regulations or consider FSIS' history and expertise in implementing the regulations and review of labels. OIG addressed some, but not all, of these concerns in its final audit report. Despite FSIS' misgivings about the audit, the Agency generally agreed with OIG's recommendations, and OIG accepted FSIS' decisions on all its recommendations.

FSIS took subsequent action to satisfy OIG's recommendations and, based on such action, OCFO closed the audit on June 29, 2021. For example, on June 7, 2021, the Agency revised FSIS Directive 7221.1, *Prior Labeling Approval,*[11] to clarify that IPP are to routinely select generically approved labels when performing General Labeling Tasks.[12] FSIS also documented internal Standard Operating Procedures to assist LPDS analysts with the label evaluation process, including formalizing a Quality Control program to randomly review label adjudications.

FSIS also took action to address OIG's finding that three establishments it visited during its audit did not make required modifications to their labeling records. Although this finding was only based on a review of four labels, FSIS nonetheless published a *Constituent Update* to remind all establishments that FSIS label approval, including approval of voluntarily submitted generic labels, is contingent on the establishment making the revisions noted by FSIS.[13] FSIS also recently updated FSIS Directive 7221.1 to clarify that, as part of the General Labeling Task, IPP are to routinely verify that establishments make required modifications to their labels.

FSIS acknowledges OIG's finding that FSIS requested changes to 74 percent of the generic labels voluntarily submitted to the Agency by industry, which OIG reviewed during its audit. For a number of reasons, however, this finding does not accurately reflect the overall compliance of generically approved labels. First, industry typically submits generically approved labels to FSIS to resolve questions about some aspect of the label's compliance. Thus, the labels OIG audited were, by their very nature, more likely to have minor deficiencies than generically approved labels not voluntarily submitted to FSIS. Second, nearly all the deficiencies identified were very minor and did not require label revocation. Moreover, none of the identified deficiencies created a health or safety concern or provided the establishment with an economic advantage.

Based on the above, FSIS maintains its view that generic labels typically comply with labeling regulations. The great majority of errors that do occur are minor, do not require label revocation, and are not of public health or economic significance. As such, FSIS did not conduct another assessment prior to publication of this final rule. However, as discussed, FSIS has already taken action to address OIG's recommendations and successfully close the audit, such as reissuing Directive 7221.1 to clarify that IPP are to include review of generic labels as part of the General Labeling Task and verify that establishments have made required modifications, if any, to such labels. In addition, FSIS will continue to train and support IPP on this issue via webinars, askFSIS, and other outreach including participating in IPP training conducted by the FSIS Center for Learning (CFL).

Comment: An individual commenter argued that the sample size of the 2016 assessment was not adequate to effectively gauge industry compliance with generic labeling requirements. The commenter also noted that FSIS did not provide a link to the results of that assessment in the proposed rule. The commenter recommended that, moving forward, FSIS perform additional generic labeling assessments.

Response: As discussed in the proposed rule, the 2016 assessment was a limited assessment conducted to address concerns about the effectiveness of generic labeling and establish protocols for a potential future national assessment (85 FR 56538, 56541). Labeling policy experts reviewed 270 labels for compliance with generic labeling requirements.[14] These 270 labels reflect a representative sample from the five Federally regulated establishments subject to the assessment. Thus, the sample size was adequate to gauge their compliance with generic labeling requirements.

FSIS did not produce a report outlining the comprehensive results of the assessment. Instead, in line with the assessment's methodology, FSIS drafted

[10] Audit Report 24601–0002–23 available at *https://www.usda.gov/sites/default/files/audit-reports/24601-0002-23.pdf.*

[11] FSIS Directive 7221.1 is available at: *https://www.fsis.usda.gov/policy/fsis-directives/7221.1.*

[12] The General Labeling Task is a set of surveillance procedures that IPP use to verify the ongoing compliance of labels, including generic labels, at establishments. FSIS Directive 7221.1, *Prior Labeling Approval,* provides instructions to IPP for conducting the General Labeling task.

[13] *FSIS Constituent Update: Tips for Faster Label Approval Process.* August 9, 2019, available at: *https://www.fsis.usda.gov/news-events/news-press-releases/constituent-update-august-9-2019-0.*

[14] Methodology available at: *https://www.fsis.usda.gov/guidelines/2016-0019.*

an assessment summary letter for each individual establishment. FSIS also discussed the overall results of the assessment in the proposed rule, noting that the assessment found a high level of compliance with the generic labeling requirements and identified only three labels with deficiencies necessitating label revocation (85 FR 56538, 56541). None of these deficiencies involved food safety.

FSIS may conduct future assessments, as needed, and as Agency time and resources permit to gauge ongoing industry compliance with generic labeling, including the provisions in this final rule. However, the Agency determined that an assessment was not necessary prior to publication of this final rule, given its previous assessments have shown a high level of industry compliance with generic labeling requirements.

B. Cost of Label Review

Comment: One individual stated that the proposed rule is not necessary because the costs associated with FSIS' label review process are already relatively low.

Response: FSIS disagrees. The cost of label submissions and evaluations vary and is dependent on the complexity of the individual label. FSIS estimates that the total industry and Agency net cost savings under this rule from the reduction in FSIS label submissions to be $5,615,403 discounted at the 7 percent discount rate over a 10-year period, present value. FSIS is focused on making the label approval process more efficient while ensuring food safety and preventing misbranded products.

C. Increase in Deficient Labels

Comment: Several individuals expressed concerns that expanding generic approval to other categories of labels will substantially increase the number of deficient labels in commerce. Some individuals also suggested that expanding generic labeling will encourage establishments to intentionally abuse the labeling system. In addition, some individuals stated that periodic IPP verification of generic labels is insufficient to identify and prevent misbranded labels before they cause harm to consumers.

Response: FSIS disagrees. First, FSIS' experience with generic label approval does not support the assertion that expanding generic approval will substantially increase the number of deficient labels in commerce. Generic labeling has been in place in some form since 1983. This final rule, like previous expansions of generic approval eligibility, will continue to require that establishments comply with FSIS' labeling regulations. Establishments have been required to include the following features on their product labels for many years: product name (9 CFR 317.2(c)(1) and (e), 381.117, and 590.411(c)(1)); inspection legend/establishment number (9 CFR 312.2(b), 317.2(c)(5) and (i), 381.96, 381.123, and 590.411(c)(5)); handling statement (9 CFR 317.2(k), 381.125(a), and 590.410(a)(1)–(2)); net weight (9 CFR 317.2(c)(4) and (h), 381.121, and 590.411(c)(4)); ingredients statement (9 CFR 317.2(c)(2) and (f), 381.118, and 590.411(c)(1)); signature line (9 CFR 317.2(c)(3) and (g), 381.122, and 590.411(c)(2)); nutrition facts panels (9 CFR part 317, subpart B; part 381, subpart Y; and 590.411(e)); and safe-handling instructions (9 CFR 317.2(l) and 381.125(b)). FSIS IPP will continue to verify that establishments' labels include these features and otherwise comply with labeling requirements. Moreover, as discussed above, FSIS has evaluated the compliance of generically approved labels after previous expansions of generic approval eligibility and found that they typically comply with labeling regulations. FSIS expects that the categories of labels added to generic approval by this rule will have a similarly high compliance rate, and any increase in the number of deficient labels entering commerce resulting from the expansion of generic label approval by this rule will be minimal.

FSIS' experience with generic label approval also does not support the assertion that expanding generic label approval will encourage establishments to intentionally abuse the labeling system. Past incidents of establishments intentionally misusing generic label approval have been rare, and FSIS does not expect that to change with this rule. IPP routinely perform labeling verification activities in federally inspected establishments to identify and deter such activity. Moreover, the costs associated with noncompliance, such as the costs to replace deficient labels or the disruption of production, disincentive such behavior. In addition, if any such activity does occur, FSIS may take action to control misbranded products and take enforcement action under the FSIS Rules of Practice (9 CFR part 500).

In addition, FSIS disagrees with the assertion that IPP verification of generic labels is insufficient to identify and prevent misbranded labels before they cause harm to consumers. IPP have consistently demonstrated their ability to review generic labels and ensure a high level of compliance with labeling requirements. FSIS will revise and reissue instructions to IPP regarding the verification of generic labels as necessary. For instance, FSIS recently reissued FSIS Directive 7221.1 to provide IPP with updated instructions for conducting the General Labeling task in the Public Health Information System (PHIS) [15] that are consistent with this final rule. As discussed, the Agency has also updated the FSIS Guideline for Label Approval to be consistent with this final rule. FSIS will also update and administer generic labeling training webinars for IPP, as necessary. Moreover, this rule is expected to reduce the number of labels submitted to FSIS, freeing up resources that will allow the Agency to better focus on providing labeling support to industry and IPP. FSIS will focus its time and resources on preventing more non-compliances through new and improved labeling guidance, outreach, and other support services for its stakeholders, including via phone, askFSIS, and the Small Plant Help Desk. In addition, IPP will continue to verify generic labels for compliance on a routine basis and inform establishments of the need to correct any deficiencies they identify.

D. Organic Claims

Comment: A consulting firm and a trade association asked FSIS to expand generic approval to all ''organic'' labeling on a product, rather than limiting it to ''organic'' claims listed in the ingredients statement.

Response: FSIS will not expand generic approval to all ''organic'' labeling at this time. There are additional requirements for labeling a total product as ''organic'' as opposed to just a particular ingredient. For example, approving an entire product as ''organic'' requires the review of supporting documentation on ''organic'' processing, including ''organic'' certificates. Such claims need to be reviewed by LPDS staff that have expertise in the types of supporting documentation needed to determine compliance. Such ''organic'' claims are, therefore, not easily verifiable by IPP. Thus, FSIS will continue to require prior approval for labels that display ''organic'' claims outside the ingredients statement, including those certifying a total product as ''organic.''

Comment: Several individuals stated that the rule will weaken regulatory oversight of ''organic'' claims on meat,

[15] PHIS is FSIS' dynamic, comprehensive data analytic system, which was launched as part of the Agency's effort to collect, consolidate and analyze data in order to improve public health.

poultry, and egg products. They also stated that allowing ''organic'' claims in the ingredients statement will mislead consumers into believing they are buying certified organic products.

Response: The final rule will not weaken oversight of ''organic'' claims. FSIS regulations will continue to require that all ''organic'' claims be truthful and not misleading. LPDS analysts will continue to evaluate and approve ''organic'' claims displayed outside of the ingredients statement. IPP will verify the truthfulness of generically approved ''organic'' ingredient claims made in the ingredients statement. IPP verify, through record review and observation, that all ingredients used in the production of the product are present on the product formulation record and that all ingredients in the product formulation are declared in the ingredients statement on the product label by common or usual name in descending order of predominance. IPP also verify, through record review and observation, that the appropriate label is applied to the product. IPP directly observe that all ingredients used in a product formulation are appropriately declared on the final meat, poultry, or egg product labels. The AMS National Organic Program will also continue to provide oversight of organic claims.

FSIS also disagrees that listing some ingredients as ''organic'' in the ingredients statement will mislead consumers. So long as they are truthful, the AMS National Organic Program regulations,[16] which were first published in December 2000,[17] permit ''organic'' claims to appear in the ingredient statements of non-certified products. FSIS did not propose to change those requirements.

E. Negative Claims

Comment: One producer asked FSIS to clarify whether ''gluten free'' claims qualify for generic approval under the rule. Another individual specifically opposed any action that would deregulate ''gluten free'' labeling.

Response: The term ''gluten free'' is considered a negative claim and will receive generic approval under this final rule. However, the final rule will not deregulate ''gluten free'' labeling or change recordkeeping requirements. Such claims must still be truthful and not misleading in accordance with 9 CFR 317.8, 381.1, and 381.129. As discussed above, IPP will routinely verify the accuracy of generically approved labels. Specifically, for ''gluten free'' claims, IPP will verify that the product does not have any gluten containing ingredients and that there is adequate support for the claims in the labeling record.

Comment: Some individuals stated that the rule will increase the likelihood that meat, poultry, and egg products in commerce contain undeclared allergens or other ingredients that consumers must avoid for health, ethical, or religious reasons. A few individuals also stated that generic approval of ''negative'' claims would encourage producers to publish fraudulent ingredients statements.

Response: FSIS disagrees that the expansion of generic labeling will increase the likelihood that meat, poultry, or egg products will contain undeclared ingredients or allergens. The final rule will not change the requirement that ''negative'' claims must be truthful and not misleading. This final rule also will not change any requirements pertaining to product ingredient statements, which must continue to be truthful and list all ingredients in the product formula (9 CFR 317.2 and 381.118).

When LPDS evaluates labels during prior label review, they ensure that: the up to eight labeling features required by the meat, poultry, and egg products inspection regulations are present on the label; any claims are appropriately supported; and that any undefined claims, ad copy, or other information that may be false or misleading is not included on the label. As part of this process, LPDS compares written product formulations provided by establishments to the ingredients listed on their product labels. LPDS does *not,* however, physically inspect products as they are being made to ensure that only the ingredients listed on the label are used in final food products. IPP conduct reviews of this kind in the establishment, after the relevant label has been approved, whether generically or on a per-case basis by LPDS analysts.[18] IPP review labels and compare them to actual product formulations to verify that the ingredients used in the production of the product are listed accurately on the label, that the label is not misleading, and that it is otherwise in compliance with all labeling requirements. IPP will also continue to perform general labeling tasks to verify the accuracy of ''negative'' claims.

IPP will also continue to verify that establishments accurately control and label the most common food allergens. In accordance with FSIS Directive 7230.1, *Ongoing Verification of Product Formulation and Labeling Targeting the Eight Most Common (''BIG 8'') Food Allergens,* IPP identify products that may contain allergens and routinely conduct allergen formulation verification tasks at the establishment. These tasks include a record review and direct observation component to ensure that all ingredients, including allergens, used in a product formulation are appropriately declared on the final meat, poultry, or egg product labels.

Additionally, the final rule will not expand generic approval to all types of ''negative'' claims (*e.g.,* ''no antibiotics administered''). FSIS is only expanding generic approval to ''negative'' claims that identify the absence of certain ingredients or types of ingredients that are not listed in the ingredients statement and are easily verifiable by IPP. In FSIS' experience, errors or omissions for these types of claims are rare.

Comment: A trade association stated that some ''negative'' claims, including ''preservative free,'' ''no artificial ingredients,'' and ''no MSG added,'' are difficult for IPP to verify. Thus, the commenter asked that FSIS either provide updated guidance on these terms before publication of the final rule or modify the rule to exclude problematic claims from generic approval.

Response: FSIS disagrees that ''negative'' ingredient claims are difficult for IPP to verify. IPP have access to product formulas for all products produced at Federal establishments, including those products with labeling bearing ''negative'' ingredient claims. The General Labeling Task and ''Big 8'' Formulation Verification Task in PHIS require IPP to compare the product formula with the ingredients listed on the label. In doing so, IPP will also verify that ''negative'' ingredient claims are truthful and not misleading. In addition, FSIS has updated and reissued FSIS Directive 7221.1 and the FSIS Guideline for Label Approval to include additional guidance and instructions pertaining to ''negative'' claims. FSIS will also continue to answer questions and provide labeling support to IPP and industry through askFSIS. In addition, FSIS will perform more outreach and develop webinars about ''negative'' claims.

Comment: Some non-profit organizations and individual commenters stated that FSIS should not

[16] 7 CFR part 205.

[17] 65 FR 80548, December 21, 2000.

[18] See FSIS Directive 7221.1, *Prior Labeling Approval and* FSIS Directive 7000.1, *Verification of Non-Food Safety Consumer Protection Regulatory Requirements.*

generically approve animal raising claims, including ''negative'' claims pertaining to the raising of the animal.

Response: FSIS agrees. As discussed in the proposed rule, some claims, including animal raising claims, benefit from LPDS evaluation due to their complex nature and need for supporting documentation (85 FR 56538, 56545). Therefore, this final rule does not revise any Agency policy or regulation concerning animal raising claims. As stated in the proposed rule (85 FR 56538, 56542), generic approval will not apply to ''negative'' claims relating to the raising of the animal from which the product is derived, *e.g.,* ''no antibiotics administered''.

F. Certified Claims

Comment: One trade association requested that FSIS allow generic approval of any certified claims, *e.g.,* ''certified non-GMO,'' that are preapproved by a third-party certifier. In the alternative, the commenter asked that FSIS develop specific standards for third-party certifiers, approve certifiers based on those standards, and allow the generic approval of certified claims where the certification was issued by an approved certifier. The commenter argued that IPP can easily verify such claims by reviewing the labeling record.

Response: FSIS will not expand generic approval to certified claims, preapproved by a third-party certifier. FSIS will continue to review such claims, including certified animal raising claims, certified non-GMO claims, and other certifications issued by third party certifiers. Certified claims include the specific claim, identification of the certifying entity verifying the claim, and a web-address for interested parties to obtain additional information on the standards applied that are being certified. Evaluation of these claims includes reviewing the claim, standards for the claim, as well as certificates for applicable products and establishments. The labeling record must include proof of current certification, accompanied by certification criteria, which must be evaluated by labeling experts. Therefore, certified claims are not easily verifiable by IPP.

G. Temporary Label Approval

Comment: A few trade associations requested that FSIS expand generic approval to cover temporary label extensions for time sensitive claims (*e.g.,* ''new,'' ''now,'' or ''improved'').

Response: FSIS will not expand generic approval to extensions of the use of time sensitive label claims (*e.g.,* ''new,'' ''now'' or ''improved''). Temporary use of labels bearing a time sensitive claim beyond six months may not extend longer than 180 days, as stated in the Policy Book, unless FSIS LPDS grants an applicant's request for additional time (9 CFR 412.1(f)). To receive such an extension, an applicant must demonstrate that denial of the request would create undue economic hardship and that extending use of the label would not misrepresent the product, give the applicant an unfair competitive advantage, or present any health, safety, or dietary problems to the consumer (9 CFR 412.1(f)(1)). Furthermore, according to the Policy Book, applicants seeking an extension for time sensitive claims must demonstrate that production or distribution delays precluded the use of the approved labeling as scheduled or that labeling inventory needs for the 180-day period, were overestimated due to poor sales. The Policy Book also allows the extended use of time sensitive claims in situations where it is customary to distribute ''new'' products to various geographical regions if the processor can assure adequate controls over the segregation and distribution of the products. In addition, the Policy Book allows FSIS to approve the extended use of time sensitive claims in situations where the applicant is test marketing a product, but only if it can demonstrate that just 15 percent or less of the total market is involved in the test marketing.

Because applicants must demonstrate compliance with several detailed requirements in order to use time sensitive claims beyond 180 days, such extensions are not good candidates for generic approval. IPP cannot easily verify compliance with such criteria and, thus, the Agency is concerned that allowing the extension of time sensitive claims on a generic basis would result in use of the labels well beyond the 180-day limit. FSIS LPDS will continue to evaluate all extension requests for the use of time-sensitive claims to ensure that applicants have demonstrated compliance with pertinent regulations and policy.

Comment: One trade association requested that FSIS allow establishments to submit temporary and permanent label approval requests simultaneously. According to the commenter, companies sometimes need to submit labels for a temporary label approval to account for an alternate ingredient substitution that requires a change to the ingredients 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 twice. The commenter states that FSIS should streamline this process by allowing establishments to submit a combined temporary and permanent approval request.

Response: Extending temporary label approval of labeling with deficiencies to include a sketch approval of the corrected label is outside the scope of this rule. Temporary approval of the use of deficient labels requires that the label meets the criteria described in 9 CFR 412.1(f)(1)(i–iv), which is a different set of criteria than that used to evaluate the corrected label.

H. Voluntary Submissions

Comments: Several commenters, including a consulting firm and a few trade associations, stated that FSIS should continue to evaluate generically approved labels voluntarily submitted to the Agency, because, according to the commenters, it is necessary to protect establishments from legal liability. These commenters also noted that the proposal to eliminate this review may lead to more non-compliant labels and product recalls.

Response: FSIS' decision to no longer review generic labels voluntarily submitted to the Agency will not likely lead to more non-compliant labels and product recalls. FSIS remains committed to helping its stakeholders navigate labeling requirements. However, evaluating generic labels submitted for voluntary review is an inefficient use of Agency resources as the labels may be applied to products entering commerce without formal FSIS approval, provided they meet the conditions in 9 CFR 412.2. Moreover, industry can receive more timely assistance by utilizing Agency resources or contacting FSIS, given that voluntarily submitted labels receive a lower review priority than other labels. Thus, rather than review generically approved labels, FSIS will focus its time and resources on preventing more non-compliances through new and improved labeling guidance, outreach, and other support services for its stakeholders, including via phone, askFSIS, and the Small Plant Help Desk. In addition, IPP will continue to verify generic labels for compliance on a routine basis and inform establishments of the need to correct any deficiencies they identify.

In addition, FSIS review of generic labels was never intended to protect

industry from legal liability. Ultimately, establishments bear full legal responsibility for ensuring that their final product labels are truthful, accurate, and otherwise in compliance with all applicable regulations.

Comment: Some commenters, including a few trade associations, stated that FSIS' review of generically approved labels is sometimes necessary to help industry and IPP resolve labeling issues. The commenters asked FSIS to clarify whether it will continue to assist industry and IPP with generic labeling issues by other means. If voluntary review is eliminated, the commenters requested that FSIS develop additional generic labeling guidance and resources for industry and IPP. One trade association also asked FSIS to establish a help desk for rapid answers to generic labeling questions.

Response: Given voluntarily submitted labels are not prioritized for review, submission of such labels is not an efficient means to resolve labeling questions or other issues for IPP or industry. It is more efficient for industry and IPP to resolve such issues by referencing Agency resources, such as published labeling guidance and webinars, or by contacting FSIS. FSIS will continue to provide IPP and industry with generic labeling assistance and timely answers to generic labeling questions via phone or askFSIS. Thus, there is no need for FSIS to create a new help desk for answering questions or resolving issues. Moreover, a benefit of the final rule is that staff hours that were previously spent adjudicating generic labels, will be redirected toward other Agency priority initiatives that better support IPP and industry through, amongst other things, the development of new and improved training for inspectors, updated instructions for IPP, outreach, and guidance on labeling, including generic labeling.

Comment: Some trade associations and individual commenters stated that the proposal to eliminate review of labels that can be generically approved will hurt new or small producers who do not have the expertise or resources to navigate complex labeling requirements. In addition, one trade association stated the Agency must continue the practice of reviewing generic labeling to fulfill its mission under the Small Business Regulatory Enforcement Fairness Act (SBREFA).

Response: FSIS disagrees with these comments. Although FSIS will no longer review generic labels, the Agency will continue to be responsive to small business inquiries about compliance with the Agency's regulations and otherwise fulfill its obligations under SBREFA. FSIS will continue to answer inquiries by new or small producers seeking information and advice on compliance with Agency statutes and regulations and the interpretation and application of law to specific sets of facts supplied by the producers. As discussed above, FSIS will continue to provide many resources to help industry, including new and small producers, comply with generic labeling requirements. For example, such producers can directly contact LPDS, whose staff members are readily available to provide detailed answers to their generic labeling questions via phone or askFSIS. Small producers can also utilize FSIS' Small Plant Help Desk to find answers to common questions from small and very small plant owners and operators across the country or submit a question to FSIS subject matter experts. In addition, new and small producers can easily access FSIS' comprehensive labeling guidance, which is readily available on its website.[19] Moreover, FSIS plans to develop additional generic labeling materials, training, webinars, and other support services to assist new or small producers. Thus, new or small producers should not need to hire experts or additional staff to comply with FSIS' labeling requirements.

Comment: One trade association stated that FSIS has a legal duty to continue reviewing any label submitted to the Agency, including generically approved labels.

Response: FSIS disagrees. The Acts require that the labels be ''approved'' by the Secretary (21 U.S.C. 457(c), 607(d), and 1036(b)); however, they do not require that the approval system be centralized or decentralized. They also do not prescribe any particular type of system for the granting of label approvals. Therefore, the Acts permit the Agency to classify certain types of labels and labeling features as eligible for ''generic'' approval.

Comment: One individual asked FSIS to clarify whether it conducted a cost-benefit analysis of its decision to stop reviewing voluntarily submitted labels.

Response: The cost-benefit analysis that FSIS published in the proposed rule (85 FR 56538, 56546) and the updated analysis in the ''Alternative Regulatory Approaches'' section of this final rule considered the alternative of having LPDS continue to evaluate labels that would otherwise be generically approved. FSIS rejected this alternative because, among other things, these labels are reviewed at a slower pace and industry could more quickly get FSIS assistance on these types of labels via phone, askFSIS, the Small Plant Help Desk, or other Agency resources. Additional information on the analysis of this alternative is found below under the heading ''Alternative 2—*The Final Rule, Except Industry Would Still Have the Option to Have LPDS Evaluate Labels that Would Otherwise be Generically Approved*.''

I. Geographic Landmark Claims

Comment: Some trade associations, individual commenters, and the EU opposed generic approval of geographic landmark claims. They are concerned that the rule will eliminate regulatory oversight for such claims, increase the prevalence of misbranded products, and allow establishments to mislead consumers regarding the origin of their products by, for example, using foreign flags on domestic product labels. These commenters also stated that prior label approval of geographic landmark claims is necessary to preempt violations of international agreements.

Response: FSIS disagrees with these comments. This final rule does not change current regulations pertaining to the use of geographic landmarks, such as foreign flags, on product labels or the recordkeeping requirements to support such claims. The Acts require all labeling to be truthful and not misleading (21 U.S.C. 601(n)(1), 453(h)(1), and 1036(b)). Moreover, geographic landmark claims must continue to specifically comply with 9 CFR 317.8(b)(1) and 381.129(b)(2). These regulations permit, under certain conditions, the display of foreign flags on domestic products. As discussed in the proposed rule, IPP will routinely conduct verification and enforcement activities to verify that geographic landmark claims comply with all requirements (85 FR 56538, 56543).

FSIS will also continue to conduct export certification activities for FSIS-regulated products intended for export to foreign countries. During this process, IPP verify that such products meet country-specific requirements, including labeling requirements, that have been officially communicated to FSIS by the importing country. Thus, the Agency does not expect any issues with regards to obligations it may have to its international trade partners.

Comment: A trade association and a non-profit organization stated that allowing generic approval of geographic landmark claims may weaken, delay, or otherwise conflict with future ''Product of USA'' rulemaking. Thus, they asked that FSIS delay any geographic landmark or country of origin specific

[19] Website available at: *https://www.fsis.usda.gov/inspection/compliance-guidance/labeling.*

label rule changes until after such rulemaking is complete. In addition, the comments stated that this final rule may weaken the oversight and integrity of ''Product of USA'' labels and similar claims, such as ''local'' or ''regional.'' They therefore asked that these geographic landmark labels continue to go through the prior label review process.

Response: This final rule will not conflict or interfere with any future ''Product of USA'' rulemaking. The rule simply modifies the label approval process to allow for generic approval of *graphical* representations of geographic landmarks displayed on a product label, such as a foreign country's flag, monument, or map. It does not modify the provisions of 9 CFR 317.8 and 381.129, which regulate the use of geographic claims to prevent false or misleading labeling. It also does not modify the label approval process for written claims related to geographical significance or those that make a country of origin statement on the label of any meat or poultry product ''covered commodity.'' [20] Such claims are already eligible for generic approval.[21] It likewise does not affect the current labeling requirements or the label approval process for similar types of written statements, such as ''local'' or ''regional.''

The final rule will also not weaken regulatory oversight of labels that display geographic landmarks. Although geographic landmark claims will now be generically approved, the rule does not change any labeling requirements for such labels. The use of geographic landmarks must be truthful and not misleading. Moreover, IPP will routinely verify the accuracy of such labels.

J. Front-of-Package Nutrition Statements

Comment: A trade association requested that FSIS expand generic approval to include front-of-package (FOP) statements that repeat information from the nutrition facts panel.

Response: FSIS will not expand generic approval to include FOP statements that repeat information from the nutrition facts panel. FSIS considers certain FOP labeling statements, such as those highlighting select nutrients from the nutrition facts panel placed on the principal display panel, to be nutrient content claims. The requirements for defined nutrient content claims are listed in the regulations. However, unlike traditional nutrient content claims which are defined in FSIS regulations and are eligible for generic approval, such as ''low fat,'' there are no guidelines for the multiple types of FOP labeling statements on product labels. Therefore, FSIS needs to continue to require prior evaluation by the Agency to ensure these statements are truthful and not misleading.

K. Miscellaneous Comments

Comment: A non-profit organization requested that FSIS modify the final rule to state that illustrations and depictions of farms, animals grazing, and animals' living environments are animal raising claims and, as such, are not eligible for generic approval. A few non-profit organizations also asked FSIS to adopt uniform standards for common animal raising claims and require third-party verification of all such claims, whether made pictorially or textually.

Response: The purpose of this final rule is to expand eligibility for generic approval to specific categories of labeling. The final rule will not, and is not intended to, exclude certain types of labeling from eligibility or to establish any new regulations or policies regarding animal raising claims.

Comment: One trade association asked FSIS to engage with stakeholders before it updates its labeling guidance to assure the updated guidance meets the needs of end users. The commenter stated that updating guidance without industry input, especially when substantive changes are being made to the guidance, can cause confusion and, in the case of labeling, delay bringing products to market.

Response: Consistent with its current practices for developing all guidance, FSIS is committed to a public process for updating or publishing new labeling guidance. The availability of all FSIS guidance is announced in the **Federal Register** or elsewhere and made available for public comment. FSIS considers all input received from its stakeholders and makes changes, as appropriate, to any guidance documents.

Comment: One individual and a software company stated that FSIS should use existing software to automatically review labels. According to the commenters, this would reduce the time spent by FSIS reviewing labels and allow the Agency to concentrate on other priorities. The software company also proposed that FSIS adopt a public-private label review partnership much like AMS uses for organic certification.

Response: These comments are outside the scope of this rulemaking, as they do not pertain to the Agency's proposed expansion of generic labeling. Regardless, FSIS is not convinced that existing software can adequately review labels for compliance with FSIS regulations and policies. FSIS does, however, use an electronic label system to allow for easier label submission. Using the Label Submission and Approval System [22] (LSAS), establishments can submit label applications, supporting materials, and appeals to FSIS via the internet. While the system will not check labels automatically for errors, it will scan them for some common mistakes in the label submission process, including illegibility, missing information on the transmittal form, and missing supporting documentation. The system also includes a feature that helps submitters determine whether a label can be generically approved, or if it must be submitted to FSIS for prior approval.

Comment: An individual recommended that FSIS take steps to improve its generic labeling surveillance and enforcement program.

Response: IPP have consistently demonstrated their ability to review generic labels and ensure a high level of compliance with labeling requirements. Moreover, FSIS has already taken steps to improve its verification system by reissuing FSIS Directive 7221.1 to clarify that, as part of the General Labeling Task, IPP are to routinely review generic labels and verify that establishments have made required modifications to such labels. FSIS has also updated Directive 7221.1 to be consistent with this final rule. In addition, FSIS will continue to train and support IPP on generic labeling via webinars, askFSIS, and other outreach, including having LPDS participate in IPP training conducted by CFL. This final rule promotes the effective use of Agency resources and will allow FSIS to devote more time to better supporting IPP through the development of new and improved training and guidance on, amongst other things, the surveillance, enforcement, and verification activities related to generic labeling.

IV. Executive Orders 12866 and 13563

Executive Orders (E.O.s) 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety

[20] See 9 CFR 317.8(b)(40) and 381.129(f).

[21] See 9 CFR 412.2(b).

[22] FSIS' Label Submission and Approval System (LSAS) is a web-based software application that integrates and implements an electronic label application process for establishments to submit label applications to FSIS.

effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This final rule has been designated by the Office of Information and Regulatory Affairs a ''significant'' regulatory action under section 3(f) of E.O. 12866. Accordingly, the rule has been reviewed by the Office of Management and Budget under E.O. 12866.

Economic Impact Analysis

FSIS has updated the benefits estimates in this final regulatory impact analysis as compared to the preliminary regulatory impact analysis published in the proposed rule. These changes include: updating wage rates to 2021 dollars for food scientists and technologists; updating wage rates to 2021 dollars for labeling analysts in LPDS; and updating the number of labeling analysts in LPDS during fiscal year 2021.

Need for the Rule

The final rule will expand the types of meat, poultry and egg product labels that are generically approved by FSIS. Therefore, this rule will reduce the number of labels evaluated by FSIS and will reduce the costs to industry. The labels submitted for FSIS evaluation are becoming more complex and more time-consuming for industry to prepare and for FSIS to evaluate. The final rule will improve the efficiency of the label approval system by expanding generic labeling and making the system more convenient and cost efficient for the industry. This final rule also will enhance market efficiency by promoting a faster introduction of new products into the marketplace to meet consumer demand.

Baseline

Based on FSIS' LSAS data, FSIS evaluated 15,459 unique labels during the 2019 fiscal year (FY). Of these, 5,229 (approximately 34 percent) would have been generically approved if this final rule was in place in 2019. This amount (5,229) includes 632 labels currently eligible for generic approval, which firms voluntarily submitted for FSIS review. Many of the 15,459 labels were evaluated by FSIS more than once because they were returned to the producer to make corrections and then resubmitted for FSIS evaluation. FSIS has observed through its prior label approval system that corrections are rare on the types of claims that can now be generically approved under this final rule. In FY 2019, there were 26,158 label adjudications, which includes the total number of evaluations and reevaluations of labels reviewed. See Table 2 below for additional details.

TABLE 2—LABEL EVALUATIONS AND ADJUDICATIONS, FY 2016–2019

FSIS labels	2016	2017	2018	2019
Labels FSIS Would Not have Evaluated Under the Final Rule	8,534	5,812	6,025	5,229
Total Labels FSIS Evaluated *	22,846	17,958	17,635	15,459
Total Label Adjudications **	30,857	25,125	27,580	26,158

* This is the total number of labels FSIS evaluated, including the labels that would have been generically approved under the final rule.
** Label adjudications include some labels being reevaluated.

FSIS expanded the types of labels and label changes that may be generically approved several times, starting in 1983 when the Agency evaluated 130,000 labels. In 1991, the number of labels evaluated peaked at 167,500. The 1995 final rule (60 FR 67444) amended the prior label approval process by expanding the types of labels and label changes that may be generically approved. From 2003–2010, the number of label adjudication per year averaged 57,457, with a minimum of 43,255 in 2003 and a maximum of 66,061 in 2010. The 2013 final rule (78 FR 66826, November 7, 2013) further expanded generic labeling, decreasing the number of label adjudications to 30,857 in FY 2016 (Table 2). FSIS also finalized a rule permitting generic approval for certain egg product labels in 2020 (85 FR 68640, October 29, 2020).

The number of FSIS label adjudications decreased after the expansions of generically approved labels. However, the remaining label submissions after each expansion are more time-consuming for industry to prepare and for FSIS to evaluate. This is because the labels requiring submission after each expansion are generally more complex, with special statements or claims that require FSIS to evaluate a significant amount of supporting documentation.

Expected Costs of the Final Rule

The final rule will not impose any new quantifiable costs on producers that submit labels for FSIS evaluation. Instead, the final rule will reduce the regulatory burden on producers that submit labels for evaluation and does not change the recordkeeping requirements. Producers already are using generically approved labels and maintaining all labeling records and thus are experienced in submitting labels for FSIS evaluation.

Expected Benefits of the Final Rule

Industry Impacts

Industry will realize cost savings from the reduction in FSIS label submissions under the final rule. Industry is required to use FSIS Form 7234–1 (OMB control number: 0583–0092) for the initial FSIS label submission. The estimated time to complete this form is 75 minutes per response, which includes reviewing instructions, searching existing data sources, gathering and maintaining the data needed (recordkeeping), and completing and reviewing the collection of information.[23] FSIS estimates 15 minutes of the 75 minutes are dedicated to recordkeeping. The recordkeeping time is not included in the final rule's regulatory impact analysis because the recordkeeping requirements will not change under the final rule; that is, even if the establishment does not need to submit the label to FSIS, the establishment is still required to maintain records to support the label. Therefore, the average industry time to prepare one label submission for FSIS evaluation is 60 minutes (75 minutes minus 15 minutes). FSIS also assumed food scientists and technologists perform this work at a mean hourly wage of $40.46.[24] A benefits and

[23] FSIS Form 7234–1 Application for Approval of Labels, Marking or Device. Last modified 11/16/2011. Available at: *https://www.fsis.usda.gov/sites/default/files/2020-08/FSIS_7234-1_Approval_of_Labels_2.pdf.*

[24] BLS Occupational Employment Statistics, Occupational Employment and Wages, May 2021. 19–1021 Food Scientists and Technologists. <*https://www.bls.gov/news.release/pdf/ocwage.pdfoes/current/oes191012.htm#nat*> Accessed on 9/16/2022. Last Modified 03/31/2022.

overhead factor of two [25] was applied to estimate the total labor cost per label submission of $80.92.

To determine the annual reduction of label submissions, FSIS relied on the average number of labels that FSIS would not have evaluated under the final rule from 2016 to 2019, which was 6,400 labels, ((8,534 + 5,812 + 6,025 + 5,229)/4), Table 2. Accordingly, FSIS estimates a decrease of 64,000 label evaluations over 10 years under the final rule (6,400 * 10). As shown in Table 3, FSIS estimates that industry will realize a discounted cost savings of $3,637,429 (at a 7 percent discount rate) and $4,417,690 (at a 3 percent discount rate) by FSIS generically approving an additional 64,000 labels over a 10-year period. The cost savings is $517,888 when annualized at the 7 and 3 percent discount rate, over 10 years. The primary estimate is over 10 years, but for illustrative purposes, Table 3 shows the potential cost savings at the 7 and 3 percent discount rate over 20 years.

TABLE 3—ESTIMATED INDUSTRY COST SAVINGS

[2021 Dollars]

Total industry cost savings from reduced need for FSIS label evaluation	Present value cost savings at 7%	Present value cost savings at 3%
Total over 10 years	$3,637,429	$4,417,690
Annualized total over 10 years	517,888	517,888
Total over 20 years	5,486,513	7,704,866
Annualized total over 20 years	517,888	517,888

Agency Impacts

During FY 2021, FSIS employed 15 labeling analysts in LPDS with an average hourly salary of $72.21 (($53.00 * 36.25%) + $53.00 = $72.21 for a GS–13 step 3,[26] with an adjusted benefits factor of 36.25 percent).[27] Prior to this final rule, on average, LPDS analysts evaluated labels four hours per day, five days a week, at a cost of $21,663 per week. Under the final rule, LPDS analysts will evaluate labels for three hours per day, five days a week, at a cost of $16,247 per week, because of the reduction in labels submitted to FSIS.

Under the final rule, the Agency will realize a discounted cost savings of $1,977,974 (at a 7 percent discount rate) and $2,402,267 (at a 3 percent discount rate) for adjudicating fewer labels over a 10-year period. The cost savings is $281,619 when annualized at the 7 and 3 percent discount rate over 10 years. The primary estimate is over 10 years, but for illustrative purposes, Table 4 shows the potential cost savings at the 7 and 3 percent discount rate over 20 years. See Table 4 for additional details.

The Agency plans to utilize any resources made available by this final rule to work on other Agency priority initiatives, such as developing and updating policy and guidance documents, answering questions from askFSIS and other sources, and performing outreach activities. This change in Agency workload will result in more resources for the industry, which improves efficiencies for the Agency and industry alike.

FSIS also anticipates an overall faster label review process from the decline in LPDS label evaluations. This will allow new labels to enter the market faster.

TABLE 4—ESTIMATED AGENCY COST SAVINGS

[2021 Dollars]

Total agency cost savings from reduced need for FSIS label evaluation	Present value cost savings at 7%	Present value cost savings at 3%
Total over 10 years	$1,977,974	$2,402,267
Annualized total over 10 years	281,619	281,619
Total over 20 years	2,983,476	4,189,780
Annualized total over 20 years	281,619	281,619

Net Benefits

This final rule will be net beneficial because it will reduce the costs to establishments, from submitting fewer labels for FSIS evaluation, while imposing no additional cost burden. The net benefit derived from the final rule is estimated to be $5,615,403 ($3,637,429 in establishment savings plus $1,977,974 in Agency savings) discounted at the 7 percent discount rate over a 10-year period. When annualized at the 7 percent discount rate over 10 years, the net cost savings is estimated to be $799,507. For illustrative purposes, we also included the net cost savings over 20 years in Table 5. See Table 5 for details.

[25] To be consistent with analyses done by the Department of Health and Human Services, this analysis accounts for fringe benefits and overhead by multiplying wages by a factor of 2.

[26] Salary Table 2021–DCB for the locality pay area of Washington-Baltimore-Arlington, DC-MD-VA-WV-PA. Effective January 2021. Available at: *https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2021/DCB_h.pdf.*

[27] Nussle, Jim. (2008). M–08–13: MEMORANDUM FOR THE HEADS OF EXECUTIVE DEPARTMENTS AND AGENCIES. Executive Office of the President. Available at: *https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/memoranda/2008/m08-13.pdf.*

TABLE 5—ESTIMATED NET BENEFITS

[2021 Dollars]

Total agency and industry cost savings from reduced need for FSIS label evaluation	Present value cost savings at 7%	Present value cost savings at 3%
Total over 10 years	$5,615,403	$6,819,957
Annualized total over 10 years	799,507	799,507
Total over 20 years	8,469,989	11,894,645
Annualized total over 20 years	799,507	799,507

Alternative Regulatory Approaches

The Agency considered three alternatives to the final rule. The final rule was chosen as the least burdensome regulatory approach. The summary of the costs and benefits for the considered alternatives are outlined in Table 6 below.

TABLE 6—REGULATORY ALTERNATIVES CONSIDERED

Alternative	Benefits	Costs	Net benefit
(1) Take No Action	No Benefit	No potential industry or Agency cost savings.	Net benefits are less than alternative 3.
(2) The Final Rule, Except Industry Would Still Have the Option to Have LPDS Evaluate Labels that Would Otherwise be Generically Approved.	Industry could benefit from additional FSIS evaluation.	Potential for inefficient use of Agency resources. Industry would also incur costs of submitting the labels and waiting for FSIS evaluation.	Net benefits are less than alternative 3. Although industry could marginally benefit from additional FSIS evaluation, sufficient guidance is available for labels that can be generically approved. Also, industry and the Agency would incur costs from submitting and evaluating such labels.
(3) The Final Rule	Potential industry cost savings of $517,888 and Agency cost savings of $281,619, annualized at the 7 percent discount rate over 10 years.	No quantifiable costs	Net benefits are $799,507 annualized at the 7 percent discount rate over 10 years.
(4) Allow All FSIS Labels to be Generically Approved.	The Agency and industry would benefit from time savings by eliminating FSIS label evaluation.	Costs include potentially increasing the number of misbranded products.	Net benefits are less than alternative 3 as the potential costs of misbranded products from eliminating FSIS label evaluation outweighs the time savings benefit.

Alternative 1—No Action (Baseline)

FSIS considered keeping the current regulations and taking no action. Taking no action would mean that industry and the Agency would not experience costs savings from the reduction of labels submitted for FSIS evaluation under the final rule. Industry would therefore not realize the estimated reduction of 64,000 label submissions over 10 years and would not experience an annualized cost savings of $517,888 at the 7 percent discount rate over 10 years. The Agency would not experience time savings from the reduction of label evaluations. Therefore, the Agency rejects this alternative.

Alternative 2—The Final Rule, Except Industry Would Still Have the Option To Have LPDS Evaluate Labels That Would Otherwise Be Generically Approved

FSIS considered an alternative of finalizing the same generically approved label categories except FSIS would continue to evaluate those labels that would otherwise be generically approved. Prior to the final rule, industry could submit labels that could be generically approved for voluntary FSIS evaluation, although this evaluation was not needed prior to entering the market. When industry submitted these types of labels for voluntary FSIS evaluation, they were reviewed with a lower priority than other labels, and thus took more time for FSIS to approve. Although industry may marginally benefit from the additional FSIS evaluation, the process is inefficient and raises unnecessary costs. Industry can more quickly get FSIS assistance on these types of labels through other guidance, such as askFSIS.

In addition, FSIS would have to take the time to process and evaluate these labels, when reviewer time could be spent on higher priorities, such as policy related issues (*e.g.,* updating priority labeling regulations or labeling guidance). Industry would also incur costs in preparing and submitting the labels for FSIS evaluation while they can get FSIS help through other outlets without incurring these expenses. For these reasons, FSIS rejects this alternative.

Alternative 3—The Final Rule

The final rule yields cost savings for both the industry and the Agency. There is no additional cost burden from the final rule. The potential cost savings for industry is $517,888, annualized at the 7 percent discount rate over 10 years. This covers the time industry saves from not preparing and submitting the labels for FSIS evaluation.

The potential cost savings for FSIS is $281,619, annualized at the 7 percent discount rate over 10 years. This covers the time FSIS saves from not evaluating the generically approved labels. Since there is no additional burden for this final rule, FSIS determined this to be the preferred alternative.

Alternative 4—All Labels Are Generically Approved

FSIS also considered an alternative that would allow all labels to be generically approved, requiring no prior approval by FSIS. This alternative may increase the number of misbranded products going into commerce, as LPDS would no longer verify the information on complex labels. An increase in misbranded products that contain incorrect, false, or misleading information may result in a loss of consumer confidence in information on food labels. There is also cost associated with discarding and reprinting misbranded labels that the industry may

suffer. Therefore, FSIS believes the labels that will still require prior evaluation under the final rule, such as labels with animal raising, natural, or front of package nutrition labeling claims, benefit from LPDS evaluation due to the complex nature and need for supporting documentation of these claims.

This alternative would yield time savings for industry from no longer preparing and submitting labels for FSIS evaluation. FSIS would also experience time savings from no longer evaluating these labels. However, the potential costs of misbranded products entering commerce, resulting from the elimination of all LPDS label evaluation, would outweigh the benefits of the time savings.

V. Regulatory Flexibility Act Assessment

The FSIS Administrator certifies that, for the purposes of the Regulatory Flexibility Act (5 U.S.C. 601–602), this final rule will not have a significant economic impact on a substantial number of small entities in the United States. This determination was made because small producers will experience costs savings from the reduced number of label submissions for FSIS evaluation.

Based on LSAS and PHIS data, FSIS estimates 92.3 percent (4,825/5,229) of the label submissions in 2019, which would have been generically approved under the final rule, are from small or very small Hazard Analysis and Critical Control Point (HACCP) sized establishments. Under the HACCP size definitions, large establishments have 500 or more employees and small establishments have fewer than 500 but more than 10 employees. Very small establishments have fewer than 10 employees or annual sales of less than $2.5 million. Small and very small establishments, like large establishments, follow the same standards for generic and sketch approval of labels. Small and very small producers, therefore, will not be disadvantaged because the final rule will minimize the regulatory burden on all producers.

Based on 2019 LSAS data, about 12 percent (627/5,229) of labels that would have been generically approved under the final rule, were submitted from 19 label consultant firms. These firms are very small, usually having one to four employees. Many of these firms provide a range of services, including label courier services, label consultation and regulatory compliance, or label design. This final rule may impact their label courier business. However, the impact on these firms is small as their other business, such as label consultations, will not be affected. Therefore, this final rule will not have a significant economic impact on the small label consultant firms.

VI. Paperwork Reduction Act

In accordance with section 3507(d) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the information collection or recordkeeping requirements have been submitted for approval to the Office of Management and Budget (OMB).

FSIS is expanding the circumstances under which it will generically approve the labels of meat, poultry, and processed egg products. Under this final rule, more official and foreign establishments will be able to use the generic approval of product labels. As a result, fewer labels will need to be submitted and evaluated by FSIS. The relevant information collection, 0583–0092, Marking, Labeling, and Packaging, has a net reduction of 6,400 burden hours because of the increased use of generic labeling.

VII. USDA Non-Discrimination Statement

In accordance with Federal civil rights law and USDA civil rights regulations and policies, USDA, its Mission Areas, agencies, staff offices, employees, and institutions participating in or administering USDA programs are prohibited from discriminating based on race, color, national origin, religion, sex, gender identity (including gender expression), sexual orientation, disability, age, marital status, family/parental status, income derived from a public assistance program, political beliefs, or reprisal or retaliation for prior civil rights activity, in any program or activity conducted or funded by USDA (not all bases apply to all programs). Remedies and complaint filing deadlines vary by program or incident.

Program information may be made available in languages other than English. Persons with disabilities who require alternative means of communication to obtain program information (*e.g.,* Braille, large print, audiotape, American Sign Language) should contact the responsible Mission Area, agency, or staff office; the USDA TARGET Center at (202) 720–2600 (voice and TTY); or the Federal Relay Service at (800) 877–8339.

To file a program discrimination complaint, a complainant should complete a Form AD–3027, USDA Program Discrimination Complaint Form, which can be obtained online at *https://www.ocio.usda.gov/document/ad-3027,* from any USDA office, by calling (866) 632–9992, or by writing a letter addressed to USDA. The letter must contain the complainant's name, address, telephone number, and a written description of the alleged discriminatory action in sufficient detail to inform the Assistant Secretary for Civil Rights (ASCR) about the nature and date of an alleged civil rights violation. The completed AD–3027 form or letter must be submitted to USDA by:

(1) *Mail:* U.S. Department of Agriculture, Office of the Assistant Secretary for Civil Rights, 1400 Independence Avenue SW, Washington, DC 20250–9410;

(2) *Fax:* (833) 256–1665 or (202) 690–7442; or

(3) *Email: program.intake@usda.gov.*

USDA is an equal opportunity provider, employer, and lender.

VIII. E-Government Act

FSIS and USDA are committed to achieving the purposes of the E-Government Act (44 U.S.C. 3601, *et seq.*) by, among other things, promoting the use of the internet and other information technologies and providing increased opportunities for citizen access to Government information and services, and for other purposes.

IX. Executive Order 12988, Civil Justice Reform

This final rule has been reviewed under Executive Order 12988, Civil Justice Reform. Under this rule: (1) All State and local laws and regulations that are inconsistent with this rule will be preempted; (2) no retroactive effect will be given to this rule; and (3) no administrative proceedings will be required before parties may file suit in court challenging this rule.

X. Executive Order 13175, Consultation and Coordination With Indian Tribal Governments

This rule has been reviewed in accordance with the requirements of Executive Order 13175, Consultation and Coordination with Indian Tribal Governments. Executive Order 13175 requires Federal agencies to consult and coordinate with tribes on a government-to-government basis on policies that have tribal implications, including regulations, legislative comments or proposed legislation, and other policy statements or actions that have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

The USDA's Office of Tribal Relations (OTR) has assessed the impact of this rule on Indian tribes and determined that this rule does not, to our knowledge, have tribal implications that require tribal consultation. If a tribe requests consultation, FSIS will work with the OTR to ensure meaningful consultation is provided where changes, additions, and modifications identified herein are not expressly mandated by Congress.

XI. Environmental Impact

Each USDA agency is required to comply with 7 CFR part 1b of the Departmental regulations, which supplements the National Environmental Policy Act regulations published by the Council on Environmental Quality. Under these regulations, actions of certain USDA agencies and agency units are categorically excluded from the preparation of an Environmental Assessment (EA) or an Environmental Impact Statement (EIS) unless the agency head determines that an action may have a significant environmental effect (7 CFR 1b.4 (b)). FSIS is among the agencies categorically excluded from the preparation of an EA or EIS (7 CFR 1b.4 (b)(6)).

FSIS has determined that this final rule, which refines the Agency's existing label approval program, will not create any extraordinary circumstances that would result in this normally excluded action having a significant individual or cumulative effect on the human environment. Therefore, this action is appropriately subject to the categorical exclusion from the preparation of an environmental assessment or environmental impact statement provided under 7 CFR 1b.4(6) of the U.S. Department of Agriculture regulations.

XII. Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, FSIS will announce this **Federal Register** publication on-line through the FSIS web page located at: *https://www.fsis.usda.gov/federal-register.*

FSIS will also announce and provide a link to it through the FSIS *Constituent Update,* which is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, and other types of information that could affect or would be of interest to our constituents and stakeholders. The *Constituent Update* is available on the FSIS web page. Through the web page, FSIS is able to provide information to a much broader, more diverse audience. In addition, FSIS offers an email subscription service which provides automatic and customized access to selected food safety news and information. This service is available at: *https://www.fsis.usda.gov/subscribe.* Options range from recalls to export information, regulations, directives, and notices. Customers can add or delete subscriptions themselves and have the option to password protect their accounts.

List of Subjects

9 CFR Part 352

Food labeling, Meat inspection, Reporting and recordkeeping requirements.

9 CFR Part 354

Administrative practice and procedure, Animal diseases, Food labeling, Meat inspection, Rabbits and rabbit products, Reporting and recordkeeping requirements, Signs and symbols.

9 CFR Part 362

Food labeling, Poultry and poultry products, Reporting and recordkeeping requirements.

9 CFR Part 412

Food labeling, Food packaging, Meat and meat products, Meat inspection, Poultry and poultry products, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, FSIS is amending 9 CFR chapter III as follows:

PART 352—EXOTIC ANIMALS AND HORSES; VOLUNTARY INSPECTION

■ 1. The authority citation for part 352 continues to read as follows:

Authority: 7 U.S.C. 1622, 1624; 7 CFR 2.17(g) and (i), 2.55.

■ 2. In § 352.7:

■ a. Revise the section heading;

■ b. Remove the first sentence of the introductory text;

■ c. Add a sentence to the end of the introductory text.

The revision and addition read as follows:

§ 352.7 Marking and labeling of inspected products.

* * * All labels intended for use on inspected and passed exotic animal products must be approved in accordance with Part 412 of this chapter.

* * * * *

PART 354—VOLUNTARY INSPECTION OF RABBITS AND EDIBLE PRODUCTS THEREOF

■ 3. The authority citation for part 354 continues to read as follows:

Authority: 7 U.S.C. 1622, 1624; 7 CFR 2.17(g) and (i), 2.55.

■ 4. Revise § 354.60 to read as follows:

§ 354.60 Approval of official identification.

All labels intended for use on inspected and passed rabbit products which bear any official identification must be approved in accordance with part 412 of this chapter.

PART 362—VOLUNTARY POULTRY INSPECTION REGULATIONS

■ 5. The authority citation for part 362 continues to read as follows:

Authority: 7 U.S.C. 1622; 7 CFR 2.18(g) and (i) and 2.53.

■ 6. In § 362.2, revise the second sentence of paragraph (a) to read as follows:

§ 362.2 Types and availability of service.

* * * * *

(a) * * * All provisions of Part 381, Part 412, and §§ 416.1 through 416.6 of this chapter shall apply to the slaughter of poultry, and the preparation, labeling, and certification of the poultry and poultry products processed under this poultry inspection service except for the following provisions: the definitions of ''Act,'' ''animal food manufacturer,'' ''Inspection Service,'' ''inspector,'' ''Inspector in Charge,'' ''poultry,'' ''poultry product,'' ''poultry food product,'' ''poultry products broker,'' ''renderer,'' and ''U.S. Refused Entry'' in §§ 381.1 b), 381.3 (a), 381.6, 381.10, 381.13 through 381.17, 381.21, 381.29, 381.39 through 381.42, 381.175(a)(2) and (3), 381.179, 381.185 through 381.187, 381.192, and 381.195 through 381.225.

* * * * *

PART 412—LABEL APPROVAL

■ 7. The authority citation for part 412 continues to read as follows:

Authority: 21 U.S.C. 451–470, 601–695; 7 CFR 2.18, 2.53.

■ 8. In § 412.1, remove and reserve paragraph (c)(2) and revise paragraph (e).

The revision reads as follows:

§ 412.1 Label approval.

* * * * *

(e) ''Special statements and claims'' are statements, claims, logos, trademarks, and other symbols on labels as defined in this paragraph (e).

(1) The following are considered special statements and claims:

(i) Those not defined in the Federal meat and poultry products inspection regulations or the Food Standards and Labeling Policy Book;

(ii) ''Natural'' claims, regardless of whether they are defined in the Food Standards and Labeling Policy Book; and

(iii) Health claims (including graphic representations of hearts), ingredient and processing method claims (*e.g.,* high-pressure processing), structure-function claims, claims regarding the raising of animals (*e.g.,* ''no antibiotics administered''), products labeled as organic (except for those where only individual ingredients are labeled as organic), and instructional or disclaimer statements concerning pathogens (*e.g.,* ''for cooking only'' or ''not tested for *E. coli* O157:H7'').

(2) The following are not considered special statements and claims:

(i) Allergen statements (*e.g.,* ''contains soy'') applied in accordance with the Food Allergen Labeling and Consumer Protection Act;

(ii) Negative claims regarding ingredients not listed in the ingredients statement (*e.g.,* ''No MSG Added,'' ''Preservative Free,'' ''No Milk,'' ''No Pork,'' or ''Made Without Soy'');

(iii) Statements that characterize a product's nutrient content in compliance with Title 9 of the CFR, such as ''low fat''; and

(iv) Claims related to geographical significance, such as ''German Brand Made in the US,'' or those that make a country of origin statement on the label of any meat or poultry product ''covered commodity,'' [1] or displays of geographic landmarks, such as a foreign country's flag, monument, or map.

* * * * *

■ 9. In § 412.2, revise paragraph (b) to read as follows:

§ 412.2 Approval of generic labels.

* * * * *

(b) Generically approved labels are labels that bear all applicable mandatory labeling features (*i.e.,* product name, handling statement, ingredients statement, the name and place of

business of the manufacturer, packer or distributor, net weight, legend, safe handling instructions, and nutrition labeling) in accordance with Federal regulations and do not bear special statements and claims as defined in § 412.1(e).

[1] See 9 CFR 317.8(b)(40) and 381.129(f).

Done at Washington, DC.

Paul Kiecker

Administrator.

[FR Doc. 2023–00693 Filed 1–17–23; 8:45 am]

BILLING CODE 3410–DM–P

FARM CREDIT SYSTEM INSURANCE CORPORATION

12 CFR Part 1411

RIN 3055–AA19

Rules of Practice and Procedure; Adjusting Civil Money Penalties for Inflation

AGENCY: Farm Credit System Insurance Corporation.

ACTION: Final rule.

SUMMARY: This rule implements inflation adjustments to civil money penalties (CMPs) that the Farm Credit System Insurance Corporation (FCSIC) may impose under the Farm Credit Act of 1971, as amended. These adjustments are required by 2015 amendments to the Federal Civil Penalties Inflation Adjustment Act of 1990.

DATES:

Effective date: This regulation is effective on January 18, 2023.

Applicability date: The adjusted amounts of civil money penalties in this rule are applicable to penalties assessed on or after January 15, 2023, for conduct occurring on or after November 2, 2015.

FOR FURTHER INFORMATION CONTACT: Lynn M. Powalski, General Counsel, Farm Credit System Insurance Corporation, 1501 Farm Credit Drive, McLean, Virginia 22102, (703) 883–4380, TTY (703) 883–4390.

SUPPLEMENTARY INFORMATION:

I. Background

The Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (the 2015 Act) amended the Federal Civil Penalties Inflation Adjustment Act of 1990 (the Inflation Adjustment Act) [1] to improve the effectiveness of civil monetary penalties and to maintain their deterrent effect. The Inflation Adjustment Act provides for the regular evaluation of CMPs and requires FCSIC, and every other Federal agency with authority to impose CMPs, to ensure that CMPs continue to maintain their deterrent values.[2]

FCSIC must enact regulations that annually adjust its CMPs pursuant to the inflation adjustment formula of the amended Inflation Adjustment Act and rounded using a method prescribed by the Inflation Adjustment Act. The new amounts are applicable to penalties assessed on or after January 15, 2023, for conduct occurring on or after November 2, 2015. Agencies do not have discretion in choosing whether to adjust a CMP, by how much to adjust a CMP, or the methods used to determine the adjustment.

II. CMPs Imposed Pursuant to Section 5.65 of the Farm Credit Act

First, section 5.65(c) of the Farm Credit Act, as amended (Act), provides that any insured Farm Credit System bank that willfully fails or refuses to file any certified statement or pay any required premium shall be subject to a penalty of not more than $100 for each day that such violations continue, which penalty FCSIC may recover for its use.[3] Second, section 5.65(d) of the Act provides that, except with the prior written consent of the Farm Credit Administration, it shall be unlawful for any person convicted of any criminal offense involving dishonesty or a breach of trust to serve as a director, officer, or employee of any System institution.[4] For each willful violation of section 5.65(d), the institution involved shall be subject to a penalty of not more than $100 for each day during which the violation continues, which FCSIC may recover for its use.

FCSIC's current § 1411.1 provides that FCSIC can impose a maximum penalty of $231 per day for a violation under section 5.65(c) and (d) of the Act.

III. Required Adjustments

The 2015 Act requires agencies to make annual adjustments for inflation. Annual inflation adjustments are based on the percent change between the October Consumer Price Index for all Urban Consumers (CPI–U) preceding the date of the adjustment, and the prior year's October CPI–U. Based on the CPI–U for October 2022, not seasonally adjusted, the cost-of-living adjustment

[1] Public Law 101–410, 104 Stat. 890 (Oct. 5, 1990), as amended by Public Law 104–134, title III, § 31001(s)(1), 110 Stat. 1321–373 (Apr. 26, 1996); Public Law 105–362, title XIII, § 1301(a), 112 Stat. 3293 (Nov. 10, 1998); Public Law 114–74, title VII, § 701(b), 129 Stat. 599 (Nov. 2, 2015), codified at 28 U.S.C. 2461 note.

[2] Under the amended Inflation Adjustment Act, a CMP is defined as any penalty, fine, or other sanction that: (1) Either is for a specific monetary amount as provided by Federal law or has a maximum amount provided for by Federal law; (2) is assessed or enforced by an agency pursuant to Federal law; and (3) is assessed or enforced pursuant to an administrative proceeding or a civil action in the Federal courts. All three requirements must be met for a fine to be considered a CMP.

[3] 12 U.S.C. 2277a–14(c).

[4] 12 U.S.C. 2277a–14(d).