

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 number 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 provision 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