DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Parts 306, 317, 320, 327, and 381

[Docket No. 92–012F]

RIN 0583–AB92

Prior Labeling Approval System

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: The Food Safety and Inspection Service (FSIS) is amending the Federal meat and poultry products inspection regulations by expanding the types of labeling, authorized for use on meat and poultry products by official establishments in the United States and foreign establishments certified under foreign inspection systems, which would not require submittal to FSIS for approval prior to use. In addition, FSIS is amending the Federal meat and poultry products inspection regulations to permit the submission of only sketch labeling, except for temporary approvals, in those instances where labeling is required to be submitted for approval and to require retention of certain labeling records. This final rule eliminates unnecessary duplication in the labeling approval system, and contributes to President Clinton's initiatives for greater efficiency in government services, (e.g., it is consistent with the principles of the National Performance Review to cut red tape, put customers first, and eliminate what is not needed).

EFFECTIVE DATE: July 1, 1996.

FOR FURTHER INFORMATION CONTACT: Ms. Cheryl Wade, Director, Food Labeling Division, Regulatory Programs, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250, Area Code (202) 254–2590.

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 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 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 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)).

Under the latter provisions, the Department has a longstanding interpretation of the language to mean that the Secretary of Agriculture or his or her representative has the responsibility to approve all labels or other labeling to be used on federally inspected and imported products prior to the distribution of such products from establishments that distribute such products in interstate or foreign commerce. Without approved labeling, products may not be sold or offered for sale or otherwise distributed in commerce. The term ''labeling,'' as defined in section 1(p) of the FMIA and section 4(s) of the PPIA (21 U.S.C. 601(p) and 453(s), respectively), means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.

The aforementioned provisions also apply to establishments that operate solely within designated States. 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 their carcasses, or products thereof, are prepared for use as human food solely for distribution within such State, requirements at least equal to titles I and IV of the FMIA and specified sections of the PPIA as applicable. Once a State is designated, the inspection requirements of the FMIA and PPIA apply to establishments that slaughter livestock and poultry and/or prepare or process meat and/or poultry products therefrom, solely for distribution within the State.

Section 1(m)(8) of the FMIA (21 U.S.C. 601(m)(8)) and section 4(g)(8) of the PPIA (21 U.S.C. 453(g)(8)) provide that any carcass, part thereof, meat or meat food product or any poultry product is adulterated ''* * * if any valuable constituent has been in whole or in part omitted or abstracted therefrom; or if any substance has been substituted, wholly or in part therefor; or if damage or inferiority has been concealed in any manner; or if any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is* * * .'' Furthermore, section 1(n)(1) of the FMIA (21 U.S.C. 601(n)(1)) and section 4(h)(1) of the PPIA (21 U.S.C. 453(h)(1)) prescribe that any carcass, part thereof, meat or meat food product or poultry product is considered misbranded if its labeling is false or misleading in any particular.

In order to prevent product adulteration and misbranding, the FMIA and PPIA further authorize the Secretary to prescribe, whenever he or she determines such action is necessary for the protection of the public, (1) the styles and sizes of type to be used with respect to material required to be incorporated in labeling to avoid false or misleading labeling, and (2) definitions and standards of identity or composition for meat and poultry products (section 7(c) of the FMIA, 21 U.S.C. 607(c), and section 8(b) of the PPIA, 21 U.S.C. 457(b)).

Current Regulations

The labeling provisions of the meat and poultry products inspection regulations specify the required features of meat and poultry product labels for immediate containers of domestic product (9 CFR part 317 and 9 CFR part 381, subpart N) and for imported product (9 CFR part 327 and 9 CFR part 381, subpart T). These include: (1) The standardized, common or usual, or descriptive name of the product; (2) an ingredients statement containing the common or usual name of each ingredient listed in descending order of predominance; (3) the name and place of business of the manufacturer, packer, or distributor; (4) an accurate statement of the net quantity of contents; (5) the inspection legend; and (6) special handling instructions if product is perishable; i.e., ''Keep Frozen'' and ''Keep Refrigerated.'' These essential labeling features must be prominently and informatively displayed on the principal display panel or the information panel of the product label.

The regulations contain other provisions to ensure that no statement, word, picture, design, or device which is false or misleading in any particular or conveys any false impression or gives any false indication of origin, identity, or quality, appears in any marking or other labeling (9 CFR 317.8 and 381.129).

Any marking or labeling which is determined to be false or misleading within the meaning of the FMIA or the PPIA and the regulations promulgated thereunder causes the article to which it relates to be misbranded, and, 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)), and 9 CFR 335.12 and 381.233 of the Federal meat and poultry products inspection regulations, the Administrator, FSIS, may withhold the use of such marking or labeling.

In addition to providing substantive labeling requirements, the Federal meat and poultry products inspection regulations provide specific information regarding permitted and nonpermitted uses of various substances (9 CFR part 318 and part 381, subpart 0). These provisions prohibit the use of any food additive, color additive, pesticide chemical, or other added poisonous or deleterious substance, or any other substance in or on meat and poultry products that would cause such articles to be adulterated or misbranded within the meaning of the FMIA and PPIA.

The Federal meat and poultry products inspection regulations also prescribe definitions and standards of identity or composition for certain meat and poultry products (9 CFR part 319 and part 381, subpart P). Standards of composition identify the minimum amount of meat and/or poultry required in a product's recipe. Standards of identity set specific product requirements for a product's makeup. These standards often specify (1) the kind and minimum amount of meat and/or poultry; (2) the maximum amount of nonmeat ingredients, such as fat or moisture; and (3) any other ingredients allowed or expected in the final product.

Current Prior Label Approval System

In order to assure that meat and poultry products comply with the FMIA and PPIA and the regulations promulgated thereunder, FSIS conducts a prior approval program for labels and other labeling as specified in 9 CFR 317.4, 317.5, 327.14, 327.15, 381.132, 381.134, and 381.205 to be used on federally inspected meat and poultry products and imported products. This program is administered by the Food Labeling Division (FLD), Regulatory Programs, FSIS, in Washington, DC.

To obtain labeling approval, domestic meat and poultry processors and certified foreign establishments, or their representatives, must submit final labels and other final labeling, except under certain conditions. Such foreign establishments are certified by responsible officials of foreign meat and poultry inspection systems, to the Department, in accordance with parts 327 and 381, subpart T, of the Federal meat and poultry products inspection regulations as fully complying with requirements at least equal to those imposed on domestic products and establishments. Such foreign establishments are then eligible to have their meat and poultry products imported into the United States, unless the Administrator terminates their eligibility to import products in accordance with parts 327 and 381, subpart T, of the Federal meat and poultry products inspection regulations.

Meat and poultry processors and certified foreign meat establishments may submit sketch labeling (a printer's proof or other version which clearly shows all required labeling features, size, location, and indication of final color), accompanied by FSIS Form 7234, ''Application for Approval of Labels, Marking or Device,'' to FLD for review. Certified foreign poultry establishments are required to submit sketch and finished (final) labels of immediate containers for review and approval. The labeling application and sketch or final printed labeling to be used on domestic meat and poultry products and on imported meat products must be submitted to FLD in triplicate. Certified foreign poultry establishments must submit two copies of sketch and four copies of final labeling to FLD. In addition to the required information, any special claims the processor intends to make (e.g., quality claims or nutrient content claims) must also be included on the labeling. The labeling application must contain the processing procedures (sufficient to support the accuracy of the label) and handling information, including the following as indicated on the form:

1. Product name;
2. Formulation information;
3. Firm name and address;
4. How the labeling is to be used;
5. Size and type of container; and
6. Size of the principal display panel.

All such information is reviewed by an FSIS label review specialist who is responsible for assuring that the labeling complies with all Federal regulations and labeling policies.

In 1983, the Agency promulgated regulations that granted limited labeling approval authority to the inspector-in-charge (IIC) of official establishments and established limited types of generically approved labeling for official establishments (48 FR 11410). This rulemaking did not establish analogous provisions for certified foreign establishments. This rulemaking was intended to reduce the number of labels and other labeling reviewed and processed by FLD, thereby improving the efficiency of the labeling approval system by expediting the process for specific types of labeling and reducing the paperwork burden on official establishments. As a result of these regulations, the IIC currently has authority to approve the types of labeling identified in 9 CFR 317.4(e) and 381.132(c), (e.g., labeling for single ingredient products without additional claims), provided certain requirements are satisfied. However, under current regulations, official establishments are not required to submit labeling that comes within the categories of labeling the IIC can approve to the IIC for approval, but rather have the option of submitting the labeling to FLD for approval.

The regulations also specify limited types of labeling that can be approved generically. The generically approved labeling provisions allow establishments to make certain modifications to their previously approved labeling. These modifications can be designed, developed, printed, and applied to a product without submission for approval to FSIS, provided the labeling shows all mandatory information in a sufficiently prominent manner and is not false or misleading in any particular. Generically approved labeling is labeling which contains one or more of the modifications identified in 9 CFR 317.5(b) and 381.134(b), (e.g., all features of the labeling are proportionately enlarged or reduced). Under the current regulations, official establishments may submit labeling that comes within the generic approval category, at their option, to FSIS for approval. The IIC is also currently authorized to approve those types of labeling.

Currently, official establishments may submit sketch labeling to FLD for approval, but must submit final labeling to FLD for approval, except for generic or IIC approvals. Even though the IIC has the authority to approve certain final labeling, many official establishments continue to submit all final labeling to FLD for approval.

During the development of the 1983 rule, FSIS estimated the number of labels and other labeling reviewed by FLD at approximately 130,000. During fiscal year 1991, FLD processed approximately 167,500 labels—87,500 final labels and 60,000 sketch labels were reviewed and approved, 20,000 labels were reviewed but not approved, and about 43,000 labels were approved by IIC's. No records are maintained on numbers of temporary approvals, generically approved labels, or labeling inserts.

The continuing increase in the numbers of labels and other labeling submitted to FLD and limited Agency resources led to an Agency assessment of the prior labeling approval system in 1990. In exploring options for an improved labeling approval system, the Agency decided to institute a plan to automate the labeling review process and to revise internal procedures.

Advance Notice of Proposed Rulemaking

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

FSIS sought comments on these two options and welcomed comments on other options. FSIS also sought comments on the role of the IIC with regard to review or enforcement of labeling, and on whether generic approval should be provided for labeling that includes geographical, quality, health, nutrient content, or negative claims, or guarantees.

FSIS received 110 comments in response to the ANPR. After review and consideration of the comments received on the ANPR, FSIS issued a proposed rule which is discussed in the following section.

Proposed Rule

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 labeling currently authorized for use on meat and poultry products by official establishments in the United States and foreign establishments certified under foreign inspection systems which would be generically approved. The rule was proposed as a first step in the gradual streamlining and modernization of the labeling approval system. In the proposal, the Agency sought comments on a long-term plan to implement an all-generic system.

Under the proposed rule, official establishments and establishments certified by responsible officials of foreign inspection systems would be required to submit only sketch labeling in those instances where labeling was required to be submitted to FLD for approval. FSIS proposed to limit the types of labeling submitted for review and approval for domestic and imported products and to revise 9 CFR 317.4, 317.5, 381.132, 381.133, 327.14, 381.205, and 381.206. No final labeling would be approved by FLD, except temporary labeling approvals. The proposal defined a sketch label as a printer's proof or equivalent which clearly shows all labeling features (as set forth in 9 CFR 317.2 and part 381, subpart N), as well as size, location, and indication of final color and is no larger than 8½ x 14 inches. The proposed size requirement was a result of the Agency's efforts to automate the review process and to use scanning technology to record certain information from the labeling application. The proposal provided that a parent company for a corporation need only submit one labeling application for a product produced in other establishments which were owned by the corporation. The proposal indicated that this provision for corporations would reduce the burdens on the industry and the Agency in submitting and revising such applications without posing any apparent risk of misbranding. The proposal also provided that once a sketch was approved, the establishment would have the authority to print a final copy and use the labeling without any further authorization from the Agency.

Also, under the proposed rule, establishments would still be required to assure that the labeling was not false or misleading in any particular. If an establishment chose to modify an approved sketch, the establishment would be authorized to use the final labeling if such labeling complied with the requirements proposed in 9 CFR 317.5, 327.14, 381.133, and 381.205. If the labeling was not in accord with these proposed provisions, the labeling would be required to be resubmitted as a sketch for approval by FLD.

FSIS proposed to revise the IIC and generic approval authorities prescribed in 9 CFR 317.4(e), 317.5, 381.132(c), and 381.134 to alleviate the burden of labeling approval imposed upon IIC's. The IIC would retain, however, the authority to approve meat carcass ink brands and meat food product ink and burning brands. All other provisions of 9 CFR 317.4(e), 317.5, 381.132(c), and 381.134 would be combined to permit establishments to use final labeling for products in certain circumstances without the submission of a sketch to FLD and to use final labeling for products for which a sketch had been approved. FSIS proposed to add to this authority a few other provisions including the permitted use of labeling for standardized products prescribed in 9 CFR parts 319 and 381, subpart P, provided such labeling did not contain special claims, such as quality claims, nutrient content or health claims, geographical origin claims, negative claims, and guarantees, and was not a domestic product labeled with a foreign language.

FSIS proposed to permit 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 approval by FSIS:

1. Labeling for a product which has a standard of identity or composition as specified in 9 CFR part 319 or part 381, subpart P, and which does not contain any special claims, such as quality claims, nutrient content claims, health claims, negative claims, geographical origin claims, or guarantees, or which is not a domestic product labeled with a foreign language;

2. Labeling for single-ingredient products (such as beef steak, lamb chops, chicken legs, or turkey breasts) which does not contain special claims, such as quality claims, nutrient content claims, health claims, negative claims, geographical origin claims, or guarantees, or which is not a domestic product labeled with a foreign language;

3. Labeling for products marked ''For Export Only'' in U.S. establishments which does not contain any special claims, such as quality claims, nutrient content claims, health claims, negative claims, geographical origin claims, or guarantees;

4. Labeling 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 the contract specifications include specific requirements with

respect to labeling, and are made available to the IIC;

5. Labeling for shipping containers which contain fully labeled immediate containers, provided such labeling complies with 9 CFR 316.13 or 381.127.

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

7. Inspection legends, which comply with 9 CFR parts 312 and 316 and 9 CFR part 381, subpart M; and

8. Inserts, tags, liners, pasters, 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.

The proposed rule would also permit official establishments and foreign establishments certified by officials of foreign inspection systems to use final labeling, without further authorization from FSIS, that was approved by FSIS, FLD, in sketch form if the final labeling was prepared without modification or with the following modifications:

1. All features of the labeling are proportionately enlarged or reduced, provided that all minimum size requirements specified in applicable regulations are met and the labeling is legible;

2. A substitution of the abbreviation ''lb.'' for ''pound,'' or ''oz.'' for ''ounce,'' or of the word ''pound'' for ''lb.'' or ''ounce'' for ''oz.'';

3. A master or stock label 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);

4. During holiday seasons, wrappers or other covers bearing floral or foliage designs or illustrations of rabbits, chicks, fireworks, or other emblematic holiday designs are used with approved labeling (the use of such designs will not make necessary the application of labeling not otherwise required);

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

6. 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;

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

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

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

10. Any change in punctuation;

11. Newly assigned or revised establishment numbers for a particular establishment for which use of the labeling has been approved by the FLD;

12. The addition or deletion of open dating information;

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

14. 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;

15. The deletion of the word ''new'' on new product labeling;

16. 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);

17. The addition of safe handling instructions as required by 9 CFR 317.2(l) or 381.125(b).

18. 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 and 319, or 9 CFR 381.147 or 9 CFR part 381, subpart P;

19. Changes in the color of the labeling, provided that sufficient contrast and legibility remain;

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

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

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

Section 327.15 of the Federal meat inspection regulations (9 CFR 327.15) requires that all labeling used with outside containers of foreign meat product must be approved in accordance with 9 CFR part 317. However, 9 CFR 381.206 dealing with shipping containers of imported poultry products does not include such a provision. FSIS proposed to clarify 9 CFR 381.206 to indicate that shipping containers of imported poultry products would be approved in accordance with 9 CFR part 381, subpart N of the poultry products inspection regulations. This is merely a clarification of our labeling approval procedures.

FSIS proposed to transfer the responsibility of maintaining updated generically approved labeling records from the IIC to the official establishment in the United States and to require establishments certified by officials of a foreign inspection system to maintain such records. FSIS also proposed to require establishments to maintain records of labeling approved by FLD. In order to monitor compliance of regulatory labeling requirements, FSIS proposed that establishments maintain records on all labeling used and make such records available to any authorized USDA official upon request. Each record would consist of a copy of the labeling and the product formulation and processing procedure. Under the proposed rule, official establishments would not have to present to the IIC a copy of the generically approved labeling prior to its use, as is currently required under 9 CFR 317.5 and 381.134.

Sections 306.5, 327.24, 381.35 and 381.202(d) of the meat and poultry regulations (9 CFR 306.5, 327.24, 381.35, and 381.202(d)) specify the appeal procedures to be followed for decisions made by program employees or inspectors. These sections also state that denial of a labeling application by the IIC or inspector is not a basis for appeal under these sections. Since the proposed rule would not maintain the IIC's authority to approve labeling applications, there would no longer be a need to retain this provision. Therefore, the proposed rule proposed to remove these provisions from these sections.

FSIS proposed to randomly select samples of generically approved labeling from official establishments and establishments certified under a foreign inspection system in order to determine compliance with labeling requirements. If the Agency found that any such labeling was false or misleading in any particular, FSIS would initiate the proceedings set forth in 9 CFR 335.12 and 381.233 for domestic and imported products.

Although FSIS did not propose to change the general authority for temporary labeling approvals currently specified in 9 CFR 317.4(d) and 381.132(b), provisions for temporary approvals were proposed at 9 CFR 317.4(f)(1) and 381.132(f)(1). FSIS proposed that final labeling deficient in some particular could be granted a temporary approval for up to 180 days, provided, among other things, that the product was not misrepresented. FSIS also proposed that such an approval could be extended under certain circumstances. Temporary labeling approval requests would continue to be handled the same as sketch labeling approvals through submission of labeling applications to FLD.

FSIS also proposed to remove the provision set forth in 9 CFR 317.4(b) that required that paper takeoffs of lithographed labels, in lieu of sections of the metal containers, be submitted to the Agency for approval. This provision was intended to assist producers of canned products when submitting final labeling. However, because FLD would no longer review final labeling, such provision would no longer be needed.

Alternative Option Considered

In developing the proposal, FSIS considered the alternative of proposing a system where all labeling for domestic and imported products would be generically approved. Under this alternative, there would not be any labeling review and approval conducted by program employees, either at headquarters or in the field. Establishments would be authorized to design, develop, print, and apply labeling without any submission to FSIS, provided that the labeling complied with existing labeling regulations. As with generically approved labeling under the proposed rule, establishments would be required to maintain records for all labeling. These records would include a copy of the labeling used on the product and a record of the product formulation and processing procedure. In addition, similar to the proposed rule, under this alternative there would be an enhanced sampling program to assure that labeling was accurate and not misleading. It was envisioned that this sampling program would supplement, but not replace, the existing in-plant inspection task that directs inspectors of official establishments and analogous personnel of certified foreign establishments to check a sample of labeling to determine if the labeling is correct and used as intended.

After reviewing the comments received in response to the proposed rule (see following discussion), and in light of FSIS' ongoing reassessment of its labeling policies, FSIS has decided to proceed, at this time, with the gradual streamlining and modernization of the prior labeling approval system. Therefore, FSIS will expand the types of labeling that will be generically approved, as opposed to instituting at this time a system where all labeling would be generically approved. FSIS anticipates making further changes after completing the reassessment of the prior label approval system.

Discussion of Comments

FSIS received 122 comments in response to the proposed rule. The majority of the comments (88) were submitted by food manufacturers, while 13 were received from industry trade associations, 12 from food industry consultants, 5 from consumers, 3 from foreign governments, and 1 from another Federal agency. The following discussion is a summary of the major issues and comments received.

1. ''Sketch Only'' System of Approval

Many commenters supported the streamlining of the current prior labeling approval process which would eliminate the need to submit final labeling for approval, and which, in turn, would eliminate unnecessary duplication in the labeling approval system. However, a few commenters opposed a ''sketch only'' system of approval and wanted to maintain the existing system of approval. These commenters appeared to be concerned about their lack of understanding of all the existing labeling regulations and their ability to keep abreast of any future changes to the regulations. They expressed concern about the possible extent of their liability if a product were misbranded and severity of penalties that might occur as a result of an unintentionally misbranded product entering the marketplace.

FSIS believes that requiring a sketch-only system of approval for most labeling situations will alleviate unnecessary duplication in the labeling approval system. Conformance with labeling policies and regulations will be verified when labeling is submitted as a sketch. FSIS does not believe it is necessary to reverify conformance of final labeling in order to prevent mislabeling of products, and, therefore, will permit final labeling that has been approved in sketch form to be used without further authorization from FSIS, where the final labeling is prepared without modification. Final labeling, however, that is altered from the approved sketch must be resubmitted as a ''sketch'' to FSIS for approval, unless the changes made to the final labeling conform with modifications included in the generic approval category.

A few commenters suggested that a numbering system, similar to the system that is currently used to identify final approved labeling, should be developed for sketch approvals when the Agency implements a sketch-only system of approval. FSIS intends to assign formal approval numbers to approved sketches. The numbering system will be similar to the system currently used for final approvals. The sketches will be processed and filed permanently for future reference.

2. Printer's Proof for Sketch Approval

While many commenters supported a sketch-only system of approval, in many cases, the support was contingent upon the Agency clarifying its definition for a sketch as a ''printer's proof or equivalent.''

It was not the intent of the Agency to limit sketch submittals solely to actual ''printer's proofs.'' FSIS believes that the term ''equivalent,'' as used in the proposed definition of ''sketch,'' conveys that methods of sketch preparation, other than an actual ''printer's proof,'' would also be acceptable. Accordingly, FSIS will accept a printer's proof or equivalent, such as sketches that are hand drawn or computer generated or other reasonable facsimiles that clearly represent the final version of the labeling. FSIS has added examples of what would be considered equivalent to a printer's proof in the final regulation. FSIS believes it is appropriate to leave in the phrase ''or equivalent'' in order to provide the needed flexibility to meet the requirement of submission of a sketch. As FSIS moves to a sketch-only system of approval, the Agency believes it is necessary to emphasize the importance of submitting sketches prepared in a manner that clearly indicates all labeling features, including their size, location, and an indication of final colors so that final printed labeling will be accurately and correctly prepared.

3. Final Color Indication on Sketches

A few commenters objected to the need for an indication of final color on the sketch. However, after reviewing these comments, FSIS believes that these commenters may have believed that the requirement of indicating final colors on the sketch meant that FSIS would accept only color proofs or color sketches.

FSIS is not requiring that a color proof or sketch be submitted. However, FSIS

believes it is necessary to continue to require an indication of final color to ensure that the labeling requirements for proper contrast and legibility will be met on final printed labeling. In light of the comments received, FSIS has clarified the final regulations to make it clear that the requirement of indicating final colors can be met in a numbers of ways. The requirements of indication of final color may be met by: Submission of a color sketch, submission of a sketch which indicates by descriptive language the final colors, or submission with a sketch of previously approved final labeling that indicates the final colors.

4. Size Limitations for Sketch Submittals

A few commenters objected to the size limitations for sketch submittals (i.e., 8½ x 14 inches) that was proposed in an effort to accommodate the expected automation and modernization of the labeling approval process.

Although the Agency continues to move toward a more automated, modernized approval system, the Agency is not yet at the stage of development that such restrictions are necessary. Therefore, FSIS will not limit sketch submittals to the proposed size requirement of no larger than 8½ x 14 inches.

5. Temporary Approval

Several commenters requested that temporary labeling approval be extended beyond 6 months.

FSIS grants and proposed to continue to grant temporary approval for labeling deemed deficient in some particular for a period of time not to exceed 6 months, provided that (1) the proposed labeling would not misrepresent the product, (2) use of the labeling would not present any potential health, safety, or dietary problems to the consumer, (3) denial of the request would create undue economic hardship, and (4) an unfair competitive advantage would not result from granting the temporary approval.

FSIS continues to believe that changes to labeling that must be made as a result of these conditions can be accomplished within a 6-month timeframe. In certain circumstances, the current and proposed regulations allow temporary approvals to be extended beyond the 6-month timeframe. Therefore, FSIS has not extended the maximum time granted to temporary approval requests beyond that which currently exists in the regulations.

6. Expansion of the Generic Label Approval Category

Commenters concurred with the Agency's proposed expansion of the generically approved labeling categories to include those categories of labeling presently approved by the IIC. However, most commenters did not agree that standardized products should be included in the generic category. Commenters stated that not all of the existing product standards provide enough guidance to ensure labeling compliance. In addition, several commenters stated that few standards are actually codified in the Federal meat and poultry products inspection regulations, and that numerous informal standards are contained in the Standards and Labeling Policy Book.

Although FSIS acknowledges the concerns expressed, FSIS continues to believe that standardized products should be included in the generic approval category. Permitting the generic approval of labeling for these products will not affect the safety of the products. Consumers will continue to receive the information they need about the products from the ingredients statement and the Nutrition Facts panel. FSIS' prior review of these labels does not provide any additional benefits and requires resources that could be used in overseeing other areas more directly related to health and safety. In addition, including standardized products under generic approvals streamlines and makes more efficient the label review process, without compromising product safety. Furthermore, this action is consistent with the Agency's focus on using resources to reduce actual risks to the public as discussed in its February 3, 1995, HACCP proposal.

FSIS has also determined that standardized products contained in the Standards and Labeling Policy book should be eligible for generic approval.

Therefore, FSIS has modified the provison for generic approval of standardized products in two ways. First, FSIS will grant manufacturers the flexibility to generically approve labeling for standardized products found in 9 CFR part 319 or part 381, subpart P, and the Standards and Labeling Policy Book, provided such labeling does not contain any special claims or the product is not a domestic product labeled in a foreign language. Second, FSIS will allow the submission of sketch labeling for review and approval if manufacturers so desire. FSIS believes that the above modification will alleviate the concerns expressed by the commenters.

FSIS is currently reassessing the role of regulatory and policy standards in promoting meat and poultry products with better nutritional profiles (e.g., lower in fat and cholesterol). FSIS is also currently reassessing its labeling regulations. Additionally, an assessment is planned that will involve public input regarding modification or elimination of the informal policy standards in the Standards and Labeling Policy Book.

A few commenters expressed concern that labeling prepared for the Child Nutrition (CN) Program, conducted by USDA's Food and Nutrition Service, would not receive adequate review under the proposed approval system and opposed the inclusion of these product labels in the generic approval category. FSIS views CN information on the labeling as if it were a claim. Therefore, CN labeling will not be included in a generic approval category and will require review and sketch approval by FSIS.

As stated in the proposal, several commenters to the ANPR believed that the generic approval category could be expanded beyond those situations specifically identified in the ANPR. In the past, FSIS had been reluctant to expand the generic approval category further, until it could be demonstrated that this method of labeling approval would continue to provide the public with accurate, non-misleading labeling information. However, these suggestions were brought up again among the comments to the proposal. The Agency is now convinced that its present position is unnecessarily restrictive and now agrees that there are some other labeling categories that should be included in the generic approval category which would result in little, if any, risk of misbranding. Also, FSIS believes that the scope of some generic approval categories should be broadened.

After reviewing the suggestions presented by the commenters, FSIS agrees that it is appropriate to include additional categories of labeling under the generic approval category and to broaden the scope of some of the generic approval categories. Therefore, the following categories of labeling that will be generically approved have been either added or broadened in this final rule for the reasons explained below.

a. Quantitative adjustments to the nutrition labeling information, except for serving sizes, provided the changes do not affect the accuracy and consistency of the nutrition labeling information, (e.g., revising the fat content from 10 to 7 grams), for labeling that was previously approved by FLD as sketch labeling.

Meat and poultry companies will periodically need to revise nutrition information on their labeling as a result of ongoing nutrition monitoring programs. Several commenters

recognized that this particular labeling situation was not adequately addressed by the nutrition labeling regulations and suggested that quantitative nutrition labeling changes could be included in the expanded generic approval category.

FSIS never intended to require manufacturers to resubmit labeling for approval to make quantitative changes to the nutrition labeling information. Since the manufacturers are responsible for declaring accurate nutrition information, FSIS believes that quantitative nutrition information labeling changes will have little impact on the accuracy of the labeling. Requiring such labeling changes to be resubmitted through the approval process would undermine the Agency's efforts to streamline the approval process and reduce the volume of labeling submitted to FSIS for review. Furthermore, the accuracy of nutrition labeling will be monitored through the Agency's planned compliance, audit, and sampling activities. However, FSIS does not believe that it is appropriate to allow quantitative changes for serving sizes to be included in the expanded generic approval category. The need to maintain uniform serving sizes for specific products is very critical to the overall integrity of the nutrient profile of products. Thus, quantitative nutrition information labeling changes, except for serving sizes, may be generically approved for labeling that was previously approved by FLD as sketch labeling, provided the changes in no way render the labeling false or misleading in any particular.

b. Labeling for consumer test products not intended for sale.

Historically, products prepared for consumer test purposes have not presented FSIS with regulatory problems. These products are produced under controlled conditions and in limited quantities, and are not broadly distributed in the marketplace. In addition, all of the product's ingredients must be listed on the labeling and conform with all regulatory restrictions on their use. FSIS believes that permitting the generic approval of labeling for consumer test products will allow processors to more expeditiously develop and produce new, safe, wholesome products while testing consumer acceptance. Accordingly, FSIS will allow generic approval of labeling for consumer test products that will not be sold.

c. Deletion of any claim or other nonmandatory feature or information on labeling that was previously approved in sketch form, provided the deletion of the information will not render the labeling false or misleading in any particular.

Companies often delete claims and other nonmandatory information on the labeling (e.g., promotional information, cooking instructions, and recipes) as a part of their overall marketing strategy. Some examples of these situations are already included in the existing generic approval category (e.g., deletion of the word ''new'' and modification of cooking instructions (9 CFR 317.5 and 381.134)). FSIS believes there is little, if any, risk of misbranding by broadening the generic approval category to allow the deletion of any claim or other nonmandatory information, for labeling previously approved in sketch form.

d. The addition or deletion of a direct translation of the English language into a foreign language for products marked ''for export only,'' for labeling previously approved by FLD as sketch labeling.

Traditionally, the responsibility of accurately making a direct translation of the English language into a foreign language for products marked ''for export only'' has rested with manufacturers. FSIS believes that the addition or deletion of a direct translation of the English language into a foreign language for products marked ''for export only'' will not compromise the accuracy of the labeling of those products. Furthermore, FSIS is of the opinion that the inclusion of such labeling modifications in the generically approved category is consistent with the intent of this final rule. Thus, FSIS will permit generic approval of the addition or deletion of a direct translation of the English language into a foreign language for products marked ''for export only,'' whose labeling was previously approved in sketch form.

e. The substitution of any unit of measurement with its abbreviation or the substitution of an abbreviation with its unit of measurement.

In its proposal, FSIS proposed that the substitution of the abbreviation ''lb.'' for ''pound,'' or ''oz.'' for ''ounce,'' or the substitution of the word ''pound'' for ''lb.,'' or ''ounce'' for ''oz.'' on labeling would be generically approved. FSIS now believes, after reviewing the comments, that broadening the scope of this category to include the substitution of any unit of measurement with its abbreviation or the substitution of an abbreviation with its unit of measurement will not compromise the accuracy of product labeling. Thus, FSIS will permit the substitution of any unit of measurement with its abbreviation and substitution of an abbreviation with its unit of measurement, e.g., ''lb.'' for ''pound'' or ''teaspoon'' for ''tsp.''

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

FSIS had proposed to allow generic approval during holiday seasons of wrappers or other coverings bearing floral or foliage designs, illustrations, or other emblematic holiday designs.

FSIS now believes, after reviewing the comments, that allowing the generic approval of only holiday designs on wrappers or other covers is too restrictive. Therefore, FSIS has broadened the scope of this category to permit the use of any pictorial or emblematic design, or illustration on wrappers or other covers, provided such design will not render the labeling to be false or misleading. FSIS is of the opinion that the inclusion of such labeling modification in the generically approved category is consistent with the intent of this final rule.

7. Voluntary Approval for Labeling Eligible For Generic Approval

Some of the commenters who expressed support for the expansion of the generic approval category wanted to retain the option of submitting labeling to FSIS for review and approval, even when the labeling is eligible for generic approval.

As previously stated, FSIS is aware that there are some concerns about the provision to include standardized products within the generically-approved labeling category. The intent of this rulemaking is to improve the overall efficiency of the labeling approval process by limiting the amount of labeling submitted to FSIS for review and approval, which cannot be achieved if all labeling authorized to be generically approved were permitted to be submitted for review and approval. Further, permitting all labeling authorized for generic approval to be submitted for review and approval would take away from the limited resources FSIS has at its disposal which it needs to review those aspects of labeling requirements that involve potential public health concerns. Nonetheless, FSIS has always provided, and will continue to provide advice and counsel to the industry and to the public at-large concerning labeling issues. To make very clear that FSIS remains committed to providing needed advice in appropriate circumstances, FSIS has modified the proposed rule to allow manufacturers to voluntarily submit sketch labeling for standardized

products for review and approval. Many of these products have complex compositional and minimum content requirements. FSIS is also providing this option for standardized products contained in the Standards and Labeling Policy Book because many of these products also have complex compositional and minimum content requirements. FSIS has determined that manufacturers should have the option, at this time, of submitting sketch labeling for standardized products for review. However, as FSIS begins a more indepth review of its labeling requirements and practices, FSIS may propose in a future rulemaking to remove this voluntary submittal option. This would be consistent with the intent of this rulemaking, which is to limit the types of labeling submitted for review so that FSIS resources can be focused on issues that bear directly on public health and food safety.

8. Generic System of Labeling Approval

Under an all-generic system, establishments would design, develop, print, and apply labeling without submission to FSIS for review and approval. A few commenters supported the proposed concept of an all-generic labeling approval system, citing reductions in costs and improved efficiency. However, the majority of the commenters opposed an all-generic system of approval because of concerns with their ability to fully understand and consistently interpret the existing labeling policies and regulations, the potential for misbranded product to enter the marketplace, and concern with penalties for misbranding and product recalls.

FSIS is currently reassessing the proposed all-generic labeling system of approval as an alternative option in an effort to streamline and modernize the label review process.

9. Preemption Concerns

Several commenters expressed concern that the proposal acknowledged ''concurrent jurisdiction'' (i.e., the States and local governments may exercise concurrent jurisdiction over meat and poultry products that are outside official establishments for the purpose of preventing distribution of meat and poultry products that are misbranded or adulterated under the FMIA or PPIA). The comments indicated that FSIS should clearly state that the new labeling requirements will have a preemptive effect on the requirements of the various States and local governments.

The provisions of the FMIA and PPIA preclude any State or local jurisdiction from imposing ingredient, marking, or labeling requirements on products produced in federally inspected establishments that are different or in addition to Federal requirements. In this regard, State and local jurisdictions cannot impose different or additional requirements, regardless of whether the labeling is approved in sketch form by FSIS or generically approved by FSIS.

10. The IIC's Role Under a Generic Approval System

Many commenters were concerned about the responsibilities of the IIC with respect to product packaged in generically approved labeling. Commenters repeatedly stated that the role of the IIC must be clearly defined for these proposed changes to be implemented efficiently. Most commenters contended that the IIC's limited knowledge and expertise on labeling regulations and policies may lead to unwarranted interference or retention of product. In addition, some commenters stated that labeling interpretations made by individual inspectors would not contribute toward uniformity in labeling decisions.

FSIS believes some of the concerns raised by commenters will be alleviated since the Agency will issue a notice to field personnel that will clearly describe how to respond to and report label deficiencies.

FSIS is currently conducting a top to bottom review of how the Agency defines its regulatory roles, allocates resources, and is organized (60 FR 32127). The IIC's role with regard to monitoring product formulations and processing procedures will be addressed in that review but will not change or be diminished as a result of this regulation. Inspection personnel will continue to observe and monitor product formulations and processing procedures to assure conformance with general labeling requirements. If inspection personnel observe that products are not being manufactured in accordance with their formulation or believe that a situation may have health or safety significance, they are to take the appropriate action necessary to ensure that misbranded and/or adulterated product does not enter commerce. In addition, inspection personnel are to immediately contact FLD, through appropriate channels, for technical assistance.

11. Recordkeeping

FSIS proposed that domestic establishments and establishments certified by officials of a foreign inspection system maintain records on all labeling used, and make such records available to any authorized USDA official, upon request. Each record would consist of the product's labeling, formulation, and processing procedure. Several commenters requested clarification about the location and content of the required records.

Manufacturers of meat and poultry products will be required to maintain records of all labeling used, along with the product's formulation and processing procedure in accordance with 9 CFR part 320 of the meat inspection regulations for meat products, and in accordance with 9 CFR part 381, subpart Q of the poultry products inspection regulations for poultry products. This means that records of the actual labeling used on a product, along with the product's formulation and processing procedures must be maintained.

In regard to where the required records must be located, i.e., maintained, the final regulations, as did the proposal, require, as previously stated, the records to be maintained in accordance with 9 CFR part 320 for meat products, and in accordance with 9 CFR part 381, subpart Q for poultry products. In accordance with section 320.2 of the meat inspection regulations and section 381.176 of the poultry products inspection regulations, required records must be maintained by a person, including a corporation at the place of business where the business is conducted, except that if a person, including a corporation conducts business at multiple locations, records may be maintained at the headquarters office. FSIS does not believe it is necessary to require all establishments at multiple locations to maintain copies of the labeling records required by this final rule. However, the IIC will retain his or her authority to request the labeling records to verify the accuracy of the labeling of products as it relates to official business.

Any existing labeling files maintained by inspection personnel at federally inspected establishments will be returned to plant management at the time this regulation is implemented.

This final rule will eliminate the requirement that inspection personnel maintain labeling files. FSIS has determined, after further examination of the regulations, that the elimination of this requirement will necessitate changes in other related provisions of the meat and poultry inspection regulations (9 CFR 317.14, 381.141, and 381.137). FSIS inadvertently omitted these provisions in the proposed rule but believes such provisions must be amended to avoid confusion among inspection personnel regarding their

labeling responsibilities and to make the regulations consistent. The current provisions in 9 CFR 317.14 and 381.141 require the inspector, upon notification of an obsolete label, to return the label that is in the official labeling file to the establishment and to forward the label transmittal to FLD for further data processing. This procedure will become unnecessary because the final rule, as did the proposal, no longer, in general, requires inspection personnel to maintain labeling files. Thus, FSIS is eliminating 9 CFR 317.14 and 381.141 to relieve inspection personnel of the responsibility of handling obsolete labeling records. In addition, the provision in 9 CFR 381.137 states that no inspector shall authorize the use of any labeling or device unless he or she has on file evidence that such labeling or device has been approved in accordance with the appropriate provisions. Because inspection personnel will no longer maintain labeling files, the IIC's responsibility for authorizing the use of labeling will not be required. Thus, FSIS is revising 9 CFR 381.137 to delete the IIC's responsibility for authorizing the use of approved labeling based on evidence maintained in official labeling files. FSIS believes that amending the aforementioned provisions is consistent with the intent of this final rule.

12. Auditing the Accuracy of Generically Approved Labeling

To monitor compliance with the Federal meat and poultry products inspection regulations, FSIS proposed to select samples of generically approved labeling.

In addition to routine compliance and inspection activities, FSIS will develop and implement a sampling plan for the expanded types of labeling under the generic approval category. The sampling plan will be directed from FSIS headquarters in Washington. FSIS inspection personnel will collect all pertinent labeling records corresponding to each selected sample. These samples would be collected and forwarded to FLD for audit. FLD will evaluate the samples to determine if they comply with labeling regulations and policies.

13. Modernization of the Labeling Review System

All of the commenters responding to this issue of modernizing the labeling review system were in support of the Agency's efforts. Such commenters included those who supported sketch only approval, as well as those who supported generic approval. The commenters stated that an electronic communications system would be cost effective by eliminating unnecessary paperwork and taking advantage of new information, collection, and storage technologies.

FSIS will continue to make incremental improvements in automation as budget constraints allow. Furthermore, FSIS believes that its current efforts to automate its labeling review system are consistent with the President's initiatives for greater efficiency in government services.

Miscellaneous Changes

The proposal stated that products labeled ''for export only'' in U.S. establishments that do not contain any special claims would be permitted to be labeled with generically approved labeling and thus labeling for such products would not have to be submitted in sketch form to FSIS for approval. However, after further consideration, FSIS has concluded that products designated ''for export only'' and destined to foreign countries should be reviewed and approved under the same provisions proposed for other products manufactured in U.S. establishments. FSIS acknowledges its responsibility for ensuring the accuracy of all labeling of meat and poultry products manufactured in Federal establishments, regardless of the product's destination. Also, most countries that receive product from the United States do not have label review programs. Therefore, these countries depend on FSIS review and approval as their assurance that imported products are accurately labeled. Thus, FSIS has decided to withdraw this provision of its proposal, and to require, as it did prior to its proposal, that labeling designated ''for export only'' be submitted to FSIS for approval, except when such labeling comes within the categories of labeling that will be generically approved. As FSIS reforms its prior labeling approval system, more of these labels will be considered for inclusion in the generic approval category. Although FSIS is continuing to provide labeling review services for these exporters, it will explore the possibility of charging user fees in the future for such services.

As stated in the proposal, where sketch labeling is required to be submitted to FLD for review and approval, a parent company for a corporation may submit only one labeling application for a product produced in other establishments, which are owned by the corporation. FSIS has clarified this matter in the Federal meat and poultry products regulations.

On August 8, 1994, FSIS published in the Federal Register a final rule on the placement of nutrition labeling and other mandatory labeling on meat and poultry products (59 FR 40209). That rule included a provision identifying as generically approved, final labeling bearing nutrition labeling information which was approved in sketch form or other version that clearly shows all required features, size, location, and identification of final color, by FSIS (9 CFR 317.5(c) and 381.134(c)). This final rule on prior labeling approval, as did the proposed rule, identifies as generically approved, final labeling, which would include labeling bearing nutrition information, that was submitted for approval and approved by FSIS in sketch form. Therefore, the current provisions in 9 CFR 317.5(c) and 381.134(c) are no longer needed. Accordingly, FSIS is amending the Federal meat and poultry products inspection regulations to eliminate 9 CFR 317.5(c) and 381.134(c).

This final rule, as did the proposal, will eliminate the need for FSIS inspection personnel to maintain labeling records. Consequently, FLD will no longer need labeling applications to be submitted in triplicate form. Accordingly, FSIS is clarifying this requirement in the Federal meat and poultry products inspection regulations 9 CFR 317.4(c) and 381.132(c) to reflect that labeling applications only need to be submitted in duplicate form.

Effective Date

After careful consideration of the changes necessary to implement the revised labeling system, FSIS has decided to make this rule effective 6 months from the date of publication. The Agency believes that a longer implementation period will alleviate unnecessary delays in the labeling review process. This longer implementation period will also minimize burdens related to the transfer of labeling records from the IIC's to the establishments, inspection personnel and industry orientation to new procedures, the auditing of generically approved labels, and various other miscellaneous changes. In addition, the longer implementation period will allow the Agency time to develop and issue to its inspection personnel, official guidelines for implementing this regulation.

Executive Order 12866

The final rule has been reviewed under Executive Order 12866 and has been determined to be significant. FSIS has assessed the impacts of its final rule

that expands the types of labeling, used on meat and poultry products, that are generically approved; i.e., establishments will be able to use certain labeling on meat and poultry products without submission of the labeling to FSIS for approval by the IIC or FLD, in Washington, DC. This rule eliminates unnecessary duplication in the labeling approval system.

Benefits of the Final Rule

This regulation will benefit consumers, the meat and poultry industry, and the Agency. The final rule will reduce market inefficiencies caused by delays in new product introduction attributable to the labeling application and review process. Industry will be able to be more responsive to their consumers. Consumers will also benefit because new products will be introduced into the marketplace faster.

This final rule will reduce requirements for the submission of labeling for review and approval by FSIS. The final rule will streamline the label submission process from two steps (sketch and final) to a one step process (sketch only). Also, meat and poultry manufacturers will be able to make numerous labeling modifications without submitting certain labels for approval. This streamlined process will reduce the burden on industry by making the labeling approval process more convenient and cost-effective. Furthermore, those establishments that use representatives to present their labels to FLD for review will also save time and money. These savings will be realized because fewer labels will be required to be submitted to FLD. It is estimated that the reduction in the submission of labeling will save the meat and poultry establishments at least 20,000 hours.

This final rule will result in a savings of approximately $3 million in direct label application costs to the industry. This $3 million was derived by estimating that approximately 82,600 fewer labels, at a cost of $37 per label, would be submitted to FLD annually as a result of this final rule. Unknown additional savings will be realized by the industry, depending on the degree to which industry uses the generic approval authority for labeling for standardized products. This $3 million savings estimate differs from the savings that were attributed to the elimination of labeling application costs stated in the proposed rule ($5 million) because this final rule contains provisions for either generic approval or voluntary submission for review and approval of labeling for standardized products. The proposed rule contained provisions for mandatory generic approval of labeling for standardized products. This rule will reduce the paperwork burdens of industry by eliminating the application process for specific types of labeling.

Shifting responsibility for maintaining labeling records from the inspector will enable FSIS to redirect its inspection resources to areas more directly related to food safety. In addition, this rule is consistent with FSIS' February 3, 1995, Pathogen Reduction; Hazard Analysis and Critical Control Point Systems proposal and FSIS' other regulatory reform initiatives that are intended to focus inspection and other Agency resources on activities that have a direct bearing on food safety.

Costs of the Final Rule

This final rule requires that establishments submit only one labeling application for FSIS approval (sketch labeling) instead of two applications in those instances where labeling must be approved by FSIS. This final rule also expands the types of labeling that can be generically approved. For standardized products, this rule permits the voluntary submittal of sketch labeling for review, if desired by the manufacturer.

FSIS estimates that this final rule will result in $3 million annual savings in direct labeling application costs. The final rule does require, however, that establishments maintain copies of all labeling used, along with the product formulations and a description of the processing procedures used to formulate the product in accordance with 9 CFR 320.2 and part 381, subpart Q, for all labeling submitted for review and approval by FSIS, as well as for labeling in the generic approval category. This requirement should not impose any additional cost burden on establishments because most establishments already maintain copies of their labeling.

The labeling records maintained by the establishments must be made available to Agency officials upon request. FSIS will conduct periodic sampling of generically approved labeling from the records maintained by the establishments. This sampling will be conducted to monitor compliance of generically approved labeling with all labeling requirements. Activities related to the generic labeling sampling program will be absorbed into existing Agency resources, and, thus, will not impose additional Agency costs.

Executive Order 12778

This final rule has been reviewed under Executive Order 12778, Civil Justice Reform. States and local jurisdictions are preempted under the FMIA and the PPIA from imposing any marking, labeling, packaging, or ingredient requirements on federally inspected meat and poultry products that are in addition to, or different from, those imposed under the FMIA or PPIA. States and local jurisdictions may, however, exercise concurrent jurisdiction over meat and poultry products that are outside official establishments for the purpose of preventing the distribution of meat and poultry products that are misbranded or adulterated under the FMIA or PPIA, or, in the case of imported articles, which are not at such an establishment, after their entry into the United States. Under the FMIA and PPIA, States that maintain meat and poultry inspection programs must impose requirements that are at least equal to those required under the FMIA and PPIA. The States may, however, impose more stringent requirements on such State inspected products and establishments.

No retroactive effect will be given to this final rule. The administrative procedures specified in 9 CFR 306.5 and 381.35 must be exhausted prior to any judicial challenge of the application of the provisions of this rule, if the challenge involves any decision of an inspector relating to inspection services provided under the FMIA or PPIA. The administrative procedures specified in 9 CFR parts 335 and 381, subpart W, must be exhausted prior to any judicial challenge of the application of the provision of this rule with respect to labeling decisions.

Effect on Small Entities

The Administrator, FSIS, has determined that this final rule will not have a significant economic impact on a substantial number of small entities. This rule will affect small meat and poultry establishments, and other small entities involved in various label consulting activities, including those entities who specialize in obtaining label approval from FSIS. Most small meat and poultry establishments will benefit from the provisions in this rule as direct costs involved with the labeling application and approval process will be reduced. Costs involved with label design and printing will not change and would be incurred even without this final rule.

The affect of this final rule on those entities known as label expediters will depend on the percentage of their business directly involved with obtaining expedited approvals of product labels. There are about 13 firms that are involved on a consistent basis with obtaining label approvals. Eight of these 13 firms provide services other

than expedited label approvals. A reduction in the need for this service is not expected to significantly affect these entities. In addition, these firms will likely expand existing services not related to expediting label approvals. Also, certain types of labels will continue to need approval by the Food Labeling Division before they may be used. Therefore, firms whose primary service involves obtaining label approval will be able to continue providing this service.

Any impacts of this final rule on small entities will be mitigated because the Agency is providing a 6-month period before the final rule will be effective. Therefore, affected entities will be given time to adjust their current practices and/or to modify their businesses to lessen any possible negative affects of the final rule.

Paperwork Requirements

Abstract: This final rule expands the types of generically approved labeling currently authorized for use by meat and poultry establishments and certified foreign establishments. (Generically approved labeling is not required to be submitted to FSIS for review and approval.) The rule also permits the submission of only sketch labeling, except for temporary approvals, in those instances where labeling is required to be submitted for approval. The rule also requires the retention of certain records at the establishment.

Estimate of Burden: This final rule substantially reduces ''reporting'' requirements for official establishments. FSIS estimates that label submissions sent to Washington for review and approval will decrease by about 50 percent. For such submissions, FSIS estimates that 15 minutes will be the response time to prepare the label application form, submit it, along with the label, to FSIS or to a label expediter who will deliver the form and label to FSIS, and to file the records this rule requires establishments to maintain, which is approximately the same amount of time establishments currently utilize to meet paperwork requirements. FSIS believes that there will be no change in the time FSIS estimates, 60 minutes, it takes to design and develop labels in accordance with the regulations. In total, the burden associated with label approval submissions will decrease by 22,921 hours.

For generically approved labeling, FSIS estimates the addition of new generic labeling categories will result in a 50 percent increase of generically approved labels. Before this final rule, a copy of generically approved labeling was required to be filed with the inspector, and FSIS had estimated a 1 minute response time for this activity. The final rule eliminates this requirement and instead requires that a copy of the label and supporting information be maintained at the establishment. FSIS estimates it will take 2 minutes for the establishment to file this information. Therefore, there will be an increase in burden hours relating to generically approved labels by 2,691 hours.

Copies of this information collection assessment can be obtained from Lee Puricelli, Paperwork Specialist, Food Safety and Inspection Service, USDA, South Agriculture Building, Room 3812, Washington, DC 20250.

Send comments regarding the need and usefulness of the requirements, the accuracy of our burden hour estimate, ways to minimize the burden, including through the use of automated collection techniques or other forms of information technology, or any other aspect of this collection of information, to Lee Puricelli, Paperwork Specialist, see address above.

All responses to this notice will be summarized and included in the request for OMB approval. All comments will also become a matter of public record.

List of Subjects

9 CFR Part 306

Appeals, Meat inspection.

9 CFR Part 317

Food labeling, Meat inspection, Reporting and recordkeeping requirements.

9 CFR Part 320

Reporting and recordkeeping requirements.

9 CFR Part 327

Food labeling, Imports, and Meat inspection.

9 CFR Part 381

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

For the reasons set forth in the preamble, FSIS is amending 9 CFR parts 306, 317, 320, 327, and 381 as follows:

PART 306—ASSIGNMENT AND AUTHORITIES OF PROGRAM EMPLOYEES

1. The authority citation for part 306 is revised to read as follows:

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

2. Section 306.5 is amended by removing the last sentence.

PART 317—LABELING, MARKING DEVICES, AND CONTAINERS

3. The authority citation for part 317 is revised to read as follows:

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

4. Section 317.4 is revised to read as follows:

§ 317.4 Labeling approval.

(a) No final labeling shall be used on any product unless the sketch labeling of such final labeling has been submitted for approval to the Food Labeling Division, Regulatory Programs, Food Safety and Inspection Service, and approved by such division, accompanied by FSIS form, Application for Approval of Labels, Marking, and Devices, except for generically approved labeling authorized for use in § 317.5(b). The management of the official establishment or establishment certified under a foreign inspection system, in accordance with part 327 of this subchapter, must maintain a copy of all labeling used, along with the product formulation and processing procedure, in accordance with part 320 of this subchapter. Such records shall be made available to any duly authorized representative of the Secretary upon request.

(b) The Food Labeling Division shall permit submission for approval of only sketch labeling, as defined in § 317.4(d), for all products, except as provided in § 317.5(b) (2)–(9) and except for temporary use of final labeling as prescribed in paragraph (f) of this section.

(c) All labeling required to be submitted for approval as set forth in § 317.4(a) shall be submitted in duplicate to the Food Labeling Division, Regulatory Programs, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250. A parent company for a corporation may submit only one labeling application (in duplicate form) for a product produced in other establishments that are owned by the corporation.

(d) ''Sketch'' labeling is a printer's proof or equivalent which clearly shows all labeling features, size, location, and indication of final color, as specified in § 317.2. FSIS will accept sketches that are hand drawn, computer generated or other reasonable facsimiles that clearly reflect and project the final version of the labeling. Indication of final color may be met by: submission of a color sketch, submission of a sketch which indicates by descriptive language the final colors, or submission with the sketch of previously approved final labeling that indicates the final colors.

(e) Inserts, tags, liners, pasters, and like devices containing printed or graphic matter and for use on, or to be placed within, containers and coverings of product shall be submitted for approval in the same manner as provided for labeling in § 317.4(a), except that such devices which contain no reference to product and bear no misleading feature shall be used without submission for approval as prescribed in § 317.5(b)(7).

(f)(1) Consistent with the requirements of this section, temporary approval for the use of a final label or other final labeling that may otherwise be deemed deficient in some particular may be granted by the Food Labeling Division. Temporary approvals may be granted for a period not to exceed 180 calendar days, under the following conditions:

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

(ii) The use of the labeling 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 Food Labeling Division provided that the applicant demonstrates that new circumstances, meeting the above criteria, have developed since the original temporary approval was granted.

(g) The inspector-in-charge shall approve meat carcass ink brands and meat food product ink and burning brands, which comply with parts 312 and 316 of this subchapter.

5. Section 317.5 is revised to read as follows:

§ 317.5 Generically approved labeling.

(a)(1) An official establishment or an establishment certified under a foreign inspection system, in accordance with part 327 of this subchapter, is authorized to use generically approved labeling, as defined in paragraph (b) of this section, without such labeling being submitted for approval to the Food Safety and Inspection Service in Washington or the field, provided the labeling is in accordance with this section and shows all mandatory features in a prominent manner as required in § 317.2, and is not otherwise false or misleading in any particular.

(2) The Food Safety and Inspection Service shall select samples of generically approved labeling from the records maintained by official establishments and establishments certified under foreign inspection systems, in accordance with part 327 of this subchapter, as required in § 317.4, to determine compliance with labeling requirements. Any finding of false or misleading labeling shall institute the proceedings prescribed in § 335.12.

(b) Generically approved labeling is labeling which complies with the following:

(1) Labeling for a product which has a product standard as specified in part 319 of this subchapter or the Standards and Labeling Policy Book and which does not contain any special claims, such as quality claims, nutrient content claims, health claims, negative claims, geographical origin claims, or guarantees, or which is not a domestic product labeled in a foreign language;

(2) Labeling for single-ingredient products (such as beef steak or lamb chops) which does not contain any special claims, such as quality claims, nutrient content claims, health claims, negative claims, geographical origin claims, or guarantees, or which is not a domestic product labeled with a foreign language;

(3) Labeling for containers of 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, and are made available to the inspector-in-charge;

(4) Labeling for shipping containers which contain fully labeled immediate containers, provided such labeling complies with § 316.13;

(5) Labeling for products not intended for human food, provided they comply with part 325 of this subchapter;

(6) Meat inspection legends, which comply with parts 312 and 316 of this subchapter;

(7) Inserts, tags, liners, pasters, 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) Labeling for consumer test products not intended for sale; and

(9) Labeling which was previously approved by the Food Labeling Division as sketch labeling, and the final labeling was prepared without modification or with the following modifications:

(i) All features of the labeling are proportionately enlarged or reduced, provided that all minimum size requirements specified in applicable regulations are met and the labeling is legible;

(ii) The 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.'';

(iii) A master or stock label 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);

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

(v) A change in the language or the arrangement of directions pertaining to the opening of containers or the serving of the product;

(vi) 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;

(vii) Any change in the name or address of the packer, manufacturer or distributor that appears in the signature line;

(viii) Any change in the net weight, provided the size of the net weight statement complies with § 317.2;

(ix) The addition, deletion, or amendment of recipe suggestions for the product;

(x) Any change in punctuation;

(xi) Newly assigned or revised establishment numbers for a particular establishment for which use of the labeling has been approved by the Food Labeling Division, Regulatory Programs;

(xii) The addition or deletion of open dating information;

(xiii) A change in the type of packaging material on which the label is printed;

(xiv) 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;

(xv) The deletion of the word ''new'' on new product labeling;

(xvi) The addition, deletion, or amendment of special handling

statements, provided that the change is consistent with § 317.2(k);

(xvii) The addition of safe handling instructions as required by § 317.2(l);

(xviii) 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 parts 318 and 319 of this subchapter;

(xix) Changes in the color of the labeling, provided that sufficient contrast and legibility remain;

(xx) A change in the product vignette, provided that the change does not affect mandatory labeling information or misrepresent the content of the package;

(xxi) A change in the establishment number by a corporation or parent company for an establishment under its ownership;

(xxii) 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;

(xxiii) Deletion of any claim, and the deletion of non-mandatory features or non-mandatory information; and

(xxiv) The addition or deletion of a direct translation of the English language into a foreign language for products marked ''for export only.''

§ 317.4 [Removed and reserved]

6. Section 317.14 is removed and reserved.

PART 320—RECORDS, REGISTRATION, AND REPORTS

7. The authority citation for part 320 is revised to read as follows:

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

8. Section 320.1 is amended by adding a new paragraph (b)(11) to read as follows:

§ 320.1 Records required to be kept.

* * * * *

(b) * * *

(11) Records of all labeling, along with the product formulation and processing procedures, as prescribed in § 317.4 and § 317.5.

PART 327—IMPORTED PRODUCTS

9. The authority citation for part 327 is revised to read as follows:

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

10. Section 327.14(c) is revised 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 317 of this subchapter 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.

§ 327.24 [Amended]

11. Section 327.24 is amended by removing the last sentence.

PART 381—POULTRY PRODUCTS INSPECTION REGULATIONS

12. The authority citation for part 381 is revised to read as follows:

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

13. Section 381.35 is amended by revising the last sentence to read as follows:

§ 381.35 Appeal inspections; how made.

* * *. The poultry or poultry products involved in any appeal shall be identified by U.S. retained tags and segregated in a manner approved by the inspector pending completion of an appeal inspection.

14. Section 381.132 is revised to read as follows:

§ 381.132 Labeling approval.

(a) No final labeling shall be used on any product unless the sketch labeling of such final labeling has been submitted for approval to the Food Labeling Division, Regulatory Programs, Food Safety and Inspection Service, and approved by such division, accompanied by FSIS Form, Application for Approval of Labels, Marking, and Devices, except for generically approved labeling authorized for use in § 381.133(b) (2)–(9). The management of the official establishment or establishment certified under a foreign inspection system, in accordance with subpart T of this part, must maintain a copy of all labeling used, along with the product formulation and processing procedure, in accordance with subpart Q of this part. Such records shall be made available to any duly authorized representative of the Secretary upon request.

(b) The Food Labeling Division shall permit submission for approval of only sketch labeling, as defined in § 381.132(d), for all products, except as provided in § 381.133(b) (2)–(9) and except for temporary use of final labeling as prescribed in paragraph (f) of this section.

(c) All labeling required to be submitted for approval as set forth in § 381.132(b) shall be submitted in duplicate to the Food Labeling Division, Regulatory Programs, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250. A parent company for a corporation may submit only one labeling application (in duplicate) for a product produced in other establishments that are owned by the corporation.

(d) ''Sketch'' labeling is a printer's proof or equivalent which clearly shows all labeling features, size, location, and indication of final color, as specified in subpart N of this part. FSIS will accept sketches that are hand drawn, computer generated or other reasonable facsimiles that clearly reflect and project the final version of the labeling. Indication of final color may be met by: submission of a color sketch, submission of a sketch which indicates by descriptive language the final colors, or submission with the sketch of previously approved final labeling that indicates the final colors.

(e) Inserts, tags, liners, pasters, and like devices containing printed or graphic matter and for use on, or to be placed within, containers and coverings of product shall be submitted for approval in the same manner as provided for labeling in § 381.132(a), except that such devices which contain no reference to product and bear no misleading feature shall be used without submission for approval as prescribed in § 381.133(b)(9).

(f)(1) Consistent with the requirements of this section, temporary approval for the use of a final label or other final labeling that may otherwise be deemed deficient in some particular may be granted by the Food Labeling Division. Temporary approvals may be granted for a period not to exceed 180 calendar days under the following conditions:

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

(ii) The use of the labeling 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 Food Labeling Division, provided that the applicant demonstrates that new circumstances, meeting the above criteria, have developed since the original temporary approval was granted.

15. Section 381.133 is redesignated as § 381.134, and § 381.134 is redesignated as § 381.133 and revised to read as follows:

§ 381.133 Generically approved labeling.

(a)(1) An official establishment or an establishment certified under a foreign inspection system, in accordance with subpart T of this part, is authorized to use generically approved labeling, as defined in paragraph (b) of this section, without such labeling being submitted for approval to the Food Safety and Inspection Service in Washington or the field, provided the labeling is in accord with this section and shows all mandatory features in a prominent manner as required in subpart N of this part, and is not otherwise false or misleading in any particular.

(2) The Food Safety and Inspection Service shall select samples of generically approved labeling from the records maintained by official establishments and establishments certified under foreign inspection systems, in accordance with subpart T of this part, as required in § 381.132, to determine compliance with labeling requirements. Any finding of false or misleading labeling shall institute the proceedings prescribed in § 381.233.

(b) Generically approved labeling is labeling which complies with the following:

(1) Labeling for a product which has a product standard as specified in subpart 381 of this subchapter or the Standards and Labeling Policy Book and which does not contain any special claims, such as quality claims, nutrient content claims, health claims, negative claims, geographical origin claims, or guarantees, or which is not a domestic product labeled in a foreign language;

(2) Labeling for single-ingredient products (such as chicken legs or turkey breasts) which does not contain any special claims, such as quality claims, nutrient content claims, health claims, negative claims, geographical origin claims, or guarantees, or which is not a domestic product labeled with a foreign language;

(3) Labeling for containers of 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, and are made available to the inspector-in-charge;

(4) Labeling for shipping containers which contain fully labeled immediate containers, provided such labeling complies with § 381.127;

(5) Labeling for products not intended for human food, provided they comply with §§ 381.152(c) and 381.193, and labeling for poultry heads and feet for export for processing as human food if they comply with § 381.190(b);

(6) Poultry inspection legends, which comply with subpart M of this part;

(7) Inserts, tags, liners, pasters, 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) Labeling for consumer test products not intended for sale; and

(9) Labeling which was previously approved by the Food Labeling Division as sketch labeling, and the final labeling was prepared without modification or with the following modifications:

(i) All features of the labeling are proportionately enlarged or reduced, provided that all minimum size requirements specified in applicable regulations are met and the labeling is legible;

(ii) The 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.'';

(iii) A master or stock label 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);

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

(v) A change in the language or the arrangement of directions pertaining to the opening of containers or the serving of the product;

(vi) 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;

(vii) Any change in the name or address of the packer, manufacturer or distributor that appears in the signature line;

(viii) Any change in the net weight, provided that the size of the net weight statement complies with § 381.121;

(ix) The addition, deletion, or amendment of recipe suggestions for the product;

(x) Any change in punctuation;

(xi) Newly assigned or revised establishment numbers for a particular establishment for which use of the labeling has been approved by the Food Labeling Division, Regulatory Programs;

(xii) The addition or deletion of open dating information;

(xiii) A change in the type of packaging material on which the label is printed;

(xiv) 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;

(xv) The deletion of the word ''new'' on new product labeling;

(xvi) The addition, deletion, or amendment of special handling statements, provided that the change is consistent with § 381.125(a);

(xvii) The addition of safe handling instructions as required by § 381.125(b);

(xviii) 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 § 381.147 and subpart P of this part;

(xix) Changes in the color of the labeling, provided that sufficient contrast and legibility remain;

(xx) A change in the product vignette, provided that the change does not affect mandatory labeling information or misrepresent the content of the package;

(xxi) The addition, deletion, or substitution of the official USDA poultry grade shield; (xxii) A change in the establishment number by a corporation or parent company for an establishment under its ownership;

(xxiii) Changes in nutrition labeling that only involve quantitative adjustments to the nutrition labeling information, except for services sizes, provided the nutrition labeling information maintains its accuracy and consistency;

(xxiv) Deletion of any claim, and the deletion of non-mandatory features or non-mandatory information;

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

(xxvi) The addition of a descriptive term as required by § 381.129(b)(6).

16. Section 381.137 is revised to read as follows:

§ 381.137 Evidence of labeling and devices approval.

No inspector shall authorize the use of any device bearing any official inspection legend unless he or she has on file evidence that such device has been approved in accordance with the provisions of this subpart.

§ 381.141 [Removed and reserved]

17. Section 381.141 is removed and reserved.

18. Section 381.175 is amended by adding a new paragraph (b)(6) to read as follows:

§ 381.175 Records required to be kept.

* * * * *

(b) * * *

(6) Records of all labeling, along with the product formulation and processing procedures, as prescribed in §§ 381.132 and 381.133.

19. Section 381.202(d) is amended by removing the last sentence and by revising the next to the last sentence to read as follows:

§ 381.202 Poultry products offered for entry; reporting of findings to customs; handling of articles refused entry; appeals, how made; denaturing procedures.

* * * * *

(d) * * *. The poultry or poultry products involved in any appeal shall be identified by U.S. retained tags and segregated in a manner approved by the inspector pending completion of an appeal inspection.

* * * * *

20. Section 381.205(c) is revised 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 §§ 381.132 and 381.133 before products bearing such marks and other labeling will be permitted for entry into the United States.

21. Section 381.206 is amended by adding to the end thereof the following sentence:

§ 381.206 Labeling of shipping containers of poultry products offered for entry.

* * *. All labeling used with a shipping container of imported poultry products must be approved in accordance with subpart N of this part.

Done at Washington, DC, on: December 21, 1995.

Michael R. Taylor,

Acting Under Secretary for Food Safety.

[FR Doc. 95–31392 Filed 12–26–95; 3:36 pm]

BILLING CODE 3410–DM–P