

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