(b) * * *

(1) Multiplying the insured acreage for each type, if applicable, by its respective production guarantee;

(2) Multiplying the result of 11(b)(1) by the respective price election for each type, if applicable;

(3) Totaling the results of section 11(b)(2) if there is more than one type;

(4) Multiplying the total production to count (see section 11(c)), of each type, if applicable, by its respective price election;

(5) Totaling the results of section 11(b)(4) if there is more than one type;

(6) Subtracting the result of section 11(b)(4) from the result of section 11(b)(2) if there is only one type or subtracting the result of section 11(b)(5) from the result of section 11(b)(3) if there is more than one type; and

(7) Multiplying the result of section 11(b)(6) by your share.

For example:

You select 75 percent coverage level, 100 percent of the price election, and have a 100 percent share in 50.0 acres of type A prunes in the unit. The production guarantee is 2.5 tons per acre and your price election is $630.00 per ton. You harvest 10.0 tons. Your indemnity would be calculated as follows:

(1) 50.0 acres × 2.5 tons = 125.0 ton production guarantee;

(2) 125.0 ton guarantee × $630.00 price election = $78,750 value of production guarantee;

(4) 10.0 tons × $630.00 price election = $6,300 value of production to count;

(6) $78,750 − $6,300 = $72,450 loss; and

(7) $72,450 × 1.000 share = $72,450 indemnity payment.

In addition to the information in the first example, you have an additional 50.0 acres of type B prunes with 100 percent share in the same unit. The production guarantee is 2.0 tons per acre and the price election is $550.00 per ton. You harvest 5.0 tons. Your total indemnity for both types A and B would be calculated as follows:

(1) 50.0 acres × 2.5 tons = 125.0 ton production guarantee for type A and 50.0 acres × 2.0 tons = 100.0 ton production guarantee for type B;

(2) 125.0 ton guarantee × $630.00 price election = $78,750 value of production guarantee for type A and 100.0 ton guarantee × $550.00 price election = $55,000 value production guarantee for type B;

(3) $78,750 + $55,000 = $133,750 total value of production guarantee;

(4) 10.0 tons × $630.00 price election = $6,300 value of production to count for type A and 5.0 tons × $550.00 price election = $2,750 value of production to count for type B;

(5) $6,300 + $2,750 = $9,050 total value of production to count;

(6) $133,750 − $9,050 = $124,700 loss; and

(7) $124,700 loss × 1.000 share = $124,700 indemnity payment.

(c) The total production to count (in tons) from all insurable acreage on the unit will include all harvested and appraised production of natural condition prunes that meet the definition of standard prunes and any production that is harvested and intended for use as fresh fruit. The total production to count will include:

* * * * *

Signed in Washington, DC, on November 22, 2011.

William J. Murphy,

Manager, Federal Crop Insurance Corporation.

[FR Doc. 2011–31083 Filed 12–2–11; 8:45 am]

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DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Parts 316, 317, 320, 331, 354, 355, 381, 412, and 424

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

RIN 0583–AC59

Prior Label Approval System: Generic Label Approval

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: The Food Safety and Inspection Service (FSIS) is proposing 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 proposing to combine the regulations that provide for the approval of labels for meat products and poultry products into a new CFR part.

DATES: Comments must be received on or before February 3, 2012.

ADDRESSES: FSIS invites interested persons to submit comments on this proposed rule. Comments may be submitted by either of the following methods:

- *Federal eRulemaking Portal:* This Web site provides the ability to type short comments directly into the comment field on this Web page or attach a file for lengthier comments. Go to *http://www.regulations.gov.* Follow the online instructions at that site for submitting comments.
- *Mail, including diskettes or CD–ROMs, and hand- or courier-delivered items:* Send to U.S. Department of Agriculture (USDA), FSIS, OPPD, RIMD, Docket Room, Patriots Plaza 3, 1400 Independence Avenue SW., Mailstop 3782, 8–163A, Washington, DC 20250–3700.

Instructions: All items submitted by mail or electronic mail must include the Agency name and docket number FSIS–2005–0016. Comments received in response to this docket will be made available for public inspection and posted without change, including any personal information provided, to *http://www.regulations.gov.*

Docket: For access to background documents or comments received, go to the FSIS Docket Room at the address listed above between 8 a.m. and 4:30 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Jeff Canavan, Food Technologist, Labeling and Program Delivery Division, Office of Policy and Program Development, Food Safety and Inspection Service, U.S. Department of Agriculture, Beltsville, MD 20705–5273; Telephone (301) 504–0879; Fax (301) 504–0872.

SUPPLEMENTARY INFORMATION:

Background

Introduction

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. Section 2 of the FMIA (21 U.S.C. 602) and section 2 of the PPIA (21 U.S.C. 451) state that unwholesome, adulterated, or misbranded meat or meat food products and poultry or poultry food products are injurious to the public welfare; destroy markets for wholesome, not adulterated, and properly marked, labeled, and packaged products; and result in sundry losses to producers and processors of meat and poultry products, as well as injury to consumers. Therefore, Congress has granted to the Secretary broad authority to protect consumers' health and welfare.

Section 7(d) of the FMIA (21 U.S.C. 607(d)) states: ''No article subject to this title shall be sold or offered for sale by any person, firm, or corporation, in commerce, under any name or other marking or labeling which is false or misleading, or in any container of a

misleading form or size, but established trade names and other marking and labeling and containers which are not false or misleading and which are approved by the Secretary are permitted.'' The PPIA contains similar language in section 8(c) (21 U.S.C. 457(c)).

The Department's longstanding interpretation of these provisions is that they require that the Secretary of Agriculture or his or her representative approve all labels to be 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.

These prior label approval provisions also apply to establishments that do business solely within designated States (see 21 U.S.C. 451 and 602). A State is designated if it does not have, or is not effectively enforcing, with respect to establishments within its jurisdiction at which livestock or poultry are slaughtered, or at which their carcasses or products are prepared for use as human food solely for distribution within such State, requirements at least equal to those contained in titles I and IV of the FMIA and specified sections of the PPIA (21 U.S.C. 454(c)(1) and 661(c)(1)). Once a State is designated, the inspection requirements of the FMIA and PPIA apply to establishments that slaughter livestock and poultry, and prepare or process meat or poultry products, solely for distribution within the State.

Current Label Regulations

There are up to eight features required on most meat and poultry labels. The mandatory features are designed to ensure that meat and poultry products are accurately and truthfully labeled, and that they provide the necessary product information for consumers to make an informed purchasing decision. These required features of meat and poultry product labels must appear on the immediate containers of domestic products (9 CFR part 317, subpart A, and 9 CFR part 381, subpart N) and imported products (9 CFR part 327 and 9 CFR part 381, subpart T). The meat inspection regulations define an ''immediate container'' as the receptacle or other covering in which any product is directly contained or wholly or partially enclosed (9 CFR 301.2). The poultry products inspection regulations define an ''immediate container'' as any consumer package or any other container in which poultry products, not consumer packaged, are packed (9 CFR 381.1(b)).

The required features include: (1) The standardized, common or usual, or descriptive name, of the product (9 CFR 317.2(e) and 381.117); (2) an ingredients statement containing the common or usual name of each ingredient of the product listed in descending order of predominance (9 CFR 317.2(f) and 381.118); (3) the name and place of business of the manufacturer, packer, or distributor (9 CFR 317.2(g) and 381.122); (4) an accurate statement of the net quantity of contents (9 CFR 317.2(h) and 381.121); (5) the inspection legend, including the number of the official establishment (9 CFR 317.2(i) and 381.123); (6) a safe handling statement if the product is perishable; *e.g.,* ''Keep Frozen'' or ''Keep Refrigerated'' (9 CFR 317.2(k) and 381.125(a)); (7) nutrition labeling for applicable meat and poultry products; [1] and (8) safe handling instructions if the meat or poultry component of the product is not ready-to-eat (9 CFR 317.2(l) and 381.125(b)). In addition, imported meat and poultry products must bear the country of origin under the product name in accordance with 9 CFR 327.14(b)(1) and 381.205(a).

These mandatory features must be prominently and informatively displayed on the principal display panel, the information panel, or other surface of the product label. The first six features described above, including the labeling of country of origin for imported products in accordance with 9 CFR 327.14 and 381.205, have been required by the meat and poultry inspection regulations for decades. FSIS implemented regulations that require the nutrition labeling of cooked or heat-treated multi-ingredient meat and poultry products and the display of safe handling instructions in 1993 and 1994, respectively. Therefore, industry has had a significant amount of experience complying with the regulations for all required label features.

The regulations contain other provisions to ensure that no statement, word, picture, design, or device that is false or misleading in any particular, or that conveys any false impression, or that gives any false indication of origin, identity, or quality, appears in any marking or other labeling (9 CFR 317.8 and 381.129). Pursuant to the authority contained in section 7(e) of the FMIA (21 U.S.C. 607(e)) and section 8(d) of the PPIA (21 U.S.C. 457(d)), the Administrator, FSIS, may withhold the use of any marking or labeling that is false or misleading, within the meaning of the FMIA or the PPIA and the implementing regulations.

Current Prior Label Approval System and the Procedures the Agency Employs To Implement It

In order 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.

Meat and poultry establishments and certified foreign establishments submit sketch labels accompanied by FSIS Form 7234–1 (01/08/2008), ''Application for Approval of Labels, Marking or Device,'' to the Agency for evaluation. In addition to the required label information, any special claims or statements that the establishment intends to make (*e.g.,* quality claims, animal production raising claims, product origin claims, or nutrient content claims) must be included on the label, along with documentation supporting the claim. The label application must contain the basic information about the establishment and the product, including:

1. Establishment number;
2. Product name;
3. Product formulation;
4. Processing procedures and handling information;
4. Firm name and address;
5. Total available labeling space of the container;
6. Size of the principal display panel; and
7. The Hazard Analysis and Critical Control Point category under which the establishment is producing the meat or poultry product.

All such information is evaluated by a technical labeling policy expert in FSIS, who is responsible for verifying that sketch labels comply with the applicable requirements. A ''final label''

[1] Nutrition labeling is required for heat-treated and multi-ingredient meat and poultry products. New nutrition labeling requirements for ground or chopped meat and poultry products will take effect January 1, 2012 (75 FR 82148, Dec. 29, 2010).

does not have to be submitted to the Agency for evaluation and approval. Since July 1, 1996, meat and poultry establishments and certified foreign establishments have been responsible for ensuring that the labels that they apply to their meat and poultry products comply with Federal regulations. All labels are subject to FSIS verification for compliance with Agency regulations to ensure that they are accurate, truthful, and not misleading. The management of the official establishment or establishment certified under a foreign inspection system must maintain a copy of all labels and labeling used, along with the product formulation and processing procedures. Such records must be made available to any duly authorized representative of the Secretary upon request.

Generic Label Approval

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.

In 1983, FSIS estimated that it evaluated approximately 130,000 label submissions a year. That year, the Agency promulgated regulations that granted limited label approval authority to the Inspector-In-Charge (IIC) at official establishments and provided generic approval to limited types of labels (*e.g.,* labels for raw, single ingredient meat and poultry products) (48 FR 11410, March 18, 1983). This generic approval did not extend to the labels of the products of certified foreign establishments. The rulemaking was intended to reduce the number of labels and other labeling submitted for evaluation by FSIS and to lessen the paperwork burden on official establishments. The general goal was to improve the efficiency of the label approval system by streamlining the review process.

Even with the changes made by the rule, however, the number of labels and other labeling submitted to the Agency continued to grow. During fiscal year 1991, the Agency processed approximately 167,500 labels. Of these, 87,500 were final labels, and 60,000 were sketch labels that were approved. Approximately 20,000 labels were not approved. The Agency did not maintain records on the number of temporary approvals or other types of labeling (*e.g.,* insert labeling applied at retail) that were evaluated and acted upon by the Agency.

On March 25, 1992, FSIS published an Advance Notice of Proposed Rulemaking (ANPRM) (57 FR 10300, Mar. 25, 1992) on the Agency's prior label approval system. The ANPRM presented two options for making additional changes to the prior label approval system: (1) Revise the system by significantly reducing the scope of review through expansion of the categories of generically approved labels and replacing the general requirement of FSIS approval of sketch and final labels with one for sketch labels only; or (2) replace the system with a system in which all labels are generically approved and used without prior submission to FSIS for evaluation and approval.

On November 23, 1993, FSIS published a proposed rule (58 FR 62014) to amend the Federal meat and poultry products inspection regulations by expanding the types of generically approved labels authorized for use on meat and poultry products by official establishments in the United States and foreign establishments certified under foreign inspection systems. The rule was proposed as a first step in the gradual streamlining and modernization of the label approval system. In the proposal, the Agency sought comment on a long-term plan to implement a system in which all labels are generically approved. After reviewing the comments received in response to the proposed rule, and in light of FSIS's ongoing reassessment of its labeling policies, FSIS decided to proceed with a gradual streamlining and modernization of the label approval system.

On December 29, 1995 (effective July 1, 1996), FSIS published a final rule titled ''Prior Label Approval System'' (60 FR 67334). The implementing regulations, 9 CFR 317.5 and 381.133, outline the types of labels and modifications to labels that are deemed to be approved without submission to FSIS, provided that the label displays all mandatory label features in conformance with applicable Federal regulations.

FSIS permits official establishments and foreign establishments certified by officials of foreign inspection systems to use the following generically approved labeling without the submission of sketches for evaluation and approval by FSIS:

1. Labels for a product that has a standard of identity or composition as specified in 9 CFR part 319 or part 381, subpart P, or is consistent with an informal standard that the Agency has laid out in the Food Standards and Labeling Policy Book; does not bear any special claims, such as quality claims, nutrient content claims, health claims, negative claims, geographical origin claims (except as provided by 9 CFR 317.5(b)(9)(xxv) and 381.133 (b)(9)(xxviii)), or guarantees; and is not a product that is not domestic and labeled in a foreign language;

2. Labels for raw, single-ingredient products (such as beef steak, lamb chops, chicken legs, or turkey breasts) that do not bear special claims, such as quality claims, nutrient content claims, health claims, negative claims, geographical origin claims, or guarantees, and are not products that are not domestic and labeled with a foreign language;

3. Labels for containers of meat and meat food products and poultry products sold under contract specifications to Federal Government agencies when such product is not offered for sale to the general public, provided that the contract specifications include specific requirements with respect to labeling that is made available to the IIC;

4. Labels for shipping containers that contain fully labeled immediate containers, provided that the outside container's labels comply with 9 CFR 316.13 or 381.127;

5. Labels for products not intended for human food, provided that they comply with 9 CFR part 325 or 9 CFR 381.152(c) and 381.193; and labels for poultry heads and feet for export for processing as human food if they comply with 9 CFR 381.190(b);

6. Meat and poultry inspection legends that comply with 9 CFR parts 312 and 316, and 9 CFR part 381, subpart M;

7. Inserts, tags, liners, posters, and like devices containing printed or graphic matter and for use on, or to be placed within, containers and coverings of products, provided such devices contain no reference to product and bear no misleading feature;

8. Labels for consumer test products not intended for sale; and

9. Labels that were previously approved by FSIS as sketch labels, and the final labels were prepared without modification or with the following modifications:

a. All features of the label are proportionately enlarged or reduced, provided that all minimum size requirements specified in applicable

regulations are met, and the label is legible;

b. A substitution of any unit of measurement with its abbreviation or the substitution of any abbreviation with its unit of measurement, *e.g.,* ''lb.'' for ''pound,'' or ''oz.'' for ''ounce,'' or of the word ''pound'' for ''lb.'' or ''ounce'' for ''oz.'';

c. A master or stock label that has been approved from which the name and address of the distributor are omitted, and such name and address are applied before being used (in such case, the words ''prepared for'' or similar statement must be shown together with the blank space reserved for the insertion of the name and address when such labels are offered for approval);

d. Wrappers or other covers bearing pictorial designs, emblematic designs, or illustrations, *e.g.,* floral arrangements, illustrations of animals, fireworks, etc., are used with approved labels (the use of such designs will not make necessary the application of labeling not otherwise required);

e. A change in the language or the arrangement of directions pertaining to the opening of containers or the serving of the product;

f. The addition, deletion, or amendment of a dated or undated coupon, a cents-off statement, cooking instructions, packer product code information, or UPC product code information;

g. Any change in the name or address of the packer, manufacturer, or distributor that appears in the signature line;

h. Any change in net weight, provided the size of the net weight statement complies with 9 CFR 317.2 or 381.121;

i. The addition, deletion, or amendment of recipe suggestions for the product;

j. Any change in punctuation;

k. Newly assigned or revised establishment numbers for a particular establishment for which use of the label has been approved by FSIS;

l. The addition or deletion of open dating information;

m. A change in the type of packaging material on which the label is printed;

n. Brand name changes, provided that there are no design changes, the brand name does not use a term that connotes quality or other product characteristics, the brand name has no geographic significance, and the brand name does not affect the name of the product;

o. The deletion of the word ''new'' on new product labels;

p. The addition, deletion, or amendment of special handling statements, such as ''Keep Refrigerated'' or ''Keep Frozen,'' provided that the change is consistent with 9 CFR 317.2(k) or 381.125(a);

q. The addition of safe handling instructions as required by 9 CFR 317.2(l) and 381.125(b);

r. Changes reflecting a change in the quantity of an ingredient shown in the formula without a change in the order of predominance shown on the label, provided that the change in quantity of ingredients complies with any minimum or maximum limits for the use of such ingredients prescribed in 9 CFR parts 318, 319, 424, subpart C, and 381, subpart P;

s. Changes in the color of the label, provided that sufficient contrast and legibility remain;

t. The addition, deletion, or substitution of the official USDA grade shield on labels of poultry products;

u. A change in the product vignette, provided the change does not affect mandatory label information or misrepresent the content of the package;

v. A change in an establishment number by a corporation or parent company for an establishment under its ownership;

w. Changes in nutrition labeling that only involve quantitative adjustments to the nutrition labeling information, except for serving sizes, provided the nutrition labeling information maintains its accuracy and consistency;

x. Deletion of any claim, and the deletion of non-mandatory features or non-mandatory information;

y. The addition or deletion of a direct translation of the English language into a foreign language for products marked ''for export only''; and

z. A country of origin statement on any product label described in 9 CFR 317.8(b)(40) and 381.129(f) that complies with the requirements in these paragraphs.

With the implementation of the 1995 final rule on July 1, 1996, FSIS transferred the responsibility for maintaining labeling records from IICs to official establishments in the United States and to foreign establishments certified by officials of a foreign inspection system. Each record must include a copy of the labeling, the product formulation, and processing procedures (9 CFR 320.1(b)(11)). This transfer of responsibility was done to be consistent with the record keeping requirements of other production related areas, *e.g.,* Sanitation (9 CFR 416.16) and Hazard Analysis and Critical Control Point (HACCP) Systems (9 CFR 417.5). For example, establishments are required to maintain copies of their HACCP plan, hazard analysis, records documenting the monitoring of critical control points, and sanitation operating procedures. These records must be made available to FSIS personnel upon request. Establishments are required to maintain records for product formulation and labeling similar to HACCP and Sanitation Standard Operating Procedure (SOP) records because establishments are responsible for ensuring the accuracy of all final labels applied to product.

To facilitate Agency verification of compliance with regulatory labeling requirements, FSIS requires that establishments make labeling records available to any authorized USDA official upon request (9 CFR 320.4). The Agency published FSIS Directive 7221.1, Amendment 1, titled ''Prior Labeling Approval,'' on August 19, 1996, to provide instructions to Federal inspectors on their responsibilities in verifying that the modifications to the FSIS food labeling prior approval program regulations were implemented effectively and without disruption of the inspection process.

As part of the 1995 final rule, FSIS stated that it intended to proceed with the gradual streamlining and modernization of the prior label approval system. FSIS anticipated making additional changes after it completed an assessment of the modified system.

FSIS announced that it would sample labels applied by establishments under the generic label approval regulations to assess compliance with the FMIA and the PPIA (9 CFR 317.5(a)(2) and 381.133(a)(2)). To effect this sampling, the Agency issued FSIS Directive 7221.1, Amendment 1, which instituted a nationally directed surveillance plan. Following implementation of the surveillance plan, FSIS assessed whether establishments were applying the generic label regulations correctly. The Agency brought label discrepancies to the attention of establishments for correction when it found them.

The Agency has used its surveillance to assess compliance trends and to determine whether any new labeling regulations or guidance materials are needed. FSIS assembled a taskforce of employees to: (1) Develop criteria and methods to select labels for sampling; (2) develop the appropriate compliance activity to respond to labeling errors; (3) develop tracking and reporting systems; and (4) design and implement a survey of the effects of the limited generic approvals.

The results of a survey [2] showed that 685 of the 1,107 establishments

[2] Generic Label Audit System Project (1997–1998).

operating at the time of the survey (193 establishments that were selected to be surveyed were no longer operating) used generically approved labels. Of the 1,513 labels that inspection program personnel submitted to FSIS headquarters, 538 were in compliance with all Federal regulations and policies, 896 had minor labeling errors (for example, insufficient spacing around the declaration of net weight or an error in the name of the manufacturer, packer, or distributor) that were not of public health or economic significance, and 79 had labeling errors that could not be granted a temporary approval without modification (*e.g.,* an incomplete product name). Sections 317.4(f) and 381.132(f) of Title 9 of the CFR provide for the temporary use of final labels that may be deficient under the following conditions: (1) The product label does not misrepresent the product; (2) the use of the label does not present any potential health, safety, or dietary problems to the consumer; (3) denial of use would create an undue economic hardship; and (4) an unfair competitive advantage would not result from the granting of the temporary approval.

Survey Conclusions

Although 79 of the 1,513 labels that were surveyed had deficiencies that could not be granted temporary approval without modification (*e.g.,* through the use of pressure sensitive stickers to correct label features not in compliance with Federal regulations), FSIS concluded that the survey showed that the great majority of establishments surveyed could effectively use generically approved labels without first submitting sketch labels to FSIS for evaluation and approval. Furthermore, the Agency concluded that the results showed enough acceptable compliance by establishments for FSIS to confirm that the gradual implementation of generic label provisions under the 1995 final rule was effective.

Trends Toward Increased Guidance and Transparency of Labeling Policies for Industry

In the years since the survey was conducted and the last major change to the generic label regulations was made, the Agency has emphasized the importance of providing guidance and outreach to industry, trade groups, and consumers. FSIS has posted most of its labeling policy information on the Agency's Web site to increase accessibility to industry, particularly small businesses. The Labeling and Consumer Protection Reference Center was launched as a Web page in February 1999. The Web page includes a PowerPoint presentation titled ''Labeling 101,'' which is used by the Agency as a teaching tool at workshops on meat and poultry label requirements. In addition, FSIS has on its Web page guidance on animal production claims and on nutrition labeling, a glossary of meat and poultry labeling terms, the Food Standards and Labeling Policy Book, and questions and answers on various topics, such as irradiation and the labeling of ingredients. The Web page also includes FSIS Form 7234–1, Application for Approval of Labels, Marking and Device, and detailed instructions to assist establishments in preparing label applications for submission to FSIS. In addition, the Agency's labeling policy Web page contains a guidebook that provides information on FSIS labeling requirements, including generic approval. Due to these efforts, and because no other evidence has been submitted to FSIS to suggest that generically approved labeling cannot be successfully applied, FSIS has concluded that expanding the types of labeling that is generically approved is appropriate at this time.

Proposed Rule

The provisions of the generic label regulations appear to be comprehensive. However, in practical application, they are restrictive regarding the types of labels and labeling changes that are considered by the Agency to be approved without submitting such labeling to the Agency. For example, the label for a non-standardized product, such as a pepperoni pizza (bearing no special statements or claims) that was sketch approved by FSIS would need to be resubmitted for sketch approval if the establishment makes a minor formula change that affects the order of predominance in the ingredients statement. This need to resubmit exists because the generic label regulations only provide for changes to the product formula for non-standardized meat or poultry products that have been sketch approved if the order of predominance in the ingredients statement does not change. Consequently, the current label regulations require industry to submit for approval a significant amount of labeling that the Agency believes could successfully be generically approved. Expanding the types of labels that can be generically approved would lessen the burden on industry to submit labels to the Agency, while allowing the Agency to better focus on, and direct its resources to, other consumer protection and food safety activities.

FSIS is proposing to amend the meat and poultry products inspection regulations (9 CFR 317.5 and 381.133) to expand the circumstances in which the labels of meat and poultry products will be deemed to be generically approved by FSIS. If adopted, the new generic label regulations for meat and poultry will be placed in a new part 412 in Title 9. The Agency is proposing 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 part 412. This proposal, if adopted, will modernize the regulations by expanding the types of labels that FSIS considers generically approved without prior submission to the Agency. This rulemaking will also streamline the regulations by placing all the label approval regulations for meat and poultry products in one part in Title 9.

Under the proposed rule, establishments that apply generically approved labels without prior submission to the Agency will have the responsibility of ensuring that all basic required label features (*i.e.,* product name, safe handling statement, ingredients statement, address line, net weight, legend, safe handling instructions, nutrition labeling for multi-ingredient products, as well as the country of origin and mark of inspection of the foreign system for imported products) appear on their meat or poultry product labels in accordance with Federal regulations.

If this proposal is adopted, FSIS will require establishments to submit for evaluation only certain types of labeling, *e.g.,* labels for temporary approval, labels for products produced under religious exemption, labels for export with labeling deviations, and claims and special statements intended for use on labels. FSIS will continue to require the submission of such labels and special statements and claims because they are more likely to present significant policy issues that have health or economic significance. Examples of labeling that will need to be submitted for evaluation and approval before use if this proposal is adopted 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 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 regarding meat and poultry production practices; (4) claims that are undefined in FSIS regulations, such as ''gluten free;'' and (5) instructional or disclaimer statements concerning pathogens, *e.g.,* ''for cooking only'' or ''not tested for *E. coli* O157:H7;'' and (6) statements that identify a product as ''natural.'' A special statement or claim may be submitted to the Agency for approval in the context of a final label; however, FSIS will not evaluate the mandatory features (*e.g.,* handling statement and net weight) that are generically approved by the Agency. FSIS will only evaluate the special statement or claim that is presented on the label.

Under the proposal, 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. Similarly, if this proposal is adopted, 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 as a special statement or claim that requires sketch approval. The application of statements of this type are clearly prescribed in an FSIS compliance policy guide (*http://www.fsis.usda.gov/Regulations_&_Policies/Labeling_Allergens/index.asp*).

Through its prior label approval system, FSIS is aware that most establishments are voluntarily applying allergen statements to meat and poultry product labels in accordance with the Agency's compliance policy guide on the use of statements of this type.[3] FSIS plans to continue to monitor the application of allergen statements, but as long as the Agency continues to observe the widespread application of allergen statements on a voluntary basis, FSIS 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.

The proposed rule will affect several other sections in the meat and poultry inspection regulations that reference label approval or generically approved labels. 9 CFR 317.8(b)(32)(ii) requires the submission of labels bearing calendar dates, *e.g.,* ''sell by date.'' FSIS is proposing to amend this section by removing the reference to 9 CFR 317.4 for submitting labels for approval because FSIS no longer believes that labels with these types of phrases need to be submitted before use. The use of phrases relating to calendar dates is prescribed in FSIS regulations, and industry has been applying these types of labeling statements for years.

FSIS is proposing to revise the recordkeeping requirements for product labels, formulation, and processing procedures that are described in 9 CFR 320.1(b)(11) by removing the references to 9 CFR 317.4 and 317.5 and replacing them with a reference to the new label approval regulations for meat and poultry found in 9 CFR part 412.

9 CFR 327.14(c) in FSIS's regulations on meat imports references label approval by FSIS in accordance with 9 CFR part 317. FSIS is proposing to revise 9 CFR 327.14(c) to reference the new label approval regulations in 9 CFR part 412.

FSIS is proposing to remove the reference to 9 CFR 317.4 in 9 CFR 331.3(e) and to replace it with a reference to 9 CFR part 412. The Agency is also proposing replace the outdated references to the ''Labels and Packaging Staff, Meat and Poultry Inspection'' in these regulations with ''FSIS labeling program at headquarters.''

In regard to the poultry label regulations and the use of the term ''fresh,'' FSIS is proposing to amend 9 CFR 381.129(b)(6)(i) to remove the reference to the current generic label regulations. Because the requirements for the use of the term ''fresh'' are prescribed in FSIS's regulations, and the term has been used by industry for a number of years, FSIS does not consider it any longer to be a special statement or claim. Therefore, under the proposed rule, establishments will be able to use the term on labels without submitting the labels for evaluation, provided the use of this term is consistent with the provisions of 9 CFR 381.129(b)(6)(i).

Similar to the meat inspection regulations, 9 CFR 381.129(c)(2) requires the approval of phrases with regard to calendar dates on poultry products. FSIS is proposing to amend this regulation by removing the reference to 9 CFR 381.132 for label approval because FSIS considers it no longer necessary to require pre-market approval of the labels on which these types of phrases appear. The use of phrases relating to calendar dates is prescribed in FSIS poultry regulations, and FSIS published several years ago a comprehensive set of guidance material on poultry dating (*http://www.fsis.usda.gov/PDF/Labeling_Guide_on_Poultry_Food_Dating.pdf*). Thus, ample guidance exists for manufacturers to ensure that the labels on which such information is placed are truthful and not misleading without the need to submit such labels to FSIS first for pre-market evaluation.

FSIS is proposing to eliminate the requirement that any label bearing the USDA approved quality control system logo, and any wording or explanation with respect to the logo, be approved. The logo is illustrated clearly in the regulations, and its use is prescribed as well. As such, FSIS does not believe that labels bearing the logo need to be submitted for approval. If this proposal is adopted, 9 CFR 318.4(f) and 381.145(f) will be amended to remove the references to ''parts 316 and 317 of this chapter'' and ''subparts M and N,'' respectively.

FSIS is proposing to revise the recordkeeping requirements for product labels, formulation, and processing procedures described in 9 CFR 381.175(b)(6) to remove the references to 9 CFR 381.132 and 381.133. These references will be replaced with a reference to the new label approval regulations found in 9 CFR part 412.

For the same reason, FSIS is proposing to replace the references to 9 CFR 381.132 and 381.133, which discuss the approval of marks and other labeling for use on immediate containers of imported products, in 9 CFR 381.205(c) with a reference to 9 CFR part 412.

The Agency is also proposing to amend 9 CFR 381.222(d)(1) to remove the reference to 9 CFR 381.132 for label approval and to replace it with a reference to 9 CFR part 412. As with 9 CFR 331.3(e) and 331.3(e)(1), the Agency is proposing to replace the outdated references to the ''Labels and Packaging Staff, Meat and Poultry Inspection'' in 9 CFR 381.222(d)(2) and (3) with one to the ''FSIS labeling program at headquarters.''

In regard to other FSIS regulations, FSIS is proposing to amend footnote 3 in the table of approved substances (9 CFR 424.21(c)) to replace the old references for label approval to 9 CFR 317.4 and 381.32 (which should have actually been 9 CFR 381.132) with a reference to 9 CFR part 412.

Finally, FSIS is proposing to amend 9 CFR 424.22(c)(4), which discusses the need for the approval of labels of irradiated meat and poultry products, by removing the references for label approval in 9 CFR 317.4 and subparts M and N in part 381. Because the requirements for the labels of irradiated

[3] Source: FSIS Labeling and Program Delivery Division, Label Audit, 2010.

products are prescribed in FSIS's regulations, and the term has been used by industry for a number of years, FSIS no longer considers it to be a special statement or claim that requires submitting such labels for approval.

Options Considered for This Proposal

FSIS considered several options in developing this proposed rule. The first option FSIS considered was to maintain the current prior label approval system. Under this option, FSIS would not modernize its regulations by increasing the types of labels that the Agency considers generically approved and would not streamline its regulations by combining the label approval regulations for meat and poultry into one location in Title 9. Under this option, establishments and certified foreign establishments would not have to change any procedures and could continue to apply certain types of generically approved labels as provided for in the regulations. Therefore, FSIS would not need to allocate its resources to conduct rulemaking.

However, there are several major disadvantages to this option. First, the option would not be consistent with the Agency's commitment to enable manufacturers to make decisions and assume more responsibility concerning whether products that they produce are compliant with FSIS labeling regulations. Our current generic label rule was intended to reduce the number of labels and other labeling that are submitted for evaluation by FSIS and to lessen the paperwork burden on official establishments. The goal was to improve efficiency by streamlining the label evaluation and approval process. Streamlining and modernizing the prior label approval process is important to the Agency so that it can better focus on and direct its resources to other consumer protection and food safety activities.

Second, the regulations for the mandatory label features have been in place for decades, and FSIS believes that, as a result of its verification activities, establishments and certified foreign establishments can effectively apply labels with the mandatory label features without submitting them for approval to the Agency. Consequently, under this option, industry would continue to need to submit a significant number of labels for evaluation and approval because parts of the generic label regulations are unnecessarily restrictive. Specifically, the regulations require establishments to submit labels for evaluation that do not present policy issues from the standpoint of food safety, health, economic adulteration, or misbranding.

The second option that FSIS considered was: (1) Amending its regulations so that all labels, including labels for temporary approval and labels bearing claims, would be considered generically approved by the Agency; and (2) streamlining its regulations by combining the label approval regulations for meat and poultry in one location in Title 9. The primary advantages of this option are that it would streamline the Agency's label approval regulations and eliminate the burden on industry to submit labels to the Agency for approval. However, a major disadvantage of this option is that it would likely result in misbranded products in the marketplace. While the results of the generic labeling survey showed success in establishments applying certain types of labels (*e.g.,* the mandatory features that have been required by the meat and poultry inspection regulations for decades), the results of the survey cannot be used to support the generic approval of all labels because certain types of labels, *e.g.,* labels with special statements and claims, present significant policy issues and are not defined in FSIS regulations. Consequently, establishments may not be familiar with the Agency's requirements for the support or application of certain special statements or claims, which could result in increased labeling errors and misbranded product.

Industry is familiar with the requirements for mandatory label features, but the Agency believes that it needs to continue to provide pre-market evaluation and approval of certain types of labels (*e.g.,* temporary approvals and labels for product produced under a religious exemption). Further, FSIS needs to continue to provide pre-market evaluation and approval of special label statements and claims (*e.g.,* animal production raising claims and ''natural'') that present significant and evolving policy issues. The pre-market evaluation and approval of certain types of labels, and special statements and claims intended for use on labels, are needed for the Agency to verify that all labels are accurate, truthful, and not misleading before products enter commerce.

The third option FSIS considered was to: (1) Expand the types of labels that would be subject to generic approval; and (2) streamline its regulations by combining the label approval regulations for meat and poultry in one location in Title 9 of the CFR. Under this option, FSIS would expand the types of labels that the Agency considers generically approved (*i.e.,* any labels that bear mandatory features without special statements or claims). The Agency would continue to require the submission of certain types of label, *e.g.,* labels for temporary approval, labels for export products with label deviations, and products produced under religious exemptions.

Under this option, Federal establishments and certified foreign establishments would be responsible for ensuring that the basic required features on labels are applied in accordance with all applicable regulations. Temporary approvals, labels for export products that deviate from domestic labeling requirements, and labels for products produced under religious exemption, however, would represent exceptions that FSIS would need to evaluate on a case by case basis. Therefore, these limited types of labels would have to be submitted to FSIS for evaluation and approval before use. In addition, manufacturers would be required to submit special statements and claims intended to be used on labels to the Agency for approval under this option.

A major advantage of the third option is that establishments would be responsible for developing labels that include the basic mandatory features (*i.e.,* product name, safe handling statement, ingredients statement, signature line, net weight, legend, safe handling instructions, and nutrition labeling) in accordance with Federal regulations. This option would thus allow Agency personnel to focus their efforts on evaluating claims or special statements that have consumer safety or economic implications and on labels that cannot be generically approved, *e.g.,* requests for temporary approval to use labeling that is deficient in some manner. It would substantially reduce the types of labels that would need to be submitted to the Agency, thus reducing, although not entirely eliminating, the burden for industry to submit labels to FSIS for approval.

FSIS would continue to perform verification and post-market surveillance activities in commerce to ensure that meat and poultry product labels comply with all applicable regulations. Specifically, FSIS would 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 and part 381, subpart T, to determine compliance with label requirements. If the Agency found that an establishment is using a false or misleading label, it would institute the proceedings prescribed in 9 CFR 500.8

to revoke the approval for the label. FSIS's surveillance activities would ensure that the consumer is protected under this option.

Therefore, FSIS concludes that the third option is the most feasible for rulemaking. It is an approach that will effectively enhance implementation of a generic label system that imposes less burden on industry. It promotes effective use of Agency resources. The option will not adversely affect consumer protection because FSIS will continue to evaluate labeling, *e.g.,* special statements and claims and requests for temporary approval, that have consumer safety or economic implications. Moreover, FSIS will continue its verification and compliance activities to ensure that establishments are labeling their products in conformance with Agency regulations. Finally, it will streamline FSIS regulations by putting the meat and poultry prior label approval regulations in one part in Title 9.

We invite public comment on these options as well as on other options not discussed above.

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 determined that this proposed rule maximizes net benefits to consumers and establishments by expanding the types of labels that are approved generically under the FMIA and the PPIA.

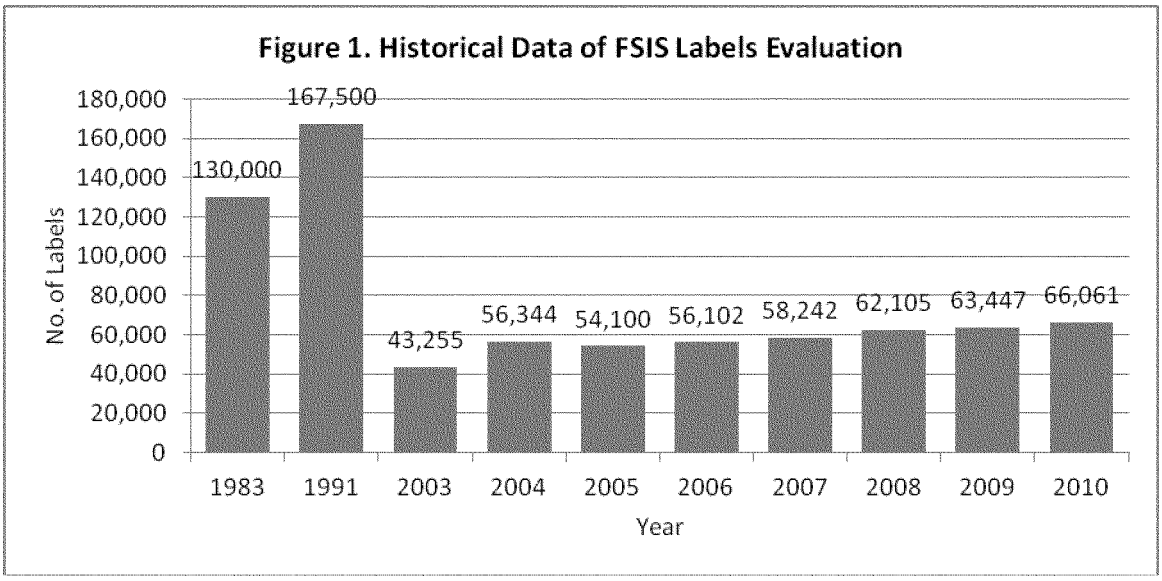
I. Need for the Rule

The purpose of the proposed rule is to 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. The proposed rule is the next step in the Agency's gradual streamlining and modernizing of the prior label approval system.

This rulemaking's intent is to reduce the number of labels evaluated by FSIS that only bear basic features (*e.g.,* product name, ingredients statement, net weight) and to reduce the amount of paperwork filed by establishments with FSIS. If finalized, 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 introduction of new products into the marketplace to meet demand while not negatively affecting consumer protection from misbranded product.

II. Historical Record of FSIS's Prior Label Approval System

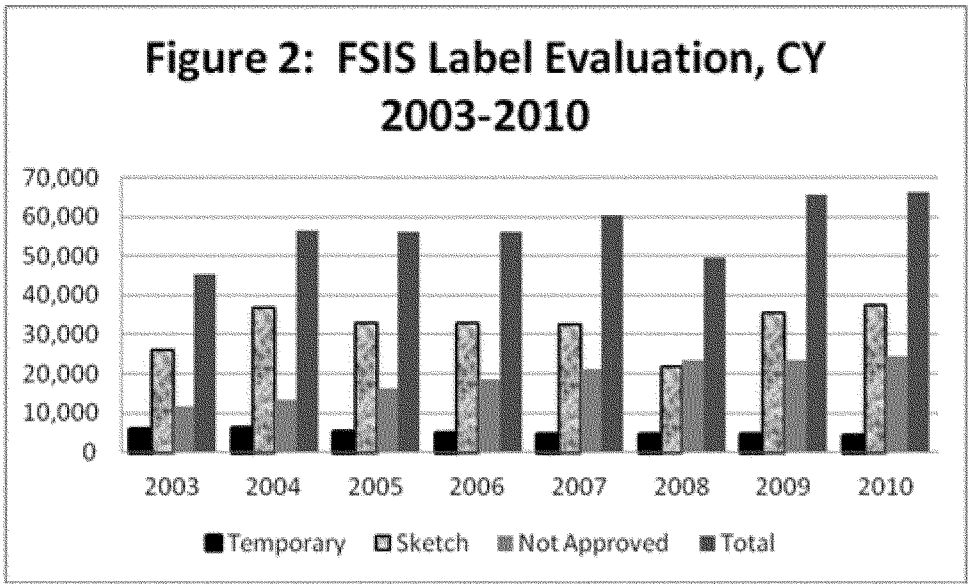
In 1983, when FSIS established limited types of generically approved labels, the Agency evaluated 130,000 labels. In 1991, the number of labels evaluated peaked at 167,500 labels. The 1995 final rule that amended the prior label approval system expanded the types of labels and label changes that may be applied in accordance with the generic label regulations. As a result, the number of labels evaluated by FSIS decreased by 74 percent to 43,255 in 2003, as depicted in Figure 1. From 2003 to 2010, the number of labels evaluated per year averaged 57,457, with a minimum of 43,255 (2003) and a maximum of 66,061 (2010).



Source: FSIS, Labeling and Program Delivery Division (LPDD), Labeling Information System (LIS) Database

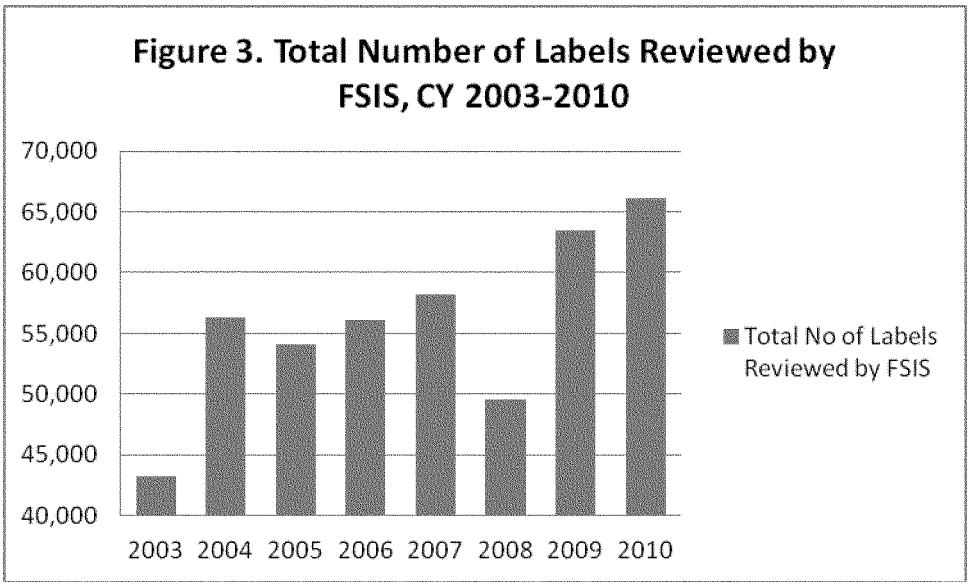
Under the current prior label approval system, FSIS evaluates and approves meat and poultry labels for temporary or sketch approval. Labels are not approved when they do not comply with Federal regulations, or when they have claims and special statements that are not substantiated or supported with sufficient documentation. As depicted in Figure 2, sketch labels make up over 50 percent of the volume of labels evaluated and approved by FSIS, while

the approval of temporary labels makes up only about 9 percent of the total volume.



Source: FSIS, LPDD, LIS Database

During 2003–2010, FSIS reviewed and evaluated a total of 459,656 labels. As depicted in Figure 3, the number of labels reviewed and evaluated by FSIS LPDD increased 53 percent, from 43,255 labels in 2003 to 66,061 labels in 2010. Each year the number of labels increased, except between 2004 and 2005, when labels decreased 4 percent, from 56,344 labels to 54,100 labels, but then increased 4 percent to 56,102 labels in 2006.



Source: FSIS, LPDD, LIS Database

When looking at the data of the Agency approval of Temporary Labels (See Table 1), we find that the approval level was at 13 percent in 2003 (5,831 labels approved), which then declined to 6 percent in 2010 (4,101 labels approved). The approval level was at its lowest in 2010 (6.2%), when the Agency approved 4,101 labels out of 66,061 labels. Since 2003, the Agency has approved 45 percent more sketch labels and 30 percent fewer temporary labels.

TABLE 1—LABEL EVALUATION AND APPROVAL PROCESS, 2003–2010

Agency action	2003	2004	2005	2006	2007	2008	2009	2010
Temporary Approval	5,831 (13%)	6,124 (11%)	5,036 (9%)	4,763 (8%)	4,404 (7.5%)	4,369 (8.8%)	4,575 (7.2%)	4,101 (6.2%)
Sketch Approval	25,870	36,967	32,795	32,956	32,588	21,693	35,588	37,465
Unapproved	11,554	13,252	16,269	18,383	21,250	23,456	23,284	24,495
Total	*43,255*	*56,343*	*54,100*	*56,102*	*58,242*	*49,518*	*63,447*	*66,061*

Examining the data closer, the number of sketch labels approved increased 64 percent, from 21,693 labels in 2008 to 35,588 labels in 2009, while the number not approved remains the same and the number of temporary slightly increased. The number of labels not approved has climbed steadily from 2003, when it was at its lowest at 11,554 labels unapproved, to its high of 24,495 labels not approved in 2010. Between 2005 and 2007, as the number of sketch label approvals leveled off in the 32,000 range, the number of labels not approved increased 30 percent, from 16,269 labels to 21,250. FSIS attributes this increase in labels not approved to the increase in special claims, statements that were not substantiated, and sketch labels that Agency personnel could not approve as modified because the labels contained several errors or major discrepancies. During this timeframe, FSIS placed much of its labeling guidance on its Web site and conducted many labeling workshops.

III. Industry Profile

A. Establishments

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 266,061 approved meat and poultry product labels used by these establishments. FSIS evaluated 66,061 of them in 2010; the remaining 200,000 were approved under the Prior Label Approval System because they met the standards for generic approval.

B. Label Consultant Firms

There are about 12 firms that submit labels to LPDD on behalf of Federal establishments. These firms provide label courier service, information, and training to their clients on FSIS labeling policies. All of the firms in this industry are small, usually having one to four employees. Many of these firms now offer consulting services, such as ensuring that import and export labels to be reviewed for compliance with USDA regulations receive expedited service and providing label outsourcing, in which a firm handles all of an establishment's food labeling needs.

IV. Benefits

A. Industry

If adopted, the proposed rule will continue the streamlining and modernization of the Agency's prior label approval system. The proposed rule will permit establishments to realize an estimated cost savings of a minimum of $8.7 million (discounted over a 10-year period) for generically approving about 584,486 additional labels over a 10-year period at about $25 per label submission.[4] In the absence of the proposed rule, establishments will not realize any cost savings because Federal regulations will continue to require establishments to submit a significant number of labels to LPDD for evaluation.[5] Establishments will also realize an increase in the number of generically approved labels over a 10-year period under the proposed rule.

TABLE 2—ESTIMATED ESTABLISHMENT COST SAVINGS (IN 2010 DOLLARS)

(A)	(B)	(C)	(D)	(E)	(F)	(G)
Year	Total number of labels developed and applied by establishments that do not require FSIS evaluation	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	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)
	Before rule		*After rule*			
0	200,000	0	200,000	$0	1.00	$0
1	250,985	50,985	301,970	$1,274,625	0.93	$1,185,401
2	253,495	52,515	306,009	$1,312,864	0.86	$1,129,063
3	256,030	54,090	310,120	$1,352,250	0.79	$1,068,277
4	258,590	55,713	314,303	$1,392,817	0.72	$1,002,828
5	261,176	57,384	318,560	$1,434,602	0.65	$932,491
6	263,788	59,106	322,893	$1,477,640	0.58	$857,031
7	266,426	60,879	327,304	$1,521,969	0.51	$776,204
8	269,090	62,705	331,795	$1,567,628	0.44	$689,756
9	271,781	64,586	336,367	$1,614,657	0.37	$597,423
10	274,499	66,524	341,022	$1,663,097	0.30	$498,929

[4] 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 LPDD.

[5] See Table 2.

TABLE 2—ESTIMATED ESTABLISHMENT COST SAVINGS (IN 2010 DOLLARS)—Continued

(A)	(B)	(C)	(D)	(E)	(F)	(G)
Year	Total number of labels developed and applied by establishments that do not require FSIS evaluation	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	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)
Total	*2,825,858*	*584,486*	*3,410,344*	*$14,612,147*		*$8,737,404*

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 LPDD.
Col F: Discount rate of 7 percent.
Col G: Discount cost savings over 10 years.
Source: FSIS Policy Analysis Division 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.

B. Agency

The proposed rule should reduce the number of labels submitted to FSIS for evaluation and enable the Agency to reallocate the staff hours saved from evaluating fewer 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 proposed rule would 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 shows the chronological progression of streamlining and modernizing the prior label approval system through various rulemakings.

TABLE 3—COMPARISON OF FSIS PRIOR LABEL APPROVAL SYSTEM RULEMAKINGS

1983	1995	2011
Prior label approval system	*Prior label approval system*	*Proposed prior label approval system*
Establishments granted limited labeling approval to the IIC.	Expanded the types of labels and modifications to labels that the Agency deemed generically approved.	Proposed to expand all types of labels and of modifications to labels that the Agency deems generically approved except in certain specified circumstances.
Label records maintained by IIC	Label records maintained by the establishments.	Label records maintained by the establishments.
Agency conducts all evaluation and approval of temporary, sketch, and final labels.	Agency conducts all evaluations and approvals of temporary and sketch labels only..	Agency conducts all evaluations and approvals of special statements and claims, labels for temporary approval, labels for products produced under a religious exemption, and labels for products for export with labeling deviations.

Source: FSIS, LPDD

TABLE 4—ESTIMATED FSIS COST SAVINGS (IN 2010 DOLLARS)

(A)	(B)	(C)	(D)	(E)	(F)	(G)	(H)
Year	Total number of labels evaluated and approved by LPDD	Total number of labels evaluated and approved by LPDD	Annual salary cost ($) of LPDD [1]	Annual salary cost ($) of LPDD [2]	Annual salary difference (D) − (E)	To apply discount rate of 7.00%	Discounted cost savings (F) * (G)
	Before rule	*After rule*	*Before rule*	*After rule*			
0	66,061	66,061	538,710	538,710	0	1.00	0
1	68,043	17,011	554,871	134,677	420,194	0.93	390,781
2	70,084	17,521	571,517	138,717	432,800	0.86	372,208
3	72,187	18,047	588,663	142,879	445,784	0.79	352,169
4	74,352	18,588	606,323	147,165	459,158	0.72	330,594
5	76,583	19,146	624,513	151,580	472,932	0.65	307,406

TABLE 4—ESTIMATED FSIS COST SAVINGS (IN 2010 DOLLARS)—Continued

(A)	(B)	(C)	(D)	(E)	(F)	(G)	(H)
Year	Total number of labels evaluated and approved by LPDD *Before rule*	Total number of labels evaluated and approved by LPDD *After rule*	Annual salary cost ($) of LPDD [1] *Before rule*	Annual salary cost ($) of LPDD [2] *After rule*	Annual salary difference (D) − (E)	To apply discount rate of 7.00%	Discounted cost savings (F) * (G)
6	78,880	19,720	643,248	156,128	487,120	0.58	282,530
7	81,247	20,312	662,545	160,811	501,734	0.51	255,884
8	83,684	20,921	682,422	165,636	516,786	0.44	227,386
9	86,195	21,549	702,894	170,605	532,290	0.37	196,947
10	88,780	22,195	723,981	175,723	548,258	0.30	164,477
Total	846,096	261,070	6,899,688	2,082,631	4,817,057		2,880,382

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 LPDD prior to rule enactment assuming a 3 percent growth factor.
Col C: Total number of labels evaluated and approved by LPDD after rule enactment, assuming a 3 percent growth factor.
Col D: Annual salary cost of LPDD staff who evaluate labels, prior to enactment of rule, assuming a 3 percent growth factor.
Col E: Annual salary cost of LPDD 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 Division calculations.

If this proposed rule becomes final, in the year before the effective date of the rule FSIS will continue to review 66,061 labels because of the lag time between the publication of the rule and industry compliance with it. In years 1–10, FSIS will experience a 69 percent reduction in the volume of labels submitted for evaluation.

Currently, FSIS employs eleven labeling policy experts to evaluate labels.[6] FSIS staff members are organized into teams based on special claims or issues, such as amenability, organic, or country of origin,[7] and evaluate labeling four hours per day, five days a week, at a cost of $10,360 per week. FSIS assumes that it 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. Thus, the proposed rule would permit the Agency to realize an estimated discounted cost savings of $2.9 million over 10 years [8] from evaluating labels because FSIS is expected to review a total of 261,070 labels under the proposed rule as compared with 846,096 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.

V. Costs

The proposed rule would 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 proposed 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 proposed 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. If this proposal is adopted, establishments will continue label production, once the labels are approved by FSIS. The cost of label design and products is not a part of this proposed rule.

VI. Summary

If this proposed rule is adopted, it will be net beneficial because it will streamline the generic label approval process, while imposing no additional cost burden on establishments. FSIS estimates that establishments will realize a discounted cost savings of $8.7 million as a result of their ability to generically approve an additional 584,486 labels over a 10-year period. Furthermore, the Agency will realize a discounted cost savings of $2.9 million for evaluating 584,486 fewer labels over a 10-year period. This cost savings in fewer staff hours being spent evaluating labels can be redirected towards other Agency initiatives. Therefore, the net benefit derived from the proposed rule is $11.6 million ($8.7 million in establishment savings plus $2.9 million in Agency savings), discounted at 7 percent, over a 10-year period.

Preliminary Regulatory Flexibility Analysis

The FSIS Administrator has determined that this proposed rule would not have a significant impact on a substantial number of small entities, as defined by the Regulatory Flexibility

[6] The average General schedule (GS) level grade of the staff is a GS–13, step 4.
[7] Each team will have a member who is knowledgeable about certain special claims.
[8] See Table 4.
[9] Ibid.

Act (5 U.S.C. 601). The proposed 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 proposed 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 possibly affected by this rule. These small and very small establishments, like the large establishments, would be permitted to generically approved labels as long as there are no special claims. Small entities would not be disadvantaged because the proposed rule would minimize the regulatory burden on all establishments. The proposed rule would 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 proposed rule will not have a significant economic impact on a substantial number of small entities (establishments and labeling consulting firms).

In making its determination, the Agency considered two alternatives to the proposed rule: the status quo and making all labels candidates for generic labeling. Keeping the status quo would mean that the Agency would continue to commit limited resources to a process that establishments can assume, if the proper guidance was available. Therefore the Agency rejects this alternative. The second alternative, making all labels generically approved, would mean that some products may be misbranded because of misleading statement and claims on the labels. Therefore the Agency rejects this alternative as well.

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.

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 proposed rule on prior labeling has been submitted for approval to OMB.

Title: Marking, Labeling, and Packaging of Meat, Poultry, and Egg Products.

OMB No.: 0583–0092.

Expiration Date of Approval:

Type of Request: Revision of a currently approved information collection.

Abstract: FSIS has been delegated the authority to exercise the functions of the Secretary as specified in the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601, *et seq.*), the Poultry Products Inspection Act (PPIA) (21 U.S.C. 451, *et seq.*), and the Egg Products Inspection Act (EPIA) (21 U.S.C. 1031, *et seq.*).

FSIS protects the public by verifying that meat, poultry, and egg products are safe, wholesome, unadulterated, and properly labeled and packaged. FSIS is requesting a revision of a currently approved information collection addressing paperwork requirements specified in the regulations related to marking, labeling, and packaging of meat, poultry, and egg products.

FSIS is proposing to expand the circumstances in which FSIS will generically approve the labels of meat and poultry products. Under this proposed rule, more official and foreign establishments would be able to use the generic approval of product labels that would also result in a reduced number of regular label approvals. Hence, FSIS is requesting a revision of the Marking, Labeling, and Packaging of Meat, Poultry, and Egg Products information collection. The total number of hours for this information collection will decrease 31,091 hours because of the increased use of generic labeling.

Estimate of Burden: FSIS estimates that it will take establishments on the average of 0.33 hours per response.

Respondents: Official establishments, plants, and foreign establishments.

Estimated Number of Respondents: 6,418.

Estimated Number of Responses per Respondent: 45.7.

Estimated Total Annual Burden on Respondents: 97,176 hours.

Copies of this information collection assessment can be obtained from John O'Connell, Paperwork Reduction Act Coordinator, Food Safety and Inspection Service, USDA, 1400 Independence Avenue SW., Room 6083, South Building, Washington, DC 20250.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of FSIS's functions, including whether the information will have practical utility; (b) the accuracy of FSIS's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments may be sent to both John O'Connell, Paperwork Reduction Act Coordinator, at the address provided above, and the Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20253. To be most effective, comments should be sent to OMB within 60 days of the publication date of this proposed rule.

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.

FSIS believes that by proceeding with this rulemaking, the Agency could potentially accept the electronic submission of requests for the evaluation of claims or special statements, which will significantly streamline the approval process.

National Environmental Policy Act

The expected environmental effects: The use of labels by meat and poultry product establishments that have been deemed to be generically approved by FSIS is an activity that will not have a significant individual or cumulative effect on the human environment. Therefore, this proposed rule is appropriately subject to the categorical exclusion from the preparation of an environmental assessment or environmental impact statement provided under 7 CFR 1b.4(6) of the U.S. Department of Agriculture regulations.

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 proposed rule online through the FSIS Web page located at *http://www.fsis.usda.gov/regulations_&_policies/ProposedRules/index.asp*.

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/News_&_Events/Email_Subscription/*. 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.

List of Subjects

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

For the reasons discussed in the preamble, FSIS is proposing to amend 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 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.''

* * * * *

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 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.

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, shall be approved by the Food Safety and Inspection Service in accordance with part 412 of these regulations 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 will 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, 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 program at headquarters, Food Safety and Inspection Service, USDA, 5601 Sunnyside Ave., Stop 5476, Beltsville, MD 20705–5476, 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, 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 section 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 deg. (*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 deg. (*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 section 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.

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 shall 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, 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 program at headquarters 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 program 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 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 shall be used on any product unless the label has been submitted for approval to the FSIS labeling program at headquarters, accompanied by FSIS Form 7234–1, Application for Approval of Labels, Marking, and Devices, and approved by such division, 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 subchapter. Such records shall 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 § 412.1(a) will be submitted to the FSIS labeling program at headquarters, in duplicate. 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 label as defined in § 412.1(d) 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 section 317.7 and part 381, subpart M.

(3) Special statements and claims as defined in § 412.1(e) and presented in the context of a final label.

(4) Requests for the temporary use of final labels as prescribed in § 412.1(f).

(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, such as health claims, negative claims (*e.g.,* gluten free), ingredient and processing method claims (*e.g.,* high pressure processing), structure-function claims, animal production and raising claims, organic claims, natural 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.

(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 program at headquarters. 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 program at headquarters 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 subchapter, 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 (*e.g.,* a statement that characterizes a product's nutrient content, such as ''low fat,'' or has geographical significance, such as ''German Brand''), and that comply with those regulations are also deemed to be approved by the Agency without being submitted for evaluation and approval.

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.

19. 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.

* * * * *

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

§ 424.22 Certain other permitted uses.

* * * * *

(c) * * *

(4) * * *

(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).

Done in Washington, DC, on November 29, 2011.

Alfred V. Almanza

Administrator.

[FR Doc. 2011–30992 Filed 12–2–11; 8:45 am]

BILLING CODE 3410–DM–P

BUREAU OF CONSUMER FINANCIAL PROTECTION

12 CFR Chapter X

[Docket No. CFPB—2011–0039]

Streamlining Inherited Regulations

AGENCY: Bureau of Consumer Financial Protection.

ACTION: Notice of streamlining project; request for information.

SUMMARY: The Bureau of Consumer Financial Protection (the Bureau) is requesting specific suggestions from the public for streamlining regulations it recently inherited from other Federal agencies. This document asks the public to identify provisions of the inherited regulations that the Bureau should make the highest priority for updating, modifying, or eliminating because they are outdated, unduly burdensome, or unnecessary. This document discusses several specific requirements that may warrant review. It also seeks suggestions for practical measures to make complying with the regulations easier.

DATES: Comments must be submitted by March 5, 2012. Commenters will have 30 additional days, until April 3, 2012, to respond to other comments.

ADDRESSES: Interested parties are invited to submit written comments electronically or in paper form. Comments should refer to ''Docket No. CFPB–2011–0039.'' Comments should be submitted to:

- *Electronic: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Research, Markets & Regulations Division, Bureau of Consumer Financial Protection, 1500 Pennsylvania Avenue NW., (Attn: 1801 L Street NW), Washington, DC 20220.
- *Hand Delivery/Courier in Lieu of Mail:* Research, Markets & Regulations Division, Bureau of Consumer Financial Protection, 1700 G Street NW., Washington, DC 20006.

In general, all comments received will be posted without change to *http://www.regulations.gov.* In addition, comments will be available for public inspection and copying at 1700 G Street NW., Washington, DC 20006, on official business days between the hours of 10 a.m. and 5 p.m. Eastern Time. You can make an appointment to inspect comments by telephoning (202) 435–7275.

All comments, including attachments and other supporting materials, will become part of the public record and subject to public disclosure. Sensitive personal information, such as account numbers or social security numbers, should not be included. Comments will not be edited to remove any identifying or contact information.

FOR FURTHER INFORMATION CONTACT: Jane Gell, Senior Counsel and Special Advisor; Daniel Brown, Counsel, Research, Markets & Regulations Division, Bureau of Consumer Financial Protection, (202) 453–7700.

SUPPLEMENTARY INFORMATION:

I. Background

The Dodd-Frank Wall Street Reform and Consumer Protection Act (Dodd-Frank Act or Act) [1] established the Bureau and, on July 21, 2011, transferred to the Bureau rulemaking authority under Federal consumer financial laws previously vested in seven other Federal agencies.[2] Accordingly, the Bureau assumed responsibility over the various regulations that these agencies had issued under this rulemaking authority.[3]

In the coming weeks, the Bureau will republish the prior agencies' regulations implementing fourteen consumer laws [4] (the ''inherited regulations'') as regulations of the Bureau, which will be codified in Chapter X of Title 12 of the Code of Federal Regulations. These republished regulations will incorporate only technical changes and will not impose new substantive obligations. The technical changes reflect the transfer of authority to the Bureau and certain other amendments made by the Dodd-Frank Act to the underlying statutes.

The inherited regulations serve important public policy purposes and provide key protections to consumers, as discussed further below. But the Bureau believes there may be opportunities to streamline the inherited regulations by updating, modifying, or eliminating outdated, unduly burdensome, or unnecessary provisions. With this document, the Bureau is seeking specific suggestions from the public for the highest priority areas for streamlining.[5]

[1] Public Law 111–203, 124 Stat. 1376 (2010).

[2] These agencies are: The Board of Governors of the Federal Reserve System (Board), the Federal Deposit Insurance Corporation (FDIC), the Federal Trade Commission (FTC), the National Credit Union Administration (NCUA), the Office of the Comptroller of the Currency (OCC), the Office of Thrift Supervision (OTS), and the Department of Housing and Urban Development (HUD).

[3] On July 21, 2011, the Bureau published a list of the rules and orders that it will enforce. *See* 76 FR 43569 (July 21, 2011). The Bureau assumed rulemaking authority for all the items on this list, except items 1 and 6 through 12 in section F (Federal Trade Commission). The Bureau also has assumed responsibility over Regulation FF, 12 CFR part 232, which the Board issued pursuant to its authority under the Fair Credit Reporting Act, and which was inadvertently omitted from the list.

[4] These fourteen laws are: The Consumer Leasing Act, the Electronic Fund Transfer Act (except with respect to Section 920 of that Act), the Equal Credit Opportunity Act, the Fair Credit Reporting Act (except with respect to Sections 615(e) and 628 of that act), the Fair Debt Collection Practices Act, Subsections (b) through (f) of Section 43 of the Federal Deposit Insurance Act, Sections 502 through 509 of the Gramm-Leach-Bliley Act (except for Section 505 as it applies to Section 501(b)), the Home Mortgage Disclosure Act, the Real Estate Settlement Procedures Act, the S.A.F.E. Mortgage Licensing Act, the Truth in Lending Act, the Truth in Savings Act, Section 626 of the Omnibus Appropriations Act, 2009, and the Interstate Land Sales Full Disclosure Act.

[5] This request for information is based in part on guidance provided by the Office of Management and Budget Memorandum for the Heads of Independent Regulatory Agencies, M–11–28,

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