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