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APR | 2001

Mr. Ray B. English
President
Foam Packaging, Inc.
Post Office Box 1075
Highway 61 South
Vicksburg, Mississippi 39181

Dear Mr. English:

This is in response to your letter of January 25, 2001, in which you requested that the Food and Drug Administration (FDA) to allow you to place the required safe handling statement for shell eggs on the inside lid of egg cartons. You stated that you received information from Gale Mason of the United States Department of Agriculture (USDA) on the safe handling statement for shell eggs, including requirements that the statement must appear on the principal display panel (PDP). We hope that the following clarifies our position.

In your letter, you stated that you have no available space on the top of the egg cartons you manufacture without changing the graphic design of every brand that you produce. You stated that some of your customers have as many as 20 brands which would cost you from \$20,000 to \$35,000 to change the labels in order to print the safe handling statement on the PDP.

Further, you stated that information from USDA stated that the "front and back" panels of the carton would be acceptable for displaying the statement. You maintained that you did not have the equipment to print on these panels. You noted that the cost for this equipment is \$230,000. To print on the sides, you pointed out, requires mold changes to every set of egg carton molds that you use, resulting in an additional cost of \$780,000. You stated that printing on the sides of the cartons is not an option for your small company.

You contended that the flexibility allowed for eggs that are to be packed or processed elsewhere, i.e., the safe handling may appear in bills of lading and invoices, is a "double standard." Thus, you request options for providing the safe handling instructions that would be economically beneficial for your company.

With regard to your request for flexibility in placement of the safe handling statement so that you may avoid having to change the graphics on each brand that you produce, we would like to point out that FDA's regulation in 21 CFR 101.15 (copy enclosed) requires that any information required on the label of foods under the authority of the Federal Food, Drug, and Cosmetic Act must appear prominently and conspicuously. The regulation further states that insufficiency of label space for the prominent placing of such required information may result from the use of label space for any word, statement, or design not required to appear on the

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label. In other words, artwork or graphics must not be considered in determining sufficiency of label space. FDA concluded that the requirement for prominence and conspicuousness for the safe handling statement is met if the statement appears on the PDP or information panel. Therefore, where there is sufficient space, notwithstanding graphics and other nonmandatory information, the safe handling statement must appear on the PDP or information panel, which are on the outside of the egg carton.

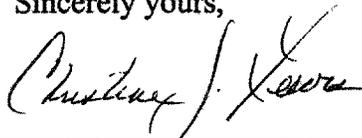
However, we do recognize that there are many requirements by States and other federal agencies such as USDA's Food Safety and Inspection Service and Agricultural Marketing Service for egg labeling that may limit the space on the PDP or information panel of some egg cartons. Thus, we will not object to the placement of the required safe handling statement inside the lid of egg cartons only in the instances where there is insufficient space on the PDP or information panel for all information required by State or federal laws.

With regard to your inability to print on the sides, we would like to point out that there appears to be sufficient space on the tops of many egg cartons such that printing on the sides of the cartons is not warranted. Thus, when there is sufficient space, the safe handling statement may appear on the PDP instead of on the information panel.

We disagree with your contention that allowing the safe handling statement to appear in bills of lading and invoices is a double standard. FDA is requiring the safe handling statement on the labels of shell eggs as a public health measure to inform consumers how they can reduce their risk of illness that may occur from consumption of improperly handled eggs. Because eggs that are to be repacked or processed are not destined for direct sale to consumers, FDA concluded that it was appropriate to allow the safe handling statements to appear in bills of lading and invoices so that the information could be conveyed to the parties responsible for ensuring that the labels of the products destined for direct sale to consumers contain the safe handling statement.

If you need further information, 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

Enclosure

(g) *Applicability.* The requirements of this section apply to foods intended for human consumption that are offered for sale, regardless of whether the foods are in conventional food form or dietary supplement form.

[58 FR 2533, Jan. 6, 1993; 58 FR 17097, Apr. 1, 1993, as amended at 58 FR 44038, Aug. 18, 1993; 59 FR 425, Jan. 4, 1994; 59 FR 15050, Mar. 31, 1994; 61 FR 40332, Aug. 2, 1996; 62 FR 49867, Sept. 23, 1997; 63 FR 26980, May 15, 1998]

§ 101.15 Food; prominence of required statements.

(a) A word, statement, or other information required by or under authority of the act to appear on the label may lack that prominence and conspicuousness required by section 403(f) of the act by reason (among other reasons) of:

- (1) The failure of such word, statement, or information to appear on the part or panel of the label which is presented or displayed under customary conditions of purchase;
- (2) The failure of such word, statement, or information to appear on two or more parts or panels of the label, each of which has sufficient space therefor, and each of which is so designed as to render it likely to be, under customary conditions of purchase, the part or panel displayed;
- (3) The failure of the label to extend over the area of the container or package available for such extension, so as to provide sufficient label space for the prominent placing of such word, statement, or information;
- (4) Insufficiency of label space (for the prominent placing of such word, statement, or information) resulting from the use of label space for any word, statement, design, or device which is not required by or under authority of the act to appear on the label;
- (5) Insufficiency of label space (for the prominent placing of such word, statement, or information) resulting from the use of label space to give materially greater conspicuousness to any other word, statement, or information, or to any design or device; or
- (6) Smallness or style of type in which such word, statement, or information appears, insufficient background contrast, obscuring designs or

vignettes, or crowding with other written, printed, or graphic matter.

(b) No exemption depending on insufficiency of label space, as prescribed in regulations promulgated under section 403 (e) or (f) of the act, shall apply if such insufficiency is caused by:

- (1) The use of label space for any word, statement, design, or device which is not required by or under authority of the act to appear on the label;
- (2) The use of label space to give greater conspicuousness to any word, statement, or other information than is required by section 403(f) of the act; or
- (3) The use of label space for any representation in a foreign language.

(c)(1) All words, statements, and other information required by or under authority of the act to appear on the label or labeling shall appear thereon in the English language: *Provided, however,* That in the case of articles distributed solely in the Commonwealth of Puerto Rico or in a Territory where the predominant language is one other than English, the predominant language may be substituted for English.

(2) If the label contains any representation in a foreign language, all words, statements, and other information required by or under authority of the act to appear on the label shall appear thereon in the foreign language: *Provided, however,* That individual serving-size packages of foods containing no more than 1½ avoirdupois ounces or no more than 1½ fluid ounces served with meals in restaurants, institutions, and passenger carriers and not intended for sale at retail are exempt from the requirements of this paragraph (c)(2), if the only representation in the foreign language(s) is the name of the food.

(3) If any article of labeling (other than a label) contains any representation in a foreign language, all words, statements, and other information required by or under authority of the act to appear on the label or labeling shall appear on such article of labeling.

§ 101.17 Food labeling warning and notice statements.

(a) *Self-pressurized containers.* (1) The label of a food packaged in a self-pressurized container and intended to b