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MAR 16 2001

Tim Considine
IGA, Inc.
8725 West Higgins Road
Chicago, Illinois 60631

Dear Mr. Considine:

This is in response to your letter of January 16, 2001, in which you requested that the Food and Drug Administration (FDA) consider amending the recent regulation that requires a safe handling statement on egg cartons. You requested that FDA allow flexibility in the placement of the label statement. We hope that the following clarifies our position.

You stated that your company sells millions of dozens of eggs each year. You requested that FDA allow the placement of the safe handling statement on the inside of the carton, in addition to the principal display panel (PDP) and 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.

With regard to your request for flexibility in placement of the safe handling statement so that you may maintain your merchandising ability, 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 label. In other words, graphics, or other nonmandatory marketing information 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.

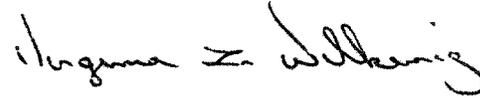
However, we do recognize that there are many requirements by States and other federal agencies such as the United States Department of Agriculture's Food Safety and Inspection Service and Agricultural Marketing Service for egg labeling that may limit the space on the PDP or information panel of some egg cartons. Thus, we will not object to the placement of

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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.

If you need further information, please let us know.

Sincerely yours,



for Christine J. Lewis, Ph.D.
Director
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

Enclosure

§ 101.15

(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 (i) 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 that 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 word 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 more than 1½ avoirdupois ounces or 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). 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 word 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