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SEP 21 2001

Walter F. Baumann
Sales and Marketing
BKS-Ovotherm International
Ricoweg 28
2351 Wiener Neudorf
Austria

Dear Mr. Baumann:

This responds to your facsimiles of August 7, September 10, and September 17, 2001 to the Food and Drug Administration (FDA) regarding the safe handling statement required on the labels of shell eggs. You requested that FDA consider 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).

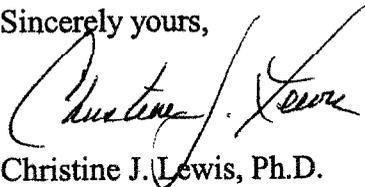
However, we have considered your request and we are now reconsidering placement of the statement on the inlid. We plan to issue a proposed rule to amend the regulation in 21 CFR 101.17(h) to include the option of placing the safe handling statement on the inlid. Until this rulemaking is complete, we 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 the United States Department of Agriculture regulations.

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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,

A handwritten signature in black ink, appearing to read "Christine J. Lewis". The signature is written in a cursive style with a large initial "C".

Christine J. Lewis, Ph.D.

Director

Office of Nutritional Products, Labeling
and Dietary Supplements

Center for Food Safety
and Applied Nutrition