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AUG 8 2001

Greg Hinton
Vice President, Sales
Rose Acre Farms
Post Office Box 1250
Seymour, Indiana 47274-3850

Dear Mr. Hinton:

This responds to your facsimile of July 20, 2001 to the Food and Drug Administration (FDA) regarding the safe handling statement required on the labels of shell eggs. You requested that FDA reconsider allowing the safe handling statement to be placed on the inside lid (inlid) of egg cartons.

As you are aware, the recently promulgated regulation 21 CFR 101.17(h) requires that the safe handling statement appear on the principal display panel (PDP) or the information panel (65 FR 76092, December 5, 2000). As defined in 21 CFR 101.1 the PDP is the "part of the label that is most likely to be displayed, presented, shown, or examined under customary conditions of display for retail sale." The information panel is defined in 21 CFR 101.2 as "that part of the label that is immediately contiguous and to the right of the [PDP] ..." or "if the top of the container is the [PDP] and the package has no alternate [PDP], the information panel is any panel adjacent to the [PDP]." Based on these definitions, the inlid of egg cartons does not meet the definition of the PDP or information panel. Thus, placement of the safe handling statement on the inlid does not comply with the placement requirements in 21 CFR 101.17(h)(2).

In a previous letter to FDA dated January 30, 2001, you requested that FDA allow the placement of the safe handling statement on the inside of the carton, as an option, in addition to the PDP or the information panel. You maintained that this flexibility would allow you to comply with this rule and still be able to merchandise your product while being in compliance with all other legal requirements for the labeling of eggs.

In response to that request, FDA issued a letter dated April 1, 2001, stating that we would permit the safe handling statement on the inlid only when there is insufficient space on the PDP or information panel for all mandatory information. We pointed out that nonmandatory information such as artwork should not be considered when determining sufficiency of label space in accordance with 21 CFR 101.15.

However, we have considered your requests and we are now reconsidering placement of the statement on the inlid. We plan to issue a proposed rule to amend the regulation in

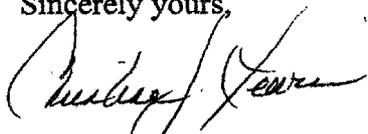
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21 CFR 101.17(h) to include the option of placing the safe handling statement on the inlid of cartons. Until this rulemaking is complete, we will consider such requests on a case-by-case basis upon request by individual companies and it is unlikely that enforcement of the placement of the safe handling instructions on the inlid will be a high priority as long as the statement on the inlid is prominent. When judging whether the safe handling statement is prominent, we may look to see if there is a referral statement on the PDP that instructs consumers to look at the inlid for the statement. (An example of such a statement is “see safe handling instructions inside.”) We may also consider whether any referral statement is in close proximity to the “Keep Refrigerated” statement that is still required by USDA regulations.

We would like to point out that the regulations in 21 CFR 101.17(h)(6) provide that States and localities may under their own jurisdictions enforce 21 CFR 101.17(h). Please understand that States and localities may choose to enforce the regulations as they now stand until they are amended through notice and comment rulemaking.

If you have further questions, please let us know.

Sincerely yours,



Christine J. Lewis, Ph.D.

Director

Office of Nutritional Products, Labeling
and Dietary Supplements

Center for Food Safety
and Applied Nutrition