

Company Name Address Address

Dear Sir/Madam:

This letter is in regard to approved labels for uncooked, breaded, boneless poultry products that also may be stuffed or filled, charmarked, or artificially colored that are currently manufactured by your establishment. Products of these types are similar to the products associated with the recall that was posted on the Food Safety and Inspection Service's (FSIS) website on March 10, 2006, involving frozen stuffed chicken entrees.

As noted in the recall notice, the frozen state, labeling, and cooked appearance of the uncooked chicken products may have caused consumers to believe that they were precooked. What we know is that these products were not cooked by consumers to a safe internal temperature. FSIS is concerned that the labeling of products of this type be adequate to inform the public of the manner of handling required to maintain the products in a wholesome condition and to prepare them safely. Moreover, the cooking instructions need to be validated to address the intended use by the consumer. While consumers may be directed to cook the products to an internal temperature of 165 degrees Fahrenheit (F), if they are directed to use a cooking method that is not practical or not likely to achieve the necessary level of food safety (e.g., microwaving or cooking frozen product in a toaster oven), the cooking instructions may not be valid.

A fundamental part of label evaluation is to ensure that labeling will be understood and followed by consumers. It is clear from the recent events that labels for other uncooked, breaded, boneless poultry products on the market, such as those that your company produces, may not be understood or followed by consumers. This lack of understanding may result in the consumers not cooking the products to the minimum internal temperature (165 degrees F) necessary for the destruction of foodborne bacteria, even though the cooking instructions on the product labeling tell them to do so. Given what the Agency learned in the recent recall and the nature of these products, the labeling of such products may not be eligible to bear the mark of inspection if the labeling does not lead consumers to provide the lethality that is necessary. The mark of inspection on poultry (and meat) products signifies that the product, as labeled, is safe and wholesome, and that the label is not misleading.

It is our strong recommendation that the labeling of the types of products in question, which are currently manufactured by your establishment, be modified to emphasize that the products are not cooked. Further enhancement of the cooking instructions and validation that lethality is achieved with all the methods of cooking preparation that are declared on the labels are necessary in our view. The Agency views the statement

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"Uncooked: For Safety, <u>Must</u> be Cooked to an Internal Temperature of 165 degrees F as Measured by Use of a Thermometer" to be the type of statement that seems appropriate on the principal display panel of the packaging to help consumers understand the need for the safe preparation of the products on their part. It is likely that, by improving the cooking instructions, as well as documenting that cooking methods are validated as part of the official labeling record, a situation like the one that that led to the recent recall could be avoided.

Certain to be of assistance to your company in making the necessary changes to product labeling and cooking method validation will be the work of the Subcommittee on Consumer Guidelines for the Safe Cooking of Poultry Products of the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) which will meet on March 22, 2006, in Arlington, Virginia. We suggest that the recommendations that are developed by the NACMCF serve as a guide for the modifications that are needed to the labels for your products such that the subject products can be assured to result in safe and wholesome products, and that the revised labeling is not misleading.

In light of the concerns outlined in this letter, we are requesting that you submit the revised labeling for the products in question to the Agency for evaluation of the necessary modifications and re-approval by May 1, 2006. If we do not receive the modified labeling submissions by that time, the labels for the subject products will be deemed to be rescinded.

If you have any questions about this matter, please do not hesitate to contact me or Rosalyn Murphy-Jenkins at Area Code (202) 205-0279.

Sincerely,

Dr. Robert C. Post, Director Labeling and Consumer Protection Staff