or any agency or instrumentality thereof; nor while using a Government-owned or lease vehicle, or while using a privately-owned vehicle in the discharge of official duties.

Moreover, candidacy for, and service in, a partisan political office shall not result in neglect of, or interference with, the performance of the duties of the employee or create a conflict, or apparent conflict, of interest.

Sections 733.103 and 733.104 of Title 5, Code of Federal Regulations, do not apply to individuals, such as career senior executives and employees of the Federal Bureau of Investigation, who are employed in the agencies and positions listed on the Web site of the United States Office of Special Counsel, at *http://www.osc.gov/haFederalFurtherRestricted.htm,* and at 5 CFR 733.105(a). These individuals are subject to the more stringent limitations described in 5 CFR 733.105 and 733.106.

Individuals who require advice concerning specific political activities, and whether an activity is permitted or prohibited under 5 CFR 733.103–733.106, should contact the United States Office of Special Counsel at (800) 854–2824 or (202) 254–3650. Requests for Hatch Act advisory opinions may be made by email to: *hatchact@osc.gov.*

The District of Columbia will be listed alphabetically after Crane, Indiana, and before Elmer City, Washington, at 5 CFR 733.107(c).

E.O. 12866, Regulatory Review

This regulation has been reviewed by the Office of Management and Budget in accordance with E.O. 12866.

Regulatory Flexibility Act

I certify that this regulation will not have a significant economic impact on a substantial number of small entities because the changes will affect only employees of the Federal Government.

List of Subjects in 5 CFR Part 733

Political activities (Government employees).

U.S. Office of Personnel Management.

Elaine Kaplan,

Acting Director.

Accordingly, the Office of Personnel Management amends 5 CFR part 733 as follows:

PART 733—POLITICAL ACTIVITY—FEDERAL EMPLOYEES RESIDING IN DESIGNATED LOCALITIES

■ 1. The authority citation for part 733 is revised to read as follows:

Authority: 5 U.S.C. 7325; Pub. L. 112–230, 126 Stat. 1616 (Dec. 28, 2012); sec. 308 of Pub. L. 104–93, 109 Stat. 961, 966 (Jan. 6, 1996).

■ 2. Section 733.107(c) is amended by adding the District of Columbia, alphabetically, to the list of other designated municipalities as set forth below.

§ 733.107 Designated localities.

* * * * *

(c) * * *

Other Municipalities

* * * * *

District of Columbia

* * * * *

[FR Doc. 2013–26741 Filed 11–6–13; 8:45 am]

BILLING CODE 6325–48–P

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Parts 317, 318, 320, 327, 331, 381, 412, and 424

[Docket No. 99–021F; FDMS Docket Number FSIS–2005–0016]

RIN 0583–AC59

Prior Label Approval System: Generic Label Approval

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: The Food Safety and Inspection Service (FSIS) is amending the meat and poultry products inspection regulations to expand the circumstances in which FSIS will generically approve the labels of meat and poultry products. The Agency also is consolidating the regulations that provide for the approval of labels for meat products and poultry products into a new Code of Federal Regulations (CFR) part.

DATES: This rule is effective January 6, 2014.

FOR FURTHER INFORMATION CONTACT: Jeff Canavan, Deputy Director, Labeling and Program Delivery Staff, Office of Policy and Program Development, Food Safety and Inspection Service, U.S. Department of Agriculture, Stop Code 3784, Patriots Plaza 3, 8–161A, 1400 Independence Avenue SW., Washington, DC 20250–3700; Telephone (301) 504–0879; Fax (202) 245–4792.

SUPPLEMENTARY INFORMATION:

Executive Summary

The Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 *et seq.*) and the Poultry Products Inspection Act (PPIA) (21 U.S.C. 451 *et seq.*) direct the Secretary of Agriculture to maintain meat and poultry product inspection programs designed to assure consumers that meat and poultry products distributed to them (including imports) are safe, wholesome, not adulterated, and properly marked, labeled, and packaged. They also prohibit the sale or offer for sale by any person, firm, or corporation of any article in commerce under any name or other marking or labeling that is false or misleading or in any container of a misleading form or size.[1] FSIS has interpreted these provisions as requiring that the Secretary of Agriculture or his or her representative approve all labels used on federally inspected and passed, and imported, meat and poultry products before the products are distributed in commerce. Without approved labels, meat and poultry products may not be sold, offered for sale, or otherwise distributed in commerce.

To ensure that meat and poultry products comply with the FMIA and PPIA and their implementing regulations, FSIS conducts a prior approval program for labels that are to be used on federally inspected meat and poultry products and imported products (see 9 CFR 317.4, 317.5, 327.14, 381.132, 381.133, 381.134, and 381.205). Under the current program, FSIS evaluates sketches of labels for approval. A ''sketch label'' is a printer's proof or other version that clearly shows all required label features, size, location, and indication of final color. To obtain sketch label approval, domestic meat and poultry establishments and certified foreign establishments, or their representatives, submit sketch labels to FSIS for evaluation, except when the label is generically approved by the Agency under 9 CFR 317.5 or 381.133.

Generic label approval refers to the prior approval of labels or modifications to labels by the Agency without submitting such labels to FSIS for sketch approval. Generic label approval requires that all mandatory label features be in conformance with FSIS regulations (9 CFR 317.5(a)(1) and 381.133(a)(1)). Although such labels are not submitted to FSIS for approval, they are deemed to be approved and, therefore, may be applied to product in accordance with the Agency's prior label approval system. Sections 317.5 and 381.133 also list the types of labels and modifications to labels that are deemed to be approved without submission to FSIS, as long as the label displays all mandatory label features in

[1] 21 U.S.C. 607(d); 21 U.S.C. 457(c).

conformance with applicable Federal regulations.

FSIS is finalizing its proposal to amend the meat and poultry products inspection regulations to expand the circumstances in which FSIS will generically approve the labels of meat and poultry products. The Agency also is consolidating the regulations that provide for the approval of labels for meat products (9 CFR 317.4) and poultry products (9 CFR 381.132) into a new part 412 in title 9 of the Code of Federal Regulations (CFR).

TABLE 1—SUMMARY OF ESTIMATED COSTS AND BENEFITS

Estimated quantified benefits, costs, and net benefits			
Entity	Annualized benefits (7% discount, millions $)	Annualized costs	Annualized net benefits (7% discount, millions $) [a]
Establishments	$1.944	$0	$1.944
Agency	.640	0	.640
Total	2.584	0	2.584

[a] Annualized total net benefits at a 3% discount rate are $2.211 million.

Background

Proposed Rule

On December 5, 2011, FSIS published a proposed rule to amend the meat and poultry products inspection regulations (9 CFR 317.5 and 381.133) to expand the circumstances under which the labels of meat and poultry products would be deemed to be generically approved [2] by the Agency (76 FR 75809). FSIS also proposed to combine the regulations that provide for the approval of labels for meat products and for poultry products (9 CFR 317.4 and 381.132) into a new part 412.

After review and consideration of all comments, FSIS is finalizing the proposed rule with four changes. FSIS proposed to stop evaluating the mandatory features on labels that are generically approved but have been submitted for review because they contain a special statement or claim. In response to comments, however, the Agency has decided continue to provide for the review of all labels. However, labels that cannot be generically approved will receive first priority. Labels that qualify for generic approval will receive second priority and may take longer to be reviewed.

In the preamble to the proposed rule, FSIS said that statements on labels that are defined in FSIS's regulations or policy guidance would not need to be submitted to FSIS for evaluation. However, the accompanying regulatory text only referred to statements that are defined in FSIS's regulations as generically approved. Therefore, to clarify FSIS's intent in the proposed rule, FSIS has amended 9 CFR 412.1(e) to provide that claims and statements that are defined in FSIS's regulations or in the Food Standards and Labeling Policy Book, except for ''natural'' and negative claims, and that comply with those regulations and policies, are deemed to be approved by the Agency without being submitted for evaluation and approval. The Agency has also amended 412.2(b) to require that labels that bear claims and statements that are not defined in the Federal meat and poultry products inspection regulations or in the Food Standards and Labeling Policy Book, including ''natural'' and negative claims, be submitted for approval.

Under the proposed rule, labeling with special statements or claims that has been reviewed by other Government agencies could not be generically approved under the Agency's regulations. However, in response to comments, FSIS has determined that a label bearing a child-nutrition (CN) box will not be considered to have a special statement or claim on it that would require sketch approval by FSIS. The CN information in CN boxes is reviewed and evaluated for approval by the Agricultural Marketing Service, removing it from the realm of a special statement or claim.

Also in response to comments asking that the Agency update the Food Standards and Labeling Policy Book before this final rule is published, FSIS has decided to stop adding policy guidance to it. FSIS will continue to amend or remove items in the book, as necessary, but it will no longer add new material to it beginning on the date that this final rule is published. The Agency will convey new labeling policy by other means, such as compliance policy guides.

Final Rule

This final rule is consistent with the proposed rule. The final rule provides that establishments are required to submit for evaluation only certain types of labeling, e.g., labels for temporary approval, labels for products produced under religious exemption, labels for products for export with labeling deviations, and labels with claims and special statements. FSIS will continue to require the submission of such labels because they are more likely to present significant policy issues that have health or economic significance. Examples of labels that must continue to be submitted for evaluation and approval before use under the final rule are: (1) Labels for chicken produced under Buddhist exemption; (2) labels for beef intestine produced for export to China that identify the product as ''beef casings,'' and (3) labels for temporary use that do not list all ingredients in the correct order of predominance.

Examples of special statements and claims for use on labels that must also continue to be submitted for evaluation and approval before use under the final rule are: (1) Claims relating a product's nutrient content to a health or a disease condition; (2) statements that identify a product as ''organic'' or containing organic ingredients; (3) claims that are undefined in FSIS regulations or the Food Standards and Labeling Policy Book, e.g., claims regarding the raising of animals, such as ''no antibiotics administered'' or ''vegetarian fed''; (4) instructional or disclaimer statements concerning pathogens, e.g., ''for cooking only'' or ''not tested for *E. coli* O157:H7;'' and (5) statements that identify a product as ''natural.''

Under this final rule, statements on labels that are defined in FSIS's regulations or the Food Standards and Labeling Policy Book, except for

[2] Generic label approval refers to the prior approval of labels or modifications to labels by the Agency without submitting such labels to FSIS for sketch approval.

''natural'' and negative claims, may be generically approved by the Agency without being submitted for evaluation and approval. Such claims include a statement that characterizes a product's nutrient content that is consistent with the applicable Agency regulation, such as ''low fat;'' that has geographical significance, such as ''Italian Style;'' or that makes a country of origin statement on the label of any meat or poultry product ''covered commodity.'' Consistent with the proposed rule, FSIS will not view the addition of an allergen statement (e.g., ''contains soy'') applied in accordance with the Food Allergen Labeling and Consumer Protection Act (FALCPA) as a special statement or claim that requires sketch approval.

Under this final rule, a label bearing a child-nutrition (CN) box will not be considered to have a special statement or claim on it that would require sketch approval by FSIS. The CN information in CN boxes is reviewed and evaluated for approval by the Agricultural Marketing Service, removing it from the realm of special statements or claims. Therefore, under this final rule a CN box on a meat or poultry product is generically approved.

When this rule becomes effective, labels that do not qualify for generic approval will receive first priority for review. Labels that do qualify for generic approval will receive a lower or second priority.

FSIS is also reorganizing the regulations in this final rule by consolidating the labeling approval rules that currently are presented separately for meat and poultry products (in 9 CFR 317.4 and 381.132, respectively) into a single, new part, 9 CFR Part 412. FSIS believes that the public will be better served by having the regulations governing label approval consolidated in one part of title 9. Rather than searching through two separate parts of title 9, 317 and 381, to find the label approval regulations, interested parties will only have to survey one, part 412, to be able to apply generically approved labels to their meat and poultry products.

Summary of and Response to Comments

FSIS received 47 separate comments to the proposed regulation from consumers (6), students (5), meat and poultry companies (9), trade associations (13), label consultants (8), health related sources (5), and an agriculture center. Just over half of the comments supported the proposal to expand generic approval. Of those, a great majority suggested expanding the generic approval system beyond that which the Agency proposed. These commenters supported the rule on the grounds that it will streamline and modernize the prior label approval system, thereby reducing the volume of paperwork and labels that need to be filed with FSIS. They also stated that it will decrease costs and utilize FSIS and industry resources more effectively. These commenters also stated that industry members will be able to devise their own approval systems, gaining time that is lost to long Agency approval times. Commenters stated that the efficient use of industry resources will also lead to faster introduction of innovative products into the marketplace and the enhancement of food safety.

Approximately nineteen commenters opposed the rule. The major reason for their opposition was concern about allergen listings on labels. Finally, seven of the comments were outside the scope of the rule. These commenters addressed issues such as the inclusion of Country of Origin Labeling on all labels; the production and sale of labels by USDA; developing better definitions of ''gluten free'' and ''wheat free;'' defining terms like ''natural;'' and reconsidering the amenability of flavors. A summary of the relevant issues raised by commenters and the Agency's responses follows.

1. Allergens

Comment: Numerous commenters believe that FSIS review of labels is a critical part of ensuring the accuracy of the ingredients statement on meat and poultry products. Commenters opposed to the proposal said that it would reduce oversight in a critical food safety area and, for that reason, would increase the likelihood that meat and poultry products containing undeclared allergens would enter the marketplace, and that more recalls would occur. One commenter stated that it was important to have FSIS review food labels and take steps to be certain that labels are clear and accurate.

Response: FSIS disagrees that the expansion of generic labeling will increase the likelihood that meat and poultry products will enter the marketplace with undeclared allergens. One of the purposes of prior label review is to ensure that the up to eight labeling features required by the meat and poultry products inspection regulations are present on the label, and that any claims are appropriately supported. Another purpose is to identify undefined claims, ad copy, or other information that may be false or misleading.

Prior label review does not, however, involve comparing the information on a label directly with the ingredients actually used in the food product that is to bear the label—the only way to determine whether allergens that have not been declared on the label have actually been used in the product. It is for inspection program personnel (IPP) to conduct reviews of this kind in the establishment, after the relevant label has been approved, whether generically or on a per-case basis by label reviewers in Washington, DC. IPP review labels and compare them to actual product formulations to verify that 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.

There were 30 allergen-related recalls of meat and poultry products during 2012. None of those recalls, however, resulted from changes that could have been identified through the Agency label review process. In some cases, labeling errors occurred because an establishment switched to a different supplier for a spice mix or blend used in product production but then did not check the new list of ingredients against its label inventory to ensure that they matched. Similarly, in other cases ingredient reformulations or product reformulations that changed the sub-listing of ingredients were not reflected on a product's label. Other labeling errors resulted from production mistakes, such as packaging the product in the wrong box.

More than 85 percent of the allergen-related recalls over the past year occurred as a result of something that happened after the label in question was approved by FSIS, a situation that prior label approval could obviously not change.

Under 9 CFR 317.2(f) and 381.118, establishments are required to list all ingredients used to formulate meat and poultry products in the ingredients statement on the product label, including potential allergens. FSIS's prior label review is not and cannot be a substitute for the careful application of labels to products by the meat and poultry industry.

Comment: Several commenters suggested that the Agency require the declaration of major allergens on the labels of FSIS-regulated foods.

Response: While a separate statement addressing specific allergens in the product is not mandatory for meat and poultry products as it is with foods regulated under the Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA), Public Law 108–282,

all ingredients in meat and poultry products must be listed on the label in the ingredients statement. As a result, all allergens are listed on the product. In addition, through its prior label approval system, FSIS is aware that most establishments are voluntarily including information consistent with the Food Allergen Labeling and Consumer Production Act of 2004 at the end of the ingredients statement, such as, ''contains milk and soy.'' FSIS plans to continue to monitor allergen statements, which establishments may apply voluntarily to labels, and will not initiate rulemaking to make allergen statements a required label feature. FSIS intends to continue to use its post-market surveillance activities to ensure that labels containing statements of this type are not false or misleading and comply with all applicable Federal regulations. FSIS also has no plans to require the listing of specific allergens on meat and poultry product labels.

2. Resource Issues

Comment: Some commenters said that industry does not understand the regulations sufficiently, or have the resources, to produce accurate labels without prior review of them by FSIS. A few were concerned that small and very small establishments will need to secure expensive legal and regulatory expertise to determine compliance with labeling requirements. They and others were also troubled by the Agency's decision to stop evaluating mandatory features that are generically approvable on a label submitted for review because of a special statement or claim.

Response: FSIS will provide labeling guidance so that small and very small establishments should not need to hire experts or additional staff to comply with FSIS's labeling requirements. In addition to the labeling guidance already available on the FSIS Web site, the Agency plans to develop additional materials to assist industry when applying labeling regulations and policies. While there is a good deal of information currently located on the Web site, it is not consolidated in one location. FSIS intends to better organize the Web site to make it easier for interested parties to find labeling and standards information posted there. Furthermore, the new web-based Label Submission and Approval System (LSAS) includes a ''generic label advisor'' to assist establishments in determining whether labels are generically approved or require sketch approval. FSIS also intends to develop Webinars and PowerPoint presentations on generic labeling to provide information to industry.

To implement this rule, FSIS will issue instructions to field personnel on their responsibilities related to expanded generic label approval. In addition, FSIS staff will be available to answer questions pertaining to generic approvals of labels.

In response to comments indicating a desire to continue submitting labels to FSIS for guidance, evaluation, and approval, the Agency has decided to continue to provide for the review of all labels. However, labels that cannot be generically approved will receive first priority. Labels submitted that can be generically approved will receive second priority and may take longer to be reviewed. While FSIS prioritizes its workload, establishments may commence to market their products with labels that have already been submitted for review. Reviewing these labels on a priority basis will not affect the Agency's projected cost savings.

As a result of its decision to continue providing for the review of all labels, FSIS, as a commenter asked, has not revised the regulatory text to state that the Agency will review only the special statement or claim, and not the rest of the submitted label, unless otherwise requested.

Comment: One commenter asked FSIS to streamline and improve the label submission form and the amount of information required to be submitted with it, eliminating, for example, the submission of processing procedures and the exact level of ingredients.

Response: While FSIS will consider ways that it can improve the label submission form, FSIS will continue to require the submission of information on processing procedures under 9 CFR 320.1 and 381.175 to assess whether the processing and labeling of the product is consistent with Hazard Analysis and Critical Control Point (HACCP) category. FSIS needs this information to verify statements or claims on the label. The information on processing procedures need not be extensive. FSIS accepts information on processing procedures as long as it is sufficient to allow the Agency to verify that the label is consistent with the product's processing. For example, the processing information submitted for a product label needs to be sufficient to justify its label description as ''smoked'' or ''cooked.''

Similarly, it is not necessary for an establishment to submit the exact levels of a product ingredient. FSIS will continue to accept a range for ingredients in a product formula, except for ingredients with regulatory limits established in FSIS or Food and Drug Administration regulations, if the establishment maintains the correct order of predominance.

3. Claims and Statements Defined in Guidance Documents

Comment: Several commenters asked what claims and statements defined in policy guidance may be considered to be generically approved. Several commenters also pointed to an inconsistency between the preamble of the proposed rule and its regulatory text. In the preamble (76 FR 75814), FSIS wrote:

> . . . statements on labels that are defined in FSIS's regulations or policy guidance, e.g., a statement that characterizes a product's nutrient content, such as ''low fat''; that has geographical significance, such as ''Italian Style''; or that makes a country of origin statement on the label of any meat or poultry product ''covered commodity,'' will not need to be submitted to FSIS for evaluation.

However, the accompanying regulatory text only referred to statements that are defined in FSIS's regulations as generically approved.

Response: In the final rule, to clarify FSIS's intent in the proposed rule, in 9 CFR 412.2(b) FSIS has provided that claims and statements that are defined in FSIS's regulations or in the Food Standards and Labeling Policy Book, (e.g., a statement that characterizes a product's nutrient content, such as ''low fat,'' has geographical significance, such as ''German Brand,'' or makes a country of origin statement on the label of any meat or poultry product ''covered commodity''), except for ''natural'' and negative claims, and that comply with those regulations and policies, are deemed to be approved by the Agency without being submitted for evaluation and approval. Similarly, in 9 CFR 412.1(e), FSIS is requiring that labels that bear claims and statements that are not defined in the Federal meat and poultry products inspection regulations or in the Food Standards and Labeling Policy Book, including ''natural'' and negative claims, be submitted for approval.

Therefore, interim policy guidance and other guidance not included in the Food Standards and Labeling Policy Book cannot be deemed approved without evaluation and review by FSIS. Interim policy typically involves novel labeling statements or claims that present significant public health or economic issues and that constitute special statements or claims. Other guidance not included in the Food Standards and Labeling Policy Book includes animal production claims; omega fatty acid guidance; allergen claims, such as ''milk free''; and whole grain claims. The Agency must approve

these statements or claims on a case-by-case basis.

Note that if a special statement or claim has been approved for an establishment under the current system, the establishment will not need to resubmit the label bearing it under this new final rule. It would only have to resubmit the label if it added a new special statement or claim to the previously approved label.

Comment: Several commenters suggested that FSIS make available a comprehensive list or guide that outlines what statements or claims need prior label approval.

Response: FSIS agrees that this is a good idea. We intend to develop a guidance document concerning claims that can and cannot be generically approved.

4. Expansion of Generic Labeling

Comment: As mentioned earlier, many of the commenters in favor of the proposed rule suggested expanding the generic approval system beyond that which was proposed.

Response: Many of the labels that commenters asked be generically approved are, under 9 CFR 412.1, which is being added to FSIS's regulations by this final rule, specifically required to be submitted for evaluation and review by FSIS. Examples of such labels and information are sketch labels for products produced under a religious exemption, sketch labels for products for foreign commerce whose labels deviate from FSIS regulations, special statements and claims, and requests for the temporary use of final labeling that is deficient in some particular. These labels are discussed later in this document.

Some of the commenters' suggested changes are not necessary because, as proposed and under this final rule, the labeling statements raised can be approved without prior submission to FSIS. An example would be foreign language labels. One commenter stated that labels containing foreign languages on products for sale in the U.S. that do not have special statements or claims should not need sketch approval from FSIS. While the current meat and poultry inspection regulations do not permit the generic approval of a label adding or deleting a direct translation of the English language into a foreign language for product sold in the U.S.,[3] this final rule will do so. These types of labels do not fall into any of the categories of labels that must be submitted to FSIS for evaluation and review. Another suggested change, that modifications to product labels reflecting changes made by suppliers should be generically approvable, is unnecessary. As in the proposal, the final rule will permit these modifications to be generically approved, and thus no expansion of the generic approval system is needed.

We were asked by a commenter if we intended to permit the generic approval of previously approved labels containing special claims when the only modification involves changes unrelated to the special claim. The answer is yes. Previously approved labels containing special claims may be generically approved if the only modification involves changes unrelated to the special claim.

Comment: Many commenters asked that FSIS allow the generic approval of final labels off of temporary labels, as well as the generic approval of temporary label extensions. Several more suggested that temporary labels that contain minor inaccuracies but present minor health risks be deemed generically approved. Others sought generic approval for different types of temporary labels on meat and poultry products. For example, commenters suggested that FSIS generically approve temporary labels when the ingredient list of a meat or poultry product changes. Another asked for generic approval of temporary labels on secondary products. Other commenters sought generic approval in other situations, such as the removal of a non-USDA-regulated ingredient from a product formula; a change of place in the order of predominance of an ingredient in a food regulated by FDA used in the formulation of a meat or poultry food product because of a change in suppliers; and a modified ''blanket'' approval based on a single temporary approval.

Response: After reviewing the comments, FSIS has determined that it would be inappropriate to allow the following types of labels to be deemed approved without Agency evaluation and review:

Labels bearing negative, ''natural,'' and ''organic'' claims: These labels are not generically approvable because they are special claims, as defined in 9 CFR 412.1(e) of this final rule.

The meat and poultry regulations do not define ''negative,'' ''natural,'' or ''organic.'' ''Negative'' labeling claims are defined in the Food Standards and Labeling Policy Book. Negative claims refer to statements highlighting the absence of an ingredient or another constituent of the food, an example of which, ''gluten free,'' has been codified in 9 CFR 412.1(e). ''No milk'' is another example of a negative claim that highlights the absence of an ingredient or another constituent of a food. A negative claim may also identify the absence of certain types of ingredients, e.g., ''no preservatives'' or ''no artificial coloring'' based on the product formulation. Consequently, negative claims can vary greatly, from a specific ingredient to a class of substances, making it difficult to determine whether a label bearing this type of claim is compliant.

''Natural'' is also a claim that is undefined in FSIS's regulations but is defined in the Food Standards and Labeling Policy Book. However, natural is a controversial claim which has come under great scrutiny in the last several years and for which FSIS is considering rulemaking.[4]

''Organic'' is not defined in FSIS's regulations. Consequently, establishments may not be familiar with the Agency's requirements for the support or application of this claim, which could result in increased labeling errors and misbranded product. While industry is familiar with the requirements for mandatory label features, as noted in the proposed rule, the Agency believes that it needs to continue to provide pre-market evaluation and approval of ''organic'' claims because they present significant and evolving policy issues.

For the above reasons, FSIS must see the ingredients listing on a label containing a negative, ''natural,'' or ''organic'' claim to be able to verify its accuracy.

Labels marked ''for export only'' (previously sketch approved with minor modifications): Exports of U.S. meat and poultry products occur in the context of U.S. government-foreign government agreements. These agreements require U.S. government approval of labels on meat and poultry products to be exported. One aspect of this approval is ensuring that any changes made to labels on meat and poultry products are allowed per the importing country's laws. Therefore, labels marked ''for export only'' cannot be generically approved.

Labeling with special statements or claims that has been reviewed by other Government agencies: Except for meat and poultry product labels that bear child-nutrition (CN) boxes, which are reviewed and approved by the Agricultural Marketing Service (AMS),

[3] 9 CFR 317.5(b)(9)(xxiv) and 381.133(b)(9)(xxv).

[4] *See* ''Product Labeling: Definition of the Term ''Natural'' and related materials (71 FR 70503, Dec. 5, 2006) and ''Product Labeling: Use of the Voluntary Claim ''Natural'' in the Labeling of Meat and Poultry Products'' and related materials (74 FR 46951, Sep. 14, 2009).

at this time, no other labeling that may be placed on meat and poultry products is reviewed by other Government agencies. While agencies such as FDA and AMS may have extra-regulatory processing marketing, or verification programs, the labels applied to meat and poultry products as part of these programs are not reviewed and approved by the other agencies. Rather, these agencies are verifying the documented production, manufacturing, or service delivery processes of suppliers of agricultural products or services. Therefore, because only the production, manufacturing, or service delivery process is being verified by these agencies, and not the label itself, they may not be generically approved under the Agency's regulations. In addition, the statements on the labels are considered special statements or claims that may not be approved without submission to and evaluation by FSIS.

Under this final rule, however, a label bearing a child-nutrition (CN) box will not be considered to have a special statement or claim on it that would require sketch approval by FSIS. The CN information in CN boxes is reviewed and evaluated for approval by the Agricultural Marketing Service, removing it from the realm of a special statement or claim. Therefore, under this final rule, a CN box on a meat or poultry product is generically approved.

Temporary label approvals and extensions: Temporary labels are not good candidates for generic approval. Temporary label approvals may not be used longer than 180 days. The Agency is concerned that allowing the extension of temporary label approvals on a generic basis would result in use of the labels well beyond the 180-day limit. Because the temporary approval would have been granted generically, FSIS would have no way of knowing the limit on the generic approval. In addition, the regulations in this final rule that outline the conditions under which temporary label approval may be granted are based on FSIS evaluating and reviewing the labels, not industry. The regulations are not, in the Agency's opinion, specific enough to assist establishments in determining when a temporary label may be granted.

Some of the temporary labels for commenters recommend generic approval would require establishments to assess the public health risk of the modification at hand, e.g., the non-declaration on the label of a particular ingredient. It would not be appropriate for establishments to conduct such an assessment. FSIS needs to assess the public health risk and potential economic adulteration when deciding to grant approval for the use of a temporary label.

For these reasons, FSIS is not expanding the scope of generic labeling approval to include temporary label approvals and extensions.

Religious exemptions: Generically approved labeling is not appropriate for the labeling of religious-exempt product because such product does not receive the mark of inspection and, therefore, deviates from the general labeling requirements for meat and poultry products.

Front-of-package labeling statements that meet the requirements for nutrient content claims, including statements of quantity: FSIS considers certain front-of-pack (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. However, unlike traditional nutrient content claims, such as ''low fat,'' that are defined in FSIS regulations, there are no guidelines for the multiple types of FOP labeling statements on labeling. Therefore, FSIS needs to continue to require prior evaluation and approval by the Agency to ensure these statements are truthful and not misleading.

Claims that may not present public health or economic concerns: These labels might include marketing promotions, logos from recognized third parties, and general wellness claims.

FSIS does not agree that labels such as these should be deemed to be approved without Agency evaluation and review. As with some of the temporary labels for which generic approval is being sought, whether a label presents a food safety issue or not requires an assessment of the public health risk presented by the label. It is appropriate that FSIS, not establishments, conduct such an assessment.

In addition, the generic approval of labels that include marketing promotions, logos from recognized third parties, general wellness claims, and other similar features that, in the opinion of industry, do not present consumer confusion issues, would still be problematic because these labels may include claims that are not addressed in the meat and poultry regulations. Some of these labels might also fall into the category of implied nutrient content claims as defined in 9 CFR 317.313(b)(2) and 381.413(b)(2), e.g., a claim that suggests that the product, because of its nutrient content, may be useful in maintaining healthy dietary practices and is made with an explicit claim or statement about a nutrient. Because FSIS does not have any regulations that cover the application of implied claims to meat and poultry labels, establishments would have great difficulty determining whether such labels are generically approved. For these reasons, these labels must continue to be submitted to FSIS for evaluation and review under this final rule.

Comment: One commenter asked whether developmental claims or messages regarding infants and children could be generically approved.

Response: No, such claims do not fit into any of the generic categories because they are not defined in FSIS regulations or in the Food Standards and Labeling Policy Book. They are special statements or claims.

5. Elimination of Evaluation and Review

Comment: Those opposed to the proposal felt that expanding the generic approval system will open it up to possible abuse, whether intentionally or through establishment ignorance, resulting in harm to consumers. Concerns included a lack of sufficient expertise, commitment, or money, as well as a lack of trust in the meat and poultry industry to police itself, particularly with regard to labeling accuracy. Commenters suggested that this would expose consumers to hundreds of thousands of adulterated and misbranded products.

Response: FSIS does not agree with these comments. Special statements and claims that are not defined in FSIS regulations or the Food Standards and Labeling Policy Book, including negative and ''natural'' claims, will continue to be evaluated and approved under this final rule. The eight required features on labels, product name; inspection legend/establishment number; handling statement; net weight; ingredients statement; signature line; nutrition facts; and safe-handling instructions have been required for many years. Establishments are required to include these basic labeling features properly on their product labels. FSIS inspection program personnel verify that establishments' labels comply with these requirements.

FSIS's decision to provide for the review of all labels, whether or not they contain special statements or claims, will assist those establishments with insufficient expertise or funds to comply with the requirements of this final rule. The reduction in the number of labels reviewed by FSIS as of result of this final rule will also allow the Agency to respond to labeling questions from the meat and poultry industry and to develop the materials needed to

successfully implement these regulations.

Comment: One commenter stated that an electronic program to automatically scan and review labels would reduce the time spent by FSIS reviewing labels and would allow labeling staff to concentrate on other food safety regulations.

Response: While no system can scan and review labels, FSIS has recently released an electronic label system to allow for easier label submission. Using the Label Submission and Approval System (LSAS), establishments are able to 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 errors in the label submission process, including illegibility, missing information on the transmittal form, and missing support 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 approval. The use of LSAS will have a positive impact on the speed and accuracy of label review.

Comment: Some commenters stated that the rule would harm industry through recalls, tagged products, loss of goodwill, and loss of valuable label inventories.

Response: FSIS disagrees with these comments. Industry is familiar with the eight mandatory labeling features that have been required for many years. Additionally, industry has had 16 years of experience applying the current generic labeling regulations.

FSIS has not observed an increase in loss of product or labels, or an increase in meat and poultry product recalls, as a result of establishments applying generically approved labels. Labels found to be deficient in some particular may be eligible for temporary approval. In addition, establishments may submit requests for temporary approval for retained product (''tagged'') as an ''extraordinary circumstance'' as described in the following compliance policy guide on the Agency's Web site: *http://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/labeling/labeling-procedures/procedures-evaluating-labeling.* Labels submitted as an extraordinary circumstance are given the highest priority for label evaluation to prevent loss of product. Labels determined to be ineligible for temporary approval without modification may be brought into compliance for use through the use of pressure sensitive stickers. Pressure sensitive stickers are used to cover or correct inaccurate or misleading information. FSIS has published a guidance document for compliance assistance on the use of pressure sensitive stickers at: *http://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/labeling/Labeling-Policies/pressure-sensitive-stickers/pressure-sensitive-stickers.* Temporary approval is not required to bring labels into compliance through the use of pressure sensitive stickers. Moreover, FSIS has regulatory authority to grant temporary approval for the use of labels that may lack some particular information if use of the labels will not misrepresent the product, present a health or safety issue, or provide an unfair economic advantage.

We recognize that this rule is more extensive than the current labeling regulations in that it increases the amount of labeling that industry can self-declare generically approved and therefore not submit to FSIS for prior approval. We therefore acknowledge the need for updated labeling information and directions to IPP in appropriately assessing the accuracy of the labeling records and whether the label has been generically approved. We intend to provide guidance and issue instructions to IPP to help them perform their in-plant labeling verification activities.

6. Implementation of the Final Rule

Comment: Many of the commenters that supported the proposed rule nonetheless had concerns about implementation of the final rule. One of these concerns was ensuring that all parties, that is, industry, the FSIS labeling staff located in Washington, DC, and IPP, understand how the generic approval program is administered, monitored, and enforced. Several commenters asked that FSIS provide an implementation plan and a consistent method and process for the clarification and redress of issues identified by IPP or establishments, along with a timetable for redress. Other implementation issues raised include:

1. FSIS issuance of a directive that details the role of IPP, including when and how to conduct a generic label verification check, how the inspector-in-charge should communicate with FSIS labeling staff, and how establishments can appeal generic labeling issues directly to the FSIS labeling staff, rather than IPP;

2. Authorizing only FSIS labeling staff, rather than IPP, to decide if a label is not eligible for generic approval, and advising IPP to contact FSIS labeling staff before taking regulatory control actions; and

3. Prohibiting the interruption of product flow unless the errors on the label constitute immediate, genuine situations of public health concern, or until it is confirmed that the errors constitute a public health concern, economic fraud, or an unfair competitive advantage.

Commenters also requested greater access to FSIS label staff and asked that the FSIS Policy and Labeling Book be updated before the final rule is published.

Response: FSIS intends to issue instructions to IPP that will address these and other issues relating to label verification activities. The instructions will include specific label tasks associated with in-plant labeling verification activities, such as verifying that all ingredients are appropriately declared on labeling. If labels are determined to be out of compliance, the instructions will provide guidance to IPP on how to document the noncompliance in the Public Health Inspection System (PHIS), and what actions are to be taken. In addition, the Agency will provide training to Agency personnel and guidance materials to industry on labeling regulations and policies, including generic labeling.

FSIS plans to provide outreach assistance to companies producing and submitting meat and poultry labels so that they may take full advantage of this time and cost saving measure. The Agency will develop compliance policy guides, webinars, and PowerPoint presentations for industry. FSIS also intends to better organize the information on its Web site to make it easier for interested parties to find labeling and standards information posted there. FSIS believes that these actions will reduce the number of label submissions to FSIS headquarters, thus increasing the availability of FSIS labeling staff.

Upon publication of this final rule, FSIS will cease adding new items to the Food Standards and Policy Labeling Book. FSIS will continue to amend or remove items in the book, as necessary, but it will no longer add new material to it beginning on the date that this final rule is published. The Agency will convey new labeling policy by other means, such as compliance policy guides.

7. Survey Data

Comment: A few commenters opposed the rule on the grounds that the Generic Label Audit System (GLAS) data supporting the proposal are not valid because of the age of the information, the manner in which labels were selected for review, and the lack of

a final report. Furthermore, commenters stated that FSIS did not complete or publish a final GLAS report. These commenters stated that a new survey needs to be conducted to determine the effects of the current rules on label compliance, public safety and health, and competition within the industry.

Response: As stated in the preamble to the proposed rule, FSIS recognizes that the data from the survey referenced in the 2011 proposed rule are over 13 years old. The Agency concluded, however, that the survey showed that the great majority of establishments surveyed could effectively use generic approval without first submitting sketch labels to FSIS for evaluation and approval. The survey results also confirmed that the gradual implementation of the generic label provisions promulgated in 1995 [5] was effective. The Agency is not aware of any reason why this situation does not continue to prevail today. In addition, FSIS has developed a significant amount of policy guidance, including labeling compliance guideline tools such as a suggested label submission checklist and a list of the 10 most common mistakes and ways to avoid them, for industry use since the survey was done. *http://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/labeling/labeling-procedures*.

8. Miscellaneous Comments

Comment: One commenter believed that it would be illegal to expand the current generic approval regulations without Congress amending the Acts to relieve the Secretary of Agriculture of the responsibility of prior approval.

Response: FSIS does not agree with this comment. FSIS has administered a generic label approval program since 1996 without requiring modification of the Acts.

Comment: One commenter asked whether 9 CFR 500.8, Procedures for rescinding or refusing of marks, labeling or containers, applies when IPP dispute an establishment's decision to generically approve a label but do not allege that the label is false or misleading.

Response: No. Section 500.8 of 9 CFR is for rescinding or refusing approval of labeling. IPP do not approve or rescind labeling. If IPP dispute an establishment's decision to generically approve a label but do not allege that the label is false or misleading, IPP retain the product in question in accordance with 9 CFR 500.2(a)(3) and issue a noncompliance record (NR) stating that the label requires sketch approval. The NR also indicates why sketch approval is required. The procedures in 9 CFR 500.8 are not usually invoked until after IPP have denied an establishment's appeal of an NR written for incorrectly generically approving a label, and the appeal has moved to the District Office for resolution.

Comment: One commenter stated that the proposed records regulations are unclear, unnecessary, and will invite disputes about records.

Response: Establishments are required to keep records of all labeling, along with the product formulation and processing procedures, as prescribed in 9 CFR 317.4, 317.5, 381.132, and 381.133. The proposal added the requirement that any additional documentation needed to support that the labels are consistent with the Federal meat and poultry regulations and policies on labeling also be kept. For example, in a situation where an establishment makes a ''no MSG'' claim, such documentation would include a sketch approval from the Agency. Furthermore, the product formulation is included on the application to verify the product is absent of the ingredient, which substantiates the validity of the claim.

Comment: One commenter asked about the use of generic approval with egg products labels.

Response: The use of generic approval with egg products labels is being considered in a separate rulemaking action.

Comment: One commenter stated that the Cost Benefit Analysis (CBA) demonstrates that other types of agency cost-saving measures should be considered instead of generic label approval expansion, and that the costs of recalls to manufacturers and, especially, harm to consumers need to be calculated and considered for accurate analysis of the proposal.

Response: The analysis summarized the likely reduction in the number of labels submitted to FSIS for evaluation because the proposed rule will enable the Agency to reallocate the staff hours from evaluating labels towards the development of labeling policy, the evaluation of new and novel labeling policy issues, and involvement in other food safety and consumer protection activities. There is no basis to believe that this action will either increase the number of recalls or harm consumers. Hence, there is no basis to include these costs in the CBA.

Executive Orders 12866 and 13563

Executive Orders (EOs) 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if a regulation is necessary, to select the regulatory approach that maximizes net benefits (including potential economic, environmental, public health and safety, and other advantages, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This action has been reviewed for compliance with EOs 12866 and 13563.

This rule has been designated a ''significant regulatory action,'' although not economically significant, under section 3(f) of EO 12866. Accordingly, the rule has been reviewed by the Office of Management and Budget.

The Agency has estimated that this final rule will result in net benefits to consumers and establishments by expanding the types of labels that are approved generically under the FMIA and the PPIA.

This final rule is consistent with regulatory retrospective efforts and E.O. 13563. The rule will be beneficial because it will streamline the generic labeling process, while imposing no additional cost burden on establishments. Consumers will benefit because industry will have the ability to introduce products to the marketplace more quickly. Moreover, the change will make better use of FSIS resources because it will reduce the number of labels required to be reviewed by the Agency.

This final rule will expand the circumstances in which the labels of meat and poultry products will be deemed to be generically approved by FSIS and to combine the regulations that provide for the generic approval of labels for meat products into a new part 412 in Title 9, Chapter III, of the CFR. It is the next step in the Agency's gradual streamlining and modernizing of the prior label approval system.

This final rule will reduce the number of labels evaluated by FSIS that only bear basic features (e.g., product name, ingredients statement, net weight) and the amount of paperwork filed by establishments with FSIS. These actions will improve the efficiency of the label approval system by streamlining the evaluation process for specific types of labels and making the label approval system more convenient and cost-effective for industry. As for consumers, this new process will enhance market efficiency by promoting a faster

[5] ''Prior Label Approval System,'' (60 FR 67334, Dec. 29, 1995).

introduction of new products into the marketplace to meet demand while not negatively affecting consumer protection from misbranded product.

The analysis of benefits and costs below is the analysis from the proposed rule. FSIS received no updates suggesting that concrete modifications to the analysis were needed, and there have been no major data changes since the proposed rule was published in December 2011. However, data were updated for the discounted cost savings to reflect the corrected discount rate calculations at 7 percent and added the discounted rate calculations at 3 percent. In addition, the total number of labels developed and applied by establishments that do not require FSIS evaluation was updated to reflect a 1 percent growth factor. After reviewing the analysis from the proposed rule, FSIS has determined that it is still accurate.

I. Baseline

Based on the Agency's Performance Based Inspection System databases, in 2011, there were about 6,099 Federal establishments. FSIS estimates that there were approximately 266,000 approved meat and poultry product labels used by these establishments. FSIS evaluated about 66,000 of them in 2010; the remaining 200,000 were approved under the Prior Label Approval System because they met the standards for generic approval.

II. Benefits

A. Industry

This final rule will permit establishments to realize an estimated cost savings of a minimum of $10.1 million (discounted at 7 percent over a 10-year period) for generically approving about 584,486 additional labels over a 10-year period at about $25 per label submission,[6] or about $12.4 million (discounted at 3 percent over a 10-year period. FSIS considers this estimate to be an upper bound, since some establishments may continue to submit generic labels, as defined by this final rule, for review. The annualized cost savings will be $1.9 million at 7 percent over 10 years, or $1.7 million at 3 percent over 10 years. In the absence of this rule, establishments will not realize any cost savings because Federal regulations will continue to require establishments to submit a significant number of labels to the Labeling and Policy Development Staff (LPDS) for evaluation.[7] Establishments will also realize an increase in the number of generically approved labels over a 10-year period under the final rule.

TABLE 2—ESTIMATED ESTABLISHMENT COST SAVINGS

[In 2010 dollars]

Year	Total number of labels developed and applied by establishments that do not require FSIS evaluation *before rule*	Increase in number of labels developed and applied by establishments that would not require FSIS evaluation	Total number of labels developed and applied by establishments that would not require FSIS evaluation *after rule*	Total cost savings Col.(C) × *$25 from reduced need for FSIS label evaluation	To apply discount rate of 7.00%	Discounted total cost savings Col. (E) × Col. (F)
(A)	(B)	(C)	(D)	(E)	(F)	(G)
0	200,000	0	200,000	$0	1.00	$0
1	202,000	50,985	252,985	1,274,625	0.9346	1,191,265
2	204,020	52,515	256,535	1,312,864	0.8734	1,146,655
3	206,060	54,090	260,150	1,352,250	0.8163	1,103,841
4	208,121	55,713	263,833	1,392,817	0.7629	1,062,580
5	210,202	57,384	267,586	1,434,602	0.7130	1,022,871
6	212,304	59,106	271,410	1,477,640	0.6663	984,551
7	214,427	60,879	275,306	1,521,969	0.6227	947,730
8	216,571	62,705	279,276	1,567,628	0.5820	912,359
9	218,737	64,586	283,323	1,614,657	0.5439	878,212
10	220,924	66,524	287,448	1,663,097	0.5083	845,352
Total	2,313,367	584,486	2,897,853	14,612,147	.....	10,095,417

Description:
Col A: Estimate is for a 10-year period. Year "0" is the year before the enactment of the rule.
Col B: Total number of labels developed and applied by official establishments that do not currently require FSIS evaluation.
Col C: Increase in the number of labels generically developed and applied by establishments as a result of the rule (i.e., would not need FSIS evaluation.
Col D: Total number of labels developed and applied by establishments after the rule was enacted.
Col E: Total cost savings realized to establishments, using an estimated $25 as the cost per label submission to LPDS.
Col F: Discount rate of 7 percent.
Col G: Discount cost savings over 10 years.
Source: FSIS Policy Analysis Staff Calculations.

Because fewer labels will need to be submitted to the Agency for evaluation, establishments will realize a cost savings because they will no longer need to incur costs to have certain types of labels evaluated by FSIS. Establishments have the option to continue submitting labels for review. FSIS believes that large and some small establishments will voluntarily use generic labeling. Some small and very small establishments will continue to

[6] The cost per label is the cost of submitting a label for review to FSIS, which averages about $25.00 per submission. This amount will be used as a proxy to estimate the cost savings to establishments that prepare their labels for review using FSIS Form 7234–1 "Application for approval of Labels, Markings, or Device" and preparing a printer's proof of the label for evaluation and approval by LPDS.

[7] See Table 2.

submit labels without a special statement or claim for review. FSIS believes that the number of labels that will continue to be submitted for review will be minimal.

B. Agency

The final rule will reduce the number of labels submitted to FSIS for evaluation and enable the Agency to reallocate the staff hours from evaluating labels towards the development of labeling policy, the evaluation of new and novel labeling policy issues, and involvement in other food safety and consumer protection activities. The final rule will streamline the approval process by amending the regulations to provide that, except in certain specified circumstances, the label of a meat or poultry product is deemed to be approved generically.

TABLE 3—ESTIMATED FSIS COST SAVINGS

[In 2010 dollars]

Year	Total number of labels evaluated and approved by LPDS *before rule*	Total number of labels evaluated and approved by LPDS *after rule*	Annual salary cost ($) of LPDS [1] *before rule*	Annual salary cost ($) of LPDS [2] *after rule*	Annual salary difference (D)–(E)	To apply discount rate of 7.00%	Discounted cost savings (F)*(G)
(A)	(B)	(C)	(D)	(E)	(F)	(G)	(H)
0	66,061	66,061	538,710	538,710	0	1.00	$0
1	68,980	16,995	554,871	134,677	420,194	0.935	392,705
2	70,019	17,505	571,517	138,717	432,800	0.873	378,024
3	72,120	18,030	588,663	142,879	445,784	0.816	363,893
4	74,284	18,571	606,323	147,165	459,158	0.763	350,289
5	76,512	19,128	624,513	151,580	472,932	0.713	337,194
6	78,807	19,702	643,248	156,128	487,120	0.666	324,589
7	81,172	20,293	662,545	160,811	501,734	0.623	312,455
8	83,607	20,902	682,422	165,636	516,786	0.582	300,774
9	86,115	21,529	702,894	170,605	532,290	0.544	289,530
10	88,698	22,175	723,981	175,723	548,258	0.508	278,707
Total	845,315	260,829	6,899,688	2,082,631	4,817,057	.....	3,328,160

Description:
Col A: Estimate is for a 10 year period. Year "0" is the year before the enactment of the rule.
Col B: Total number of labels evaluated and approved by LPDS prior to rule enactment assuming a 3 percent growth factor.
Col C: Total number of labels evaluated and approved by LPDS after rule enactment, assuming a 3 percent growth factor.
Col D: Annual salary cost of LPDS staff who evaluate labels, prior to enactment of rule, assuming a 3 percent growth factor.
Col E: Annual salary cost of LPDS personnel who evaluates labels, after rule enactment, assuming a 3 percent growth factor.
Col F: Annual salary difference between salary before rule enactment and after rule enactment, assuming a 3 percent growth factor.
Col G: Discount rate of 7 percent.
Col H: Discount cost savings.
Footnotes:
[1] Total salary is based on a staff of 11 personnel paid at the average rate of a GS–13, step 4 of $47.09 per hour: 11 staff persons would review labels at a cost of $538,710 per year ($47.09 an hour × 4 hours a day × 11 persons × 5 days a week = $10,359.80. $10,359.80 × 52 weeks = $538,710).
[2] Total salary is based on a staff of 11 personnel paid at the average rate of a GS–13, step 4 at $47.09 per hour: 11 staff persons would review labels at a cost of $134,677.40 per year ($47.09 an hour × 1 hour a day × 11 persons × 5 days a week = $2,589.95 × 52 weeks = $134,677.40.
Source: FSIS Policy Analysis Staff calculations.

Currently (represented as year 0), FSIS reviews 66,000 labels. In years 1–10 (with year 1 representing the beginning of implementation), FSIS is expected to experience a 69 percent reduction in the volume of labels submitted for evaluation. Small and very small establishments may continue to send labels in for review for minor changes. While FSIS prioritizes its workload, establishments may commence to market their products with the labels that are submitted for review, which will not affect the Agency projected cost savings. FSIS will evaluate labels and labeling for one hour per day, five days a week, as a result of the reduction in the volume of labels or labeling submitted to FSIS due to this final rule. Thus, it will permit the Agency to realize an estimated discounted cost savings of $3.3 million over 10 years,[8] at a 7 percent discount rate or $4.1 million over 10 years at a 3 percent discount rate. FSIS also considers this estimate to be an upper bound because, as mentioned before, some establishments may continue to submit labels to FSIS for review that would qualify as generic under this final rule. The annualized cost savings will be $641 thousand at 7 percent over 10 years and $548 thousand at 3 percent over 10 years. FSIS is expected to review a total of 260,890 labels under the rule as compared with 845,315 under the current system.[9] This cost savings from fewer staff hours being allocated towards label evaluation can be redirected towards other food safety and consumer protection activities.

[8] See Table 3.
[9] Ibid.

III. Costs

This final rule will not impose any new costs on meat and poultry establishments that submit labels for review to FSIS and it minimizes the regulatory burden on establishments that submit labels for review. The final rule does not change the requirement that establishments maintain copies of all labeling records, along with the product formulations and a description of the processing procedures used to formulate the products in accordance with 9 CFR 320.2 and part 381, subpart Q. These labeling records must be made available to any authorized Agency official within 24 hours upon request.

The final rule also does not impose any additional cost burden on establishments because first, establishments are already applying generically approved labels and maintaining all labeling records, and second, establishments are experienced in submitting labels to FSIS for evaluation. The cost of label design and products is not a part of this final rule.

IV. Overview

This final rule is beneficial because it streamlines the generic label approval process, while imposing no additional cost burden on establishments or the Agency. FSIS estimates that establishments will realize a discounted cost savings of $10.1 million as a result of their ability to generically approve an additional 584,486 labels over a 10-year period (discounted at 7 percent) or $12.4 million over a 10-year period (discounted at 3 percent). Furthermore, the Agency will realize a discounted cost savings of $3.3 million for evaluating 584,486 fewer labels over a 10-year period (discounted at 7 percent) or 4.1 million over 10 years (discounted at 3 percent). This cost savings in fewer staff hours being spent evaluating labels can be redirected towards other Agency initiatives. The annualized cost savings will be $2.58 million ($1.9 million for establishment + $641 thousand for the Agency) at 7 percent over 10 years or $2.21 million ($1.7 million + $548 thousand) at 3 percent over 10 years. These costs savings estimates should be considered an upper bound, as described earlier. Therefore, the net benefit derived from the final rule is $13.4 million ($10.1 million in establishment savings plus $3.3 million in Agency savings), discounted at 7 percent over a 10-year period or $16.5 million ($12.4 million in establishment savings plus $4.1 million, in Agency savings), discounted at 3 percent, over a 10-year period.

Regulatory Flexibility Analysis

The FSIS Administrator certifies that for the purpose of the Regulatory Flexibility Act (5 U.S.C. 601–602), the final rule will not have a significant economic impact on a substantial number of small entities. The final changes will affect those entities in the United States that submit labels for review to FSIS. There are 6,099 meat and poultry establishments that could possibly be affected by this rule since all are eligible to submit labels for review and 12 small label consulting firms that are involved in various labeling activities, such as submitting labels to FSIS for evaluation on the behalf of meat and poultry establishments. Of the 6,099 establishments, there are about 2,616 small federally inspected establishments (with more than 10 but less than 500 employees) and 3,103 very small establishments (with fewer than 10 employees) based on HACCP Classification. Therefore, a total of 5,719 small and very small establishments could be affected by this rule. These small and very small establishments, like the large establishments, will be able to generically approve labels as long as there are no special claims on the labels. Small entities will not be disadvantaged because the final rule will minimize the regulatory burden on all establishments. The final rule will not have a significant impact on a substantial number of label consulting firms. Since the expanded use of generically approved labels in 1995, these firms have modified their consulting services to specialize in certain policy areas, e.g., the production and labeling of organic products and animal production raising practices. Therefore, the Agency believes that the final rule will not have a significant economic impact on a substantial number of small entities (establishments and labeling consulting firms).

Executive Order 12988

This rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule: (1) Preempts State and local laws and regulations that are inconsistent with this rule; (2) has no retroactive effect; and (3) does not require administrative proceedings before parties may file suit in court challenging this rule except as discussed below.

Executive Order 13175

This final rule has been reviewed in accordance with the requirements of Executive Order 13175, Consultation and Coordination with Indian Tribal Governments. The review reveals that this regulation will not have substantial and direct effects on Tribal governments and will not have significant Tribal implications.

USDA Nondiscrimination Statement

The U.S. Department of Agriculture (USDA) prohibits discrimination in all its programs and activities on the basis of race, color, national origin, gender, religion, age, disability, political beliefs, sexual orientation, and marital or family status. (Not all prohibited bases apply to all programs.) Persons with disabilities who require alternative means for communication of program information (Braille, large print, or audiotape) should contact USDA's Target Center at (202)720–2600 (voice and TTY).

To file a written complaint of discrimination, write USDA, Office of the Assistant Secretary for Civil Rights, 1400 Independence Avenue SW., Washington, DC 20250–9410 or call (202) 720–5964 (voice and TTY). USDA is an equal opportunity provider and employer.

Additional Public Notification

FSIS will announce this final rule online through the FSIS Web page located at *http://www.fsis.usda.gov/wps/portal/fsis/topics/regulations/federal-register/interim-and-final-rules*.

FSIS will also make copies of this **Federal Register** publication available 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 constituents and stakeholders. The Update is communicated via Listserv, a free electronic mail subscription service for industry, trade groups, consumer interest groups, health professionals, and other individuals who have asked to be included. The Update is also available on the FSIS Web page. In addition, FSIS offers an electronic mail subscription service which provides automatic and customized access to selected food safety news and information. This service is available at *http://www.fsis.usda.gov/wps/portal/fsis/programs-and-services/email-subscription-service*. Options range from recalls to export information to regulations, directives and notices. Customers can add or delete subscriptions themselves, and have the option to password protect their accounts.

Paperwork Requirements

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501, *et seq.*), the information collection requirement associated with this final rule on generic label approval has been submitted for approval to OMB.

FSIS is expanding the circumstances in which FSIS will generically approve the labels of meat and poultry 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 sketch labels will need to be submitted and evaluated by FSIS.

This information collection, after it is approved by OMB, will be merged with 0583–0092, Marking, Labeling, and Packaging. The merged information collection will result in a net reduction of 34,971 burden hours because of the

increased use of generic labeling resulting in fewer label submissions to FSIS.

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.

Having proceeded with this rulemaking, the Agency is now able to accept the electronic submission of requests for the evaluation of claims or special statements, which will significantly streamline the approval process.

List of Subjects in 9 CFR Parts 317, 318, 320, 327, 331, 381, 412, and 424

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

For the reasons discussed in the preamble, FSIS is amending 9 CFR Chapter III, as follows:

PART 317—LABELING, MARKING DEVICES, AND CONTAINERS

■ 1. The authority citation for part 317 continues to read as follows:

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

§§ 317.4 and 317.5 [Removed and Reserved]

■ 2. Sections 317.4 and 317.5 are removed and reserved.

■ 3. In § 317.8, revise paragraph (b)(32)(ii) to read as follows:

§ 317.8 False or misleading labeling or practices generally; specific prohibitions and requirements for labels and containers.

* * * * *

(b) * * *

(32) * * *

(ii) Immediately adjacent to the calendar date there must be a phrase explaining the meaning of the date, in terms of ''packing'' date, ''sell by'' date, or ''use before'' date, with or without a further qualifying phrase, e.g., ''For Maximum Freshness'' or ''For Best Quality.''

* * * * *

PART 318—ENTRY INTO OFFICIAL ESTABLISHMENTS; REINSPECTION AND PREPARATION OF PRODUCTS

■ 4. The authority citation for part 318 continues to read as follows:

Authority: 7 U.S.C. 138, 450, 1901–1906; 21 U.S.C. 601–695; 7 CFR 2.18, 2.53.

■ 5. In § 318.4, revise paragraph (f) introductory text to read as follows:

§ 318.4 Preparation of products to be officially supervised; responsibilities of official establishments; plant operated quality control.

* * * * *

(f) *Labeling Logo.* Owners and operators of official establishments having a total plant quality control system approved under the provisions of paragraph (c) of this section may only use, as a part of any label, the following logo.

* * * * *

PART 320—RECORDS, REGISTRATION, AND REPORTS

■ 6. The authority citation for part 320 continues to read as follows:

Authority: 21 U.S.C. 601–695; 7 CFR 2.7, 2.18, 2.53.

■ 7. In § 320.1, revise paragraph (b)(11) to read as follows:

§ 320.1 Records required to be kept.

* * * * *

(b) * * *

(11) Records of labeling, product formulas, processing procedures, and any additional documentation needed to show that the labels are consistent with the Federal meat and poultry regulations and policies on labeling, as prescribed in § 412.1 of this chapter.

PART 327—IMPORTED PRODUCTS

■ 8. The authority citation for part 327 continues to read as follows:

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

■ 9. In § 327.14, revise paragraph (c) to read as follows:

§ 327.14 Marking of products and labeling of immediate containers thereof for importation.

* * * * *

(c) All marks and other labeling for use on or with immediate containers, as well as private brands on carcasses or parts of carcasses, must be approved by the Food Safety and Inspection Service in accordance with part 412 of this chapter before products bearing such marks, labeling, or brands will be entered into the United States. The marks of inspection of foreign systems embossed on metal containers or branded on carcasses or parts thereof need not be submitted to the Food Safety and Inspection Service for approval, and such marks of inspection put on stencils, box dies, labels, and brands may be used on such immediate containers as tierces, barrels, drums, boxes, crates, and large-size fiberboard containers of foreign products without such marks of inspection being submitted for approval, provided the markings made by such articles are applicable to the product and are not false or misleading.

PART 331—SPECIAL PROVISIONS FOR DESIGNATED STATES AND TERRITORIES; AND FOR DESIGNATION OF ESTABLISHMENTS WHICH ENDANGER PUBLIC HEALTH AND FOR SUCH DESIGNATED ESTABLISHMENTS

■ 10. The authority citation for part 331 is revised to read as follows:

Authority: 21 U.S.C. 601–695; 7 CFR 2.17, 2.53.

■ 11. Amend § 331.3 by revising paragraphs (e) introductory text, (e)(1), and (e)(3) to read as follows:

§ 331.3 States designated under paragraph 301(c) of the Act; application of regulations.

* * * * *

(e) Sections 316.7, 317.3, and 412.1 of this chapter apply to such establishments, except as provided in this paragraph (e).

(1) The operator of each such establishment will, prior to the inauguration of inspection, identify all labeling and marking devices in use, or proposed for use, (upon the date of inauguration of inspection) to the Front Line Supervisor of the circuit in which the establishment is located. Temporary approval, pending formal approval under §§ 316.7, 317.3, and 412.1 of this chapter, will be granted by the Front Line Supervisor for labeling and marking devices that he determines are neither false nor misleading, provided the official inspection legend bearing the official establishment number is applied to the principal display panel of each label, either by a mechanical printing device or a self-destructive pressure sensitive sticker, and provided the label shows the true product name, an accurate ingredient statement, the name and address of the manufacturer, packer, or distributor, and any other features required by section 1(n) of the Act.

* * * * *

(3) The operator of the official establishment shall promptly forward a copy of each item of labeling and a description of each marking device for which temporary approval has been granted by the Front Line Supervisor (showing any modifications required by the Front Line Supervisor) to the FSIS Labeling and Program Delivery Staff,

accompanied by the formula and details of preparation and packaging for each product. Within 90 days after inauguration of inspection, all labeling material and marking devices temporarily approved by the Front Line Supervisor must receive approval as required by §§ 316.7, 317.3, and 412.1 of this chapter, or their use must be discontinued.

* * * * *

PART 381—POULTRY PRODUCTS INSPECTION REGULATIONS

■ 12. The authority citation for part 381 continues to read as follows:

Authority: 7 U.S.C. 138f, 450, 1901–1906; 21 U.S.C. 451–470; 7 CFR 2.18, 2.53.

■ 13. Amend § 381.129 by revising paragraphs (b)(6)(i) and (c)(2) to read as follows:

§ 381.129 False or misleading labeling or containers.

* * * * *

(b) * * *

(6)(i) A raw poultry product whose internal temperature has ever been below 26 °F may not bear a label declaration of ''fresh.'' A raw poultry product bearing a label declaration of ''fresh'' but whose internal temperature has ever been below 26 °F is mislabeled. The temperature of individual packages of raw poultry product within an official establishment may deviate below the 26 °F standard by 1 degree (i.e., have a temperature of 25 °F) and still be labeled ''fresh.'' The temperature of individual packages of raw poultry product outside an official establishment may deviate below the 26 °F standard by 2 degrees (i.e., have a temperature of 24 °F) and still be labeled ''fresh.'' The average temperature of poultry product lots of each specific product type must be 26 °F. Product described in this paragraph is not subject to the freezing procedures required in § 381.66(f)(2) of this subchapter.

* * * * *

(c) * * *

(2) Immediately adjacent to the calendar date will be a phrase explaining the meaning of such date in terms of ''packing'' date, ''sell by'' date, or ''use before'' date, with or without a further qualifying phrase, e.g., ''For Maximum Freshness'' or ''For Best Quality.''

* * * * *

§§ 381.132 and 381.133 [Removed and Reserved]

■ 14. Sections 381.132 and 381.133 are removed and reserved.

■ 15. In § 381.145, revise paragraph (f) introductory text to read as follows:

§ 381.145 Poultry products and other articles entering or at official establishments; examination and other requirements.

* * * * *

(f) *Labeling Logo.* Owners and operators of official establishments having a total plant quality control system approved under the provisions of paragraph (c) of this section may only use, as a part of any label, the following logo.

* * * * *

■ 16. In § 381.175, revise paragraph (b)(6) to read as follows:

§ 381.175 Records required to be kept.

* * * * *

(b) * * *

(6) Records of all labeling, along with the product formula, processing procedures, and any additional documentation needed to support that the labels are consistent with the Federal meat and poultry regulations and policies on labeling, as prescribed in § 412.1 of this chapter.

■ 17. In § 381.205, revise paragraph (c) to read as follows:

§ 381.205 Labeling of immediate containers of poultry products offered for entry.

* * * * *

(c) All marks and other labeling for use on or with immediate containers must be approved for use by the Food Safety and Inspection Service in accordance with part 412 of this chapter before products bearing such marks and other labeling will be permitted for entry into the United States.

■ 18. In § 381.222, revise paragraph (d) to read as follows:

§ 381.222 States designated under paragraph 5(c) of the Act; application of regulations.

* * * * *

(d) Subpart N of this part shall apply to such establishments except as provided in this paragraph (d).

(1) The operator of each such establishment shall, prior to the inauguration of inspection, identify all labeling and marking devices in use, or proposed for use (upon the date of inauguration of inspection) to the Front Line Supervisor in which the establishment is located. Temporary approval, pending formal approval under § 412.1 of this chapter, will be granted by the Front Line Supervisor for labeling and marking devices that he determines are neither false nor misleading, provided the official inspection legend bearing the official establishment number is applied to the principal display panel of each label, either by a mechanical printing device or a self-destructive pressure sensitive sticker, and provided the label shows the true product name, an accurate ingredient statement, the name and address of the manufacturer, packer, or distributor, and any other features required by section 4(h) of the Act.

(2) The Front Line Supervisor will forward one copy of each item of labeling and a description of each marking device for which he has granted temporary approval to the FSIS Labeling and Program Delivery Staff and will retain one copy in a temporary approval file for the establishment.

(3) The operator of the official establishment shall promptly forward a copy of each item of labeling and a description of each marking device for which temporary approval has been granted by the Front Line Supervisor (showing any modifications required by the Front Line Supervisor) to the FSIS Labeling and Program Delivery Staff at headquarters, accompanied by the formula and details of preparation and packaging for each product. Within 90 days after inauguration of inspection, all labeling material and marking devices temporarily approved by the Front Line Supervisor must receive approval as required by § 412.1 or their use must be discontinued.

(4) The Front Line Supervisor will also review all shipping containers to ensure that they do not have any false or misleading labeling and are otherwise not misbranded. Modifications of unacceptable information on labeling material by the use of pressure sensitive tape of a type that cannot be removed without visible evidence of such removal, or by blocking out with an ink stamp will be authorized on a temporary basis to permit the maximum allowable use of all labeling materials on hand. All unacceptable labeling material which is not modified to comply with the requirements of the regulations must be destroyed or removed from the official establishment.

* * * * *

■ 19. Add part 412 to subchapter E to read as follows:

PART 412—LABEL APPROVAL

Sec.

412.1 Label approval.

412.2 Approval of generic labels.

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

§ 412.1 Label approval.

(a) No final label may be used on any product unless the label has been submitted for approval to the FSIS Labeling and Program Delivery Staff, accompanied by FSIS Form 7234–1, Application for Approval of Labels, Marking, and Devices, and approved by such staff, except for generically approved labels authorized for use in § 412.2. The management of the official establishment or establishment certified under a foreign inspection system, in accordance with parts 327 and 381, subpart T, must maintain a copy of all labels used, in accordance with parts 320 and 381, subpart Q, of this chapter. Such records must be made available to any duly authorized representative of the Secretary upon request.

(b) All labels required to be submitted for approval as set forth in paragraph (a) of this section will be submitted to the FSIS Labeling and Program Delivery Staff. A parent company for a corporation may submit only one label application for a product produced in other establishments that are owned by the corporation.

(c) The Food Safety and Inspection Service requires the submission of labeling applications for the following:

(1) Sketch labels as defined in paragraph (d) of this section for products which are produced under a religious exemption;

(2) Sketch labels for products for foreign commerce whose labels deviate from FSIS regulations, with the exception of printing labels in foreign language or printing labels that bear a statement of the quantity of contents in accordance with the usage of the country to which exported as described in § 317.7 and part 381, subpart M of this chapter.

(3) Special statements and claims as defined in paragraph (e) of this section and presented in the context of a final label.

(4) Requests for the temporary use of final labels as prescribed in paragraph (f) of this section.

(d) A ''sketch'' label is the concept of a label. It may be a printer's proof or equivalent that is sufficiently legible to clearly show all labeling features, size, and location. The Food Safety and Inspection Service will accept sketches that are hand drawn or computer generated, or other reasonable facsimiles that clearly reflect and project the final version of the label.

(e) ''Special statements and claims'' are claims, logos, trademarks, and other symbols on labels that are not defined in the Federal meat and poultry products inspection regulations or the Food Standards and Labeling Policy Book, (except for ''natural'' and negative claims (e.g., ''gluten free'')), health claims, ingredient and processing method claims (e.g., high-pressure processing), structure-function claims, claims regarding the raising of animals, organic claims, and instructional or disclaimer statements concerning pathogens (e.g., ''for cooking only'' or ''not tested for *E. coli* O157:H7''). Examples of logos and symbols include graphic representations of hearts and geographic landmarks. Special statements and claims do not include allergen statements (e.g., ''contains soy'') applied in accordance with the Food Allergen Labeling and Consumer Protection Act.

(f)(1) Temporary approval for the use of a final label that may be deemed deficient in some particular may be granted by the FSIS Labeling and Program Delivery Staff. Temporary approvals may be granted for a period not to exceed 180 calendar days, under the following conditions:

(i) The proposed label would not misrepresent the product;

(ii) The use of the label would not present any potential health, safety, or dietary problems to the consumer;

(iii) Denial of the request would create undue economic hardship; and

(iv) An unfair competitive advantage would not result from the granting of the temporary approval.

(2) Extensions of temporary approvals may also be granted by the FSIS Labeling and Program Delivery Staff provided that the applicant demonstrates that new circumstances, meeting the above criteria, have developed since the original temporary approval was granted.

§ 412.2 Approval of generic labels.

(a)(1) An official establishment, or an establishment certified under a foreign inspection system in accordance with part 327, or part 381, subpart T of this chapter, is authorized to use generically approved labels, as defined in paragraph (b) of this section, and thus is free to use such labels without submitting them to the Food Safety and Inspection Service for approval, provided the label, in accordance with this section, displays all mandatory features in a prominent manner in compliance with part 317 or part 381, and is not otherwise false or misleading in any particular.

(2) The Food Safety and Inspection Service will select samples of generically approved labels from the records maintained by official establishments and establishments certified under foreign inspection systems, in accordance with part 327 or part 381, subpart T, to determine compliance with label requirements. If the Agency finds that an establishment is using a false or misleading label, it will institute the proceedings prescribed in § 500.8 of this chapter to revoke the approval for the label.

(b) Generically approved labels are labels that bear all applicable mandatory labeling features (i.e., product name, safe 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. Labels that bear claims and statements that are defined in FSIS's regulations or the Food Standards and Labeling Policy Book (except for natural and negative claims), such as a statement that characterizes a product's nutrient content, such as ''low fat,'' has geographical significance, such as ''German Brand,'' or makes a country of origin statement on the label of any meat or poultry product ''covered commodity'',[1] and that comply with those regulations are also deemed to be generically approved by the Agency without being submitted for evaluation and approval. Allergen statements (e.g., ''contains soy'') applied in accordance with the Food Allergen Labeling and Consumer Protection Act are also deemed generically approved.

PART 424—PREPARATION AND PROCESSING PROCEDURES

■ 20. The authority citation for part 424 continues to read as follows:

Authority: 7 U.S.C. 450, 1901–1906; 21 U.S.C. 451–470, 601–695; 7 CFR 2.18, 2.53.

■ 21. In § 424.21, revise footnote 3 in the table in paragraph (c) to read as follows:

§ 424.21 Use of food ingredients and sources of radiation.

* * * * *

(c) * * *

[3] Provided that its use is functional and suitable for the product and it is permitted for use at the lowest level necessary to accomplish the desired technical effect as determined in specific cases prior to label approval under part 412 of this chapter.

* * * * *

■ 22. In § 424.22, revise paragraph (c)(4)(i) introductory text to read as follows:

§ 424.22 Certain other permitted uses.

* * * * *

(c) * * *

(4) * * *

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

(i) The labels on packages of meat food and poultry products irradiated in their entirety, in conformance with this section and with 21 CFR 179.26(a) and (b), must bear the logo shown at the end of this paragraph. Unless the word ''Irradiated'' is part of the product name, labels also must bear a statement such as ''Treated with radiation'' or ''Treated by irradiation.'' The logo must be placed in conjunction with the required statement, if the statement is used. The statement is not required to be more prominent than the declaration of ingredients required under § 317.2(c)(2) of this chapter.

* * * * *

Done in Washington, DC on: November 1, 2013.

Alfred V. Almanza,

Administrator.

[FR Doc. 2013–26639 Filed 11–6–13; 8:45 am]

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CONSUMER PRODUCT SAFETY COMMISSION

[Docket No. CPSC–2012–0035]

16 CFR Part 1500

Revocation of Certain Requirements Pertaining to Caps Intended for Use With Toy Guns and Toy Guns Not Intended for Use With Caps

AGENCY: Consumer Product Safety Commission.

ACTION: Final rule.

SUMMARY: Section 106 of the Consumer Product Safety Improvement Act of 2008 (CPSIA) deemed the provisions of ASTM International Standard F963, ''Standard Consumer Safety Specifications for Toy Safety'' (ASTM F963), to be consumer product safety standards issued by the U.S. Consumer Product Safety Commission (CPSC, Commission, or we). Among other things, ASTM F963 contains provisions regarding sound-producing toys. Existing CPSC regulations pertaining to caps intended for use with toy guns refer to obsolete equipment, but the ASTM F963 provisions for sound-producing toys allow the use of a broader array of more precise and more readily available test equipment for sound measurement. In addition, the ASTM standard requires fewer measurements and permits use of more automated equipment that would increase the efficiency of testing. Because the existing regulations are obsolete and have been superseded by the requirements of ASTM F963, the final rule revokes the existing regulations pertaining to caps intended for use with toy guns and toy guns not intended for use with caps. The final rule is unchanged from the rule as proposed in the notice of proposed rulemaking (NPR).

DATES: The rule is effective December 9, 2013.

FOR FURTHER INFORMATION CONTACT: Richard McCallion, Office of Hazard Identification and Reduction, Consumer Product Safety Commission, 5 Research Place, Rockville, MD 20850; telephone: (301) 987–2222; email: *rmccallion@cpsc.gov*.

SUPPLEMENTARY INFORMATION:

A. Revocation of Certain Regulations Pertaining to Toy Caps and Toy Guns Not Intended for Use With Caps

On June 25, 2012, the Commission published in the **Federal Register** an NPR to revoke certain regulations pertaining to toy caps and toy guns not intended for use with caps. 77 FR 77834. The comment period for the NPR closed on August 24, 2012. The Commission received no comments on the NPR.

The regulations pertaining to caps intended for use with toys guns in 16 CFR 1500.18(a)(5), 1500.47, and 1500.86(a)(6) were originally promulgated by the U.S. Food and Drug Administration (FDA). In September 1973, the Federal Hazardous Substances Act (FHSA) and the statute's implementing regulations were transferred from the FDA to the CPSC. *See* 38 FR 27012 (September 27, 1973). One of the regulations transferred to CPSC included a ban on caps intended for use with toy guns and toy guns not intended for use with caps ''if such caps when so used or such toy guns produce impulse-type sound at a peak pressure level at or above 138 decibels. . . .'' *See* 16 CFR 1500.18(a)(5). Another regulation transferred from FDA to CPSC, 16 CFR 1500.86(a)(6), exempts toy caps that produce peak sound levels of 138 to 158 decibels if: The packaging material contains a warning regarding proper use, the manufacturer notifies CPSC, and the manufacturer participates in a program to develop toy caps that produce peak pressure levels below 138 decibels. Manufacturers participating in this program are required to provide a status report to CPSC on their progress every three months. We are revoking this exemption because there are currently no manufacturers participating in this program.

Additionally, a third transferred regulation, 16 CFR 1500.47, provides the test method for determining the sound pressure level produced by toy caps and toy guns. The method specifies the use of certain equipment, such as a microphone, preamplifier, and two types of oscilloscopes with specific response and calibration ranges. This regulation also addresses the manner in which peak sound pressure levels are measured.

Section 106 of the CPSIA mandated that the provisions of ASTM International Standard F963, ''Standard Consumer Safety Specification for Toy Safety,'' be considered consumer product safety standards issued by the Commission under section 9 of the Consumer Product Safety Act (CPSA). References to ASTM F963 in this **Federal Register** notice are to version ASTM F963–11, which became effective on June 12, 2012. Section 4.5 of ASTM F963 establishes requirements for ''sound-producing toys,'' and section 8.19 of ASTM F963 establishes ''Tests for Toys Which Produce Noise.'' In general, the ASTM F963 requirements for sound-producing toys are more stringent than 16 CFR 1500.18(a)(5) and 1500.47. For example, section 4.5.1.5 of ASTM F963 states that the peak sound pressure level of impulsive sounds produced by a toy using percussion caps or other explosive action ''shall not exceed 125'' decibels at 50 centimeters, whereas, 16 CFR 1500.18(a)(5) imposes a ban at or above 138 decibels at 25 centimeters. As another example, section 8.19.2.4 of ASTM F963 specifies a weighted scale based on human hearing damage from the type of impulse noise being generated by the toy, whereas, 16 CFR 1500.47 specifies an unweighted scale for measuring pressure level generated by impulse-type sound. Additionally, the ASTM F963 test method specifies the use of modern equipment (microphones meeting a particular specification), whereas, 16 CFR 1500.47 specifies the use of a microphone, a preamplifier (if required), and an oscilloscope. The equipment specifications in 16 CFR 1500.47 have never been updated.

Therefore, because section 106 of the CPSIA mandates the provisions of ASTM F963 to be consumer product safety standards, and because we believe that the provisions of ASTM F963, with respect to caps intended for use with toy guns, are more stringent than 16 CFR 1500.18(a)(5), the final rule revokes 16 CFR 1500.18(a)(5). Similarly, because ASTM F963 establishes a test method for toys that produce sound, and because our existing regulation refers to obsolete or unnecessary test equipment, the final rule revokes 16 CFR 1500.47. Finally, because the final rule revokes 16 CFR 1500.18(a)(5), we are also revoking the exemptions from