

January 10, 2012

Ms. Rosalyn Murphy-Jenkins
Director, Labeling and Program Delivery
Division
Food Safety and Inspection Service
United States Department of Agriculture
Washington, DC 20250

Re: Preferred Meal Systems, Inc.: Request for Regulatory Waiver

Dear Ms. Murphy-Jenkins:

Consistent with our prior communications we are hereby petitioning FSIS, on behalf of our client, Preferred Meal Systems, to exercise its regulatory authority to provisionally classify as generically approved certain labeling materials for federally inspected meat and poultry products. More specifically, and in accordance with the authority provided to the Administrator at 9 C.F.R. 303.1(h) and 9 C.F.R. 381.3(b), we are proposing a regulatory experiment whereby all such labeling materials associated with the FSIS-regulated component of a product which would otherwise be generically approved, but for their presentation of a claim of acceptability for use in USDA-monitored child nutrition programs, be treated as generically approved. As discussed in further detail below, we strongly believe that the conduct of such experiment would eliminate unnecessary delay in the marketing of products and otherwise facilitate potential program improvements, without conflicting in any way with FSIS' pursuit of agency goals and objectives.

Discussion

Preferred Meal Systems ("Preferred") is a major supplier of ready-to-eat meals to the USDA-monitored school lunch program, as well as other federal feeding programs. Since many of these products contain meat and poultry, oversight of their processing and labeling frequently lies within the jurisdiction of FSIS. With regard to labeling, like all other federally inspected processors, Preferred is required to submit labeling materials, along with related formulation and processing information, to FSIS for its review and approval prior to their use, unless such labeling materials are classified generically approved. 9 C.F.R. 317.4, 317.5, 381.132, 381.133.

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In accordance with standard industry practice, most of Preferred's labels contain a statement asserting compliance with relevant child nutrition ("CN") labeling requirements. As FSIS is aware any such labeling materials bearing these claims are subject to independent review by USDA's Agricultural and Marketing Service ("AMS"), in order to ensure their accuracy. Once this AMS review is completed, however, the labels in question are also subjected to another round of review by FSIS. Until both reviews are completed these labeling materials and the products associated with them cannot be introduced into commerce.

This multiple review process can and does introduce significant delay into Preferred's product marketing activity without providing any identifiable corresponding public benefit. As such we believe that Preferred's request provides the agency with an excellent opportunity to conduct an experiment that lies well within its authority to conduct that will serve to immediately enhance the efficiency of both Preferred's and the agency's operations.

1. Review of the labels in question provides no public benefit. Preferred respectfully suggests that the public interest is not being served in any fashion by an FSIS review of the labeling materials in question. In this regard we should emphasize that this does not constitute a criticism or commentary upon the overall utility of FSIS' prior label approval function as a whole. To the contrary Preferred believes that such a review process serves a valuable purpose in the prevention of false and misleading practices, the oversight of the safety and suitability of various restricted ingredients, and the assurance of a high level of uniformity within the market place. We would further emphasize that, if this request for a regulatory experiment is accommodated, Preferred will continue to submit labels for FSIS' review whenever warranted through the creation of a new non-standard meat or poultry item, the development of a new and untested claim, or for any other appropriate reason.

All Preferred is requesting at present is the ability to use the materials in question if (1) they are associated with an FSIS-regulated component of a product that already is, except for the inclusion of a CN-related claim, within the generically approved category, and (2) the underlying validity of the CN claim itself is reviewed and approved by appropriate experts within AMS. Under these circumstances it simply does not appear that FSIS is in any position to conduct an additional review that adds value to the process. To put it differently the only element of such a label that would serve to trigger any prior FSIS review under this circumstance is the

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presentation of the CN claim,¹ and that particular claim will continue to be reviewed by another USDA employee with all of the relevant training and direct expertise regarding its suitability.

2. The request is compatible with FSIS' pending proposal on generic label approval.

On December 5, 2011, FSIS issued a proposal which would expand the circumstances in which FSIS considers as generically approved the labeling of certain meat and poultry products. 76 F.Reg. 75,809. It remains open for comment until February 3, 2012.

Any agreement by FSIS to sanction, oversee and analyze this regulatory experiment would be fully consistent with the agency goals articulated through this proposal. More specifically FSIS indicates in this document that expanding the types of labels that can be generically approved will lessen the burden on industry to submit labels to the agency while allowing FSIS to better focus on, and direct its resources to, other consumer protection and food safety activities (75 F.Reg. 75,841). Such redirected resources could, among other things, further enhance the label review function itself, both by eliminating unnecessary delay and permitting a more effectively targeted allocation of agency resources.

In addition, a properly designed and evaluated experiment of this particular nature can only serve to further inform this rulemaking proceeding. Preferred is perfectly open to carrying out this process in a transparent fashion and in full cooperation with FSIS. If the agency chooses to include others similarly situated within such an experiment, we would have no particular objection, nor would we object to any other reasonable recordkeeping and other reporting requirements associated with the experiment. The net result would be a development of additional data, entirely consistent with the objectives of the proposal that would further allow FSIS to evaluate real world experience with an expanded generic category in a situation where immediate public and private benefits would also be achieved.

¹ In this regard we note that most of the Preferred products at issue are meals. We recognize that FSIS does not have an overall standard, formal or informal, for meals and that this has implications regarding the eligibility of the associated label for generic approval status. In the present instance, however, it is the product's very eligibility for treatment as a meal that is central to the AMS review process. Under these circumstances we believe that, within this experiment at least, the generic classification needs to be driven by the particulars of the FSIS-regulated meat or poultry component only.

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Apart from the pending proposal, accommodation of this request would otherwise further the pursuit of several other agency objectives. As FSIS increasingly focuses upon its core food safety responsibilities, it has consistently pursued a policy of critically evaluating the relative benefits of its non-food safety-related activities and has made adjustments whenever warranted. This request clearly fits within this overall paradigm. It would also free agency resources at a time when FSIS, like all other federal agencies, is required to become increasingly sensitive to budgetary concerns.

In addition such an accommodation would be consistent with the agency's, and the Department's, broader goal of improving regulation and regulatory review. In this regard Executive Order 13563, issued by President Obama on January 18, 2011, states, among other things, that all agencies should development and implement regulations that put the least burden on society consistent with obtaining regulatory objectives, should identify and use the best, most innovative and least burdensome tools for achieving regulatory ends, should take into account benefits and costs, both quantitative and qualitative, and should be particularly sensitive to regulatory requirements that may be redundant, inconsistent or overlapping.

3. A regulatory experiment is highly appropriate under the circumstances.

Preferred rejects the potential suggestion that its petition should simply be converted into a comment to the pending generic rule and folded into that administrative process only. First, the rule, as proposed, does not contemplate the contingency being discussed here. Second, even if this request were to be treated as a comment² a significant period of delay, even under the best of circumstances, will occur before any such change can be made. In the interim, the unnecessary burden will be maintained, FSIS backlogs in label review, which in recent months have frequently become substantial, and which could be materially reduced by such an accommodation, will continue, and the reviews in question will serve no public benefit.

Under these circumstances, we believe that the immediate goals of our client, those advanced by FSIS, both through the pending proposal, and its broader streamlining efforts, as well as the administration's regulatory goals, are all fully aligned. As

² In this regard, we also suggest that this petition should be placed on the comment record itself, both in the general interest of transparency and as a method of suggesting that any final rule generated by the proposal should in fact ultimately accommodate the contingency covered by this experiment.

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such, this would appear to be an ideal situation for the type of regulatory experimentation contemplated by 9 C.F.R. 303.1(h) and 381.3(b).

Conclusion

For all the above reasons, Preferred respectfully requests the authorization of an experiment that will eliminate the need for FSIS' prior review and approval of all of its meat and poultry labels which would otherwise have generically approved status, but for the fact that they are associated with meals whose label includes the presentation of a CN acceptability claim. We will be more than happy to discuss this further at your convenience and to work with FSIS to bring such experiment to a successful and mutually beneficially conclusion.

Thank you for your consideration.

Very truly yours,

A handwritten signature in black ink, appearing to read 'R. G. Hibbert', with a long horizontal line extending to the right.

Robert G. Hibbert
Counsel to Preferred Meal Systems, Inc.

cc: P. Derfler, FSIS
D. Engeljohn, FSIS