

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 2004N–0382]

RIN 0910–ZA23

Food Labeling: Safe Handling Statements: Labeling of Shell Eggs

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend the agency’s food labeling regulations to permit the egg industry to place the safe handling statement for shell eggs on the inside lid of egg cartons if the statement “Keep Refrigerated” appears on the principal display panel (PDP) or information panel. This proposed rule, if finalized, will provide the industry greater flexibility in the placement of safe handling instructions on egg cartons, while continuing to provide consumers with this important information. This proposed action is in response to numerous requests from the egg industry.

DATES: Submit written or electronic comments by [*insert date 75 days after date of publication in the Federal Register*]. See section VII for the proposed effective date of a final rule based on this proposal.

ADDRESSES: You may submit comments, identified by [Docket No. 2004N–0382], by any of the following methods:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.

- Agency Web site: <http://www.fda.gov/dockets/ecomments>. Follow the instructions for submitting comments on the agency Web site.
- E-mail: fdadockets@oc.fda.gov. Include [Docket No. 2004N–0382] in the subject line of your e-mail message.
- FAX: 301–827–6870.
- Mail/Hand delivery/Courier [For paper, disk, or CD-ROM submissions]:
Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the agency name and Docket No. or Regulatory Information Number (RIN) for this rulemaking. All comments received will be posted without change to <http://www.fda.gov/ohrms/dockets/default.htm>, including any personal information provided. For detailed instructions on submitting comments and additional information on the rulemaking process, see the “Comments” heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to <http://www.fda.gov/ohrms/dockets/default.htm> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Catalina Ferre-Hockensmith, Center for Food Safety and Applied Nutrition (HFS–820), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–2371.

SUPPLEMENTARY INFORMATION:

I. Background

A. Safe Handling Labeling of Shell Eggs

In the **Federal Register** of December 5, 2000 (65 FR 76092), FDA published a final rule entitled “Food Labeling, Safe Handling Statements, Labeling of Shell Eggs; Refrigeration of Shell Eggs Held for Retail Distribution” (hereinafter referred to as the “shell egg labeling regulation”), which established a labeling regulation in § 101.17(h) (21 CFR 101.17(h)) that requires the egg industry to place a safe handling statement on cartons of shell eggs that have not been treated to destroy *Salmonella* microorganisms. The regulation also requires retail establishments to store and display shell eggs under refrigeration. FDA issued that rule because of the number of outbreaks of foodborne illnesses and deaths caused by *Salmonella* Enteritidis (SE) that are associated with the consumption of shell eggs. Safe handling statements help consumers take measures to protect themselves from illness or death associated with consumption of shell eggs that have not been treated to destroy *Salmonella*. Refrigeration of shell eggs that have not been treated to destroy *Salmonella* helps prevent the growth of SE.

B. Placement and Prominence of FDA’s Safe Handling Statement

Section 403(f) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 343(f)) requires that mandatory label information be placed on the label with such conspicuousness as to render it likely to be read and understood by ordinary individuals under customary conditions of use. Accordingly, the shell egg labeling regulation requires the safe handling statement to appear either on the PDP or on the information panel of egg cartons.

FDA regulations define the PDP for packaged food as “the part of a label that is most likely to be displayed, presented, shown, or examined by a

consumer under customary conditions of display for retail sale” (§ 101.1). For egg cartons, the top is usually the PDP. The information panel for packaged food generally is defined by § 101.2(a) as that part of the label that is immediately contiguous and to the right of the PDP, with the following exceptions. If the part of the label immediately contiguous and to the right of the PDP is too small to accommodate the necessary information or is otherwise unusable label space, the panel immediately contiguous and to the right of that part of the label may be used (§ 101.2(a)(1)). If the package has one or more alternative PDPs, the information panel is immediately contiguous and to the right of any PDP (§ 101.2(a)(2)). If the top of a container is the PDP and the package has no alternate PDP, the information panel is any panel adjacent to the PDP (§ 101.2(a)(3)). For egg cartons, the information panel is considered to be any side panel of the carton. Thus, the shell egg labeling regulation requires the safe handling statement to appear on either the top or side of egg cartons.

C. Requests for Flexibility in Placement and Prominence of the Safe Handling Statement

FDA has received over 20 letters regarding the shell egg labeling regulation from egg producers, egg carton manufacturers, grocery retailers, an egg producer cooperative, and a consumer group. These 20 letters have been placed in Docket No. 2004N-0382 and may be seen at the Division of Dockets Management (see **ADDRESSES**). The egg industry generally supported the requirement of a safe handling statement on egg cartons but expressed concern that placing the statement on the top or sides of the carton would result in a financial hardship for their companies. The egg industry asked FDA to allow safe handling statements to be placed on the inside lid of egg cartons for the

following reasons: (1) The lack of equipment to print on the side panels of egg cartons (i.e., the information panel), (2) the high cost to purchase equipment to print on the sides of egg cartons, and (3) the high cost to change the graphic design of the PDP for each brand that manufacturers produce for each customer.

The egg industry also argued that most consumers open cartons to check eggs before purchase, so the placement of the safe handling statement on the inside lid would be sufficiently prominent and conspicuous. To support this argument, a cooperative of egg producers included results of a consumer opinion survey conducted by the U.S. Department of Agriculture's (USDA) Cooperative State Research, Education, and Extension Service, in cooperation with the University of Georgia (UGA) (hereinafter referred to as the "USDA/UGA survey") (Ref. 1). Nearly 92 percent of the consumers surveyed reported that they open up egg cartons before purchase to check for cracked eggs. The egg producers argued that consumers are quality conscious and would be likely to see and read at the time of purchase a safe handling message on the inside lid of the egg carton. One egg carton manufacturer pointed out that all of its customers (egg producers) print the nutrition labeling information on the inside lid of egg cartons. Thus, the manufacturer asserted, many consumers consider the inside lid of the carton to be the information panel.

The consumer group, who also supported the shell egg labeling regulation, asked that FDA re-evaluate the type size and readability of the safe handling statement because the safe handling statement may be illegible, particularly for elderly consumers. The consumer group did not provide data or other appropriate information to support this assertion.

In the summer of 2001, FDA responded (by letter) to these requests by stating that the agency had decided to issue a proposed rule to amend the regulation in § 101.17(h) to include the option of placing the safe handling statement on the inside lid of egg cartons. The agency stated that, until such rulemaking is complete, it would consider requests from individual companies for permission to place the safe handling statement on the inside lid of egg cartons. FDA further indicated that actions for enforcement of § 101.17(h)(2) would not be a high priority for the agency, where companies have ensured that the statement on the inside lid is prominent (e.g., there is language, i.e., a referral statement, on the PDP that instructs consumers to look at the inside lid of egg cartons for the safe handling statement). FDA also stated that, in considering whether the statement in the inside lid is prominent, it might consider whether any referral statement is in close proximity to the “Keep Refrigerated” statement required by USDA under 9 CFR 590.50.

II. Proposal

FDA is proposing to allow the egg industry to place the required safe handling statement on the inside lid of egg cartons if the statement “Keep Refrigerated” appears on the PDP or information panel.

FDA tentatively believes that the inside lid would serve as an acceptable panel for the safe handling instructions without diminishing the effectiveness of the message. Consumers must open egg cartons before removing the eggs and thus would be exposed to the instructions before cooking. Also, as noted by the USDA/UGA survey, many consumers open the lids of egg cartons to check for cracked eggs at the point of purchase. These consumers would be exposed to the instructions at this time as well.

The agency further notes that companies using inside-lid labeling may print the safe handling instructions in a larger font because there is generally more space available inside the lid for such labeling. A larger font may increase the number of consumers who read the instructions. As mentioned previously in section I.C of this document, a consumer group contended that the currently required safe handling statement may be illegible for some consumers. We solicit comment on this issue. We also solicit comment on whether it is necessary to require a referral statement on the outside lid when the safe handling instructions are placed on the inside lid.

Furthermore, the agency is aware of the industry's data showing that the cost of printing the safe handling instructions on the PDP or information panel may be prohibitively expensive for some firms. FDA believes that providing flexibility may result in a cost savings for the egg industry and, thus, for consumers.

The change to permit placement of the safe handling instructions that FDA is proposing in § 101.17(h)(2) necessitates safeguards to ensure that the egg safe handling instruction "Keep Refrigerated" is seen as soon as possible and by those who might not open egg cartons. As discussed in the shell egg labeling regulation, refrigeration is a practicable and useful measure to limit the number of viable SE in shell eggs (65 FR 76092 at 76100–76102). Because personnel involved in the production, distribution, and storage of shell eggs may not open the lid of egg cartons, some consumers may not open the eggs cartons until they cook the eggs, and because the instruction to "Keep Refrigerated" is relevant before a consumer opens the carton, the agency believes that refrigeration instruction must appear on the outside of egg cartons that have an inside-lid safe handling statement. Accordingly, FDA is proposing to amend

§ 101.17(h)(2) to require that, when the safe handling statement appears on the inside lid of the egg carton, the words, “Keep Refrigerated” appear on the PDP or information panel.

III. Analysis of Economic Impacts

A. Preliminary Regulatory Impact Analysis

FDA has examined the economic implications of this proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Executive Order 12866 classifies a rule as significant if it meets any one of a number of specified conditions, including: Having an annual effect on the economy of \$100 million, adversely affecting a sector of the economy in a material way, adversely affecting competition, or adversely affecting jobs. A regulation is also considered a significant regulatory action under Executive Order 12866 if it raises novel legal or policy issues. The Office of Management and Budget has determined that this proposed rule is a significant regulatory action as defined by Executive Order 12866.

1. Need for the Proposed Regulation

The need for this proposed regulation is to provide the shell egg industry, which includes egg producers, carton manufacturers, egg distributors, and retailers, additional flexibility in complying with FDA requirements for the placement of safe handling instructions on egg cartons, without reducing the prominence or conspicuousness of the information and without undermining

the effectiveness of the shell egg labeling regulation. Allowing the inside lid to be used for the safe handling instructions may create cost savings for firms that were concerned that complying with the shell egg labeling regulation would be a financial hardship. This proposed regulation would allow the safe handling instructions to be placed on the inside lid of egg cartons if the words “Keep Refrigerated” are placed on the PDP or information panel.

2. Options

FDA has evaluated three regulatory options to allow the safe handling statement to be printed on the inside lid of egg cartons. The options considered are the following: (1) No new regulatory action, (2) allow the safe handling statement to be placed on the inside lid with a referral statement on the outside of the carton if the words “Keep Refrigerated” are placed on the PDP or information panel, and (3) the proposed option, allow the safe handling statement to be placed on the inside lid with no referral statement required if the words “Keep Refrigerated” are placed on the PDP or information panel. The policy options are presented in an order that allows each to be built on the preceding option and facilitates comparison among the options.

The first option analyzes the existing requirement for printing the safe handling statement on egg cartons. The second option proposes flexibility in the placement of the safe handling statement on egg cartons to include the inside lid, provided that a referral statement and the words “Keep Refrigerated” are placed on the PDP or information panel. The proposed option is a modification of the second option and allows additional flexibility by removing the referral statement requirement when the safe handling statement is located on the inside lid if the words “Keep Refrigerated” are placed on the PDP or information panel. FDA estimates the cost of each option by

measuring the additional costs where they first occur—at the carton manufacturers, which is consistent with the method used in the Preliminary Regulatory Impact Analysis of the proposed shell egg refrigeration and labeling rule (64 FR 36516 at 36529, July 6, 1999).

FDA analyzed the impacts of this rule relative to a baseline that includes FDA no longer exercising enforcement discretion with regard to the placement requirements of the shell egg labeling regulation, which we believe is a reasonable scenario in the absence of this rulemaking. Because the placement requirements in the shell egg labeling regulation are not currently fully enforced, we assume, for the purposes of setting a baseline only, that if FDA did not finalize this proposed rule, we would eventually start fully enforcing the shell egg labeling regulation no earlier than 12 months and no later than 36 months following the date of publication of this proposed rule.

Option One: Require Safe Handling Labeling on the PDP or Information Panel

Option one is to maintain the labeling requirements imposed by the shell egg labeling regulation. With no new regulatory action, the total number of people who currently read the safe handling statement would remain unchanged. The benefits from the current shell egg labeling regulation would not change, so the benefits associated with this option would be zero. With no new regulatory action, the costs of the existing regulation, measured as the costs to egg carton manufacturers of printing the safe handling statement on the PDP or information panel, also would remain unchanged.

Though the agency finds no new costs associated with option one, the letters from industry provide additional information on the costs associated with compliance with the shell egg labeling regulation. The letters explained that placing the safe handling statement on the PDP may require a logo

redesign, while placing it on the information panel may require the manufacturer to purchase special equipment. One manufacturer reported the costs for the purchase of new equipment required for printing on the information panel to be approximately \$230,000 (Ref. 2). The same manufacturer estimated the costs for mold changes required for logo redesign to be approximately \$780,000 and the total costs for redesigning a logo for one complete brand to be approximately \$1,740 (Ref. 2). This latter cost estimate does not account for the potential opportunity cost of lost advertising revenue to the egg carton producer due to the reduction in space available for promotion when the safe handling statement is required on the PDP or information panel.

Option Two: Allow the Safe Handling Statement to Be Placed on the Inside Lid With a Required Referral Statement on the Outside of the Carton if the Words “Keep Refrigerated” are Placed on the PDP or Information Panel

Option two would allow the safe handling statement to be printed on the inside lid of the egg carton, provided that a referral statement and the words “Keep Refrigerated” are placed on the PDP or information panel.

a. Costs of option two: potential reduction in the numbers of consumers reached—FDA estimates that there would be no costs to the proposed flexibility. The agency believes that at least as many, if not more, consumers would read safe handling instructions on the inside lid of egg cartons than would read the statement on the PDP or information panel, based on the following factors:

1. The referral statement required on the outside panel;
2. The consumer practice of looking inside the egg carton either at the time of purchase or at a time before consumption; and

3. The potential for more space on the inside lid of egg cartons because of the relatively large surface area there.

A study has shown that labels that are larger and have less text density are more attractive (Ref. 3). Another study has shown that larger font sizes enhance label readability (Ref. 4). Because the inside lid may allow more space for printing the safe handling statement in larger font sizes, such placement may result in a larger number of consumers reading the safe handling statement than under the existing regulation and could be considered an additional benefit from the proposed flexibility. FDA seeks comment on the impact, if any, on consumer behavior of the font size of instructional labeling statements.

b. Benefits of option two: cost savings realized by egg carton manufacturers—The benefits from the proposed flexibility would be the cost savings for firms that place the safe handling statement inside the lid, rather than placing it on the PDP or information panel, accompanied by the referral statement and words “Keep Refrigerated” on the outside of the carton. No cost savings would be attributed to firms that continue to place the safe handling statement on the PDP or information panel, as required by the existing regulation. FDA assumes that a firm would choose the inside lid with referral statement option if the cost of printing the safe handling statement on the inside lid plus the cost of printing the referral statement were less than the cost of printing the safe handling statement on either the PDP or information panel.

The cost savings for a firm from the additional flexibility equal the difference between the sum of the costs of printing the safe handling statement on the inside lid and printing the referral statement, and the costs of printing the safe handling statement on either the PDP or information panel. When the

cost savings for each firm in the industry are added together, then the total cost savings from the added flexibility for the entire industry is expressed as:

$$\text{Total Cost Savings} = S1 \times (\text{IP} - \text{IN} - \text{REF}) + S2 \times (\text{PDP} - \text{IN} - \text{REF}),$$

where,

S1 represents the proportion of the industry that avoids printing the safe handling statement on the information panel by using the inside lid with referral statement option,

S2 represents the proportion of the industry that avoids printing the safe handling statement on the PDP by using the inside lid with referral statement option,

IP, PDP, and IN represent the cost to the industry of printing the safe handling statement on the information panel, PDP, and inside lid, respectively, and REF reflects the costs of printing the referral statement.

The agency estimated the cost savings associated with option two by computing the costs of full logo redesign and of a safe handling statement using the FDA Labeling Cost Model, Final Report (Ref. 5). Based on evidence elicited from experts, the labeling cost model assumes a flexography method for printing the safe handling statement on egg cartons. While other printing methods exist, such as offset lithography or rotogravure, expert elicitation suggests that the flexography method is representative for egg packaging and labeling. Furthermore, the principal determinant of the costs of printing the safe handling statement is the number of colors used, rather than the amount of space that the label occupies. For full logo redesign, we assume that six colors will be used; for a safe handling statement, we assume only one color will be used. Since the labeling cost model does not have explicit options for determining the costs of either a referral statement or an inside lid safe handling statement, we assume that each of these statements uses one color.

Therefore, the costs of printing a referral statement are assumed to be equal to the costs of printing an inside lid safe handling statement.

Under these cost assumptions, the labeling cost model predicts that no firm would choose the inside lid with referral statement option over the information panel option in the absence of a need for logo redesign, because the inside lid with referral statement option will cost twice as much as placing all of the information on the information panel. This is because the cost of printing a safe handling statement on the inside lid is equivalent to the cost of printing it on an information panel. A firm choosing the inside lid alternative would incur the additional cost of printing a referral statement on the information panel, which is also assumed to be equivalent to the costs of a safe handling statement on the information panel. Therefore, the model predicts that all potential cost savings from added flexibility come from firms that would otherwise have had to redesign their logo on the PDP.

In practice, there could also be cost savings for firms that, in the absence of the proposed flexibility, might have chosen to print the safe handling statement on an information panel (e.g., if specialized, new machinery were required for printing it on an information panel but not on the inside lid). However, because of the way that the labeling costs are computed by the labeling cost model as described previously, we do not take this possibility into account. Consequently, the value generated by the labeling cost model underestimates the true cost savings that would be realized from this option because there would also be costs savings for firms that would otherwise place the safe handling statement on an information panel. Because we do not know how large these costs savings might be, we request comments on this possibility. Finally, the cost savings estimated using the labeling cost model

do not account for any producer surplus generated by making available valuable marketing space on the PDP that would otherwise have been used to display the safe handling statement. To the extent producer surplus is generated, the costs savings estimated from the labeling cost model will understate the true gains from the proposed flexibility.

The agency ran the labeling cost model for option two, using both a 12-month and a 36-month compliance period. The labeling costs are reported in table 1 of this document as a range that includes three numbers. The top and bottom numbers reported in each cell are the low and high cost estimates for the relevant label and compliance period. The middle number is the estimate of the most likely cost to industry for the relevant label and compliance period.

The most likely cost estimate for a full logo redesign with a 12-month compliance period is \$31.4 million, with low and high estimates of \$23.6 and \$56.8 million. These represent the estimates of the total costs to the industry if all firms have to redesign the logos on their egg cartons in order to print the safe handling statement. The figures likely overestimate the costs of the safe handling statement, because most firms will not need to redesign their logos. For a 12-month compliance period, the low and high costs of adding a safe handling statement are estimated to be \$4.5 and \$11.6 million, with the most likely cost estimate to be \$6.6 million.

For a full logo redesign and a 36-month compliance period, the low and high costs are estimated to be \$6.1 and \$14.8 million, with the most likely cost estimate to be \$8.2 million. For a 36-month compliance period, the low and high costs of adding a safe handling statement are estimated to be \$1.2 and \$3.1 million, with the most likely cost estimate to be \$1.7 million. The higher costs reported for the 12-month compliance period compared with the

36-month compliance period reflects the loss of inventories of cartons not in compliance with the regulation that would be incurred in the shorter compliance period.

TABLE 1.—COSTS FOR A SAFE HANDLING STATEMENT AND FOR FULL LOGO REDESIGN

Compliance Period	Full Logo Redesign (2002 \$)	Safe Handling Statement (2002 \$)
12 months	Low: \$23.6 million Most likely: \$31.4 million High: \$56.8 million	Low: \$4.5 million Most likely: \$6.6 million High: \$11.6 million
36 months	Low: \$6.1 million Most likely: \$8.2 million High: \$14.8 million	Low: \$1.2 million Most likely: \$1.7 million High: \$3.1 million

Monte Carlo simulations of the total cost savings from the added flexibility were performed using the above expression, with distributional assumptions, for both the 12-month and 36-month compliance period estimates reported in table 1 of this document. Lognormal distributions, rather than fixed values, were assumed to reflect uncertainty about the true values of the industry shares, S1 and S2, that would avoid printing the safe handling statement on either the PDP or information panel. Triangular distributions were used to reflect uncertainty about the true cost of each label change. This distribution was appropriate since it incorporates all of the knowledge that we have about the true cost of each label change. The three numbers in each cell reported in table 1 of this document were used as parameters for the triangular distributions.

The lognormal distribution is appropriate for representing the uncertainty in the true values of S1 and S2 because it is not symmetric in general; almost all of its values lie between 0 and 1 when certain values of the mean and variance are assumed, and it can accommodate a wide range of prior beliefs about the true values of S1 and S2. One prior belief is that the true value of S1 is close to 0. We chose a lognormal distribution of mean 0.1 and variance 0.1 to represent the uncertainty surrounding this belief. We chose a lognormal

distribution of mean 0.4 and variance 0.1 to represent the uncertainty surrounding our belief of the true value of S2. The findings from the Monte Carlo simulation are reported in table 2 of this document.

TABLE 2.—TOTAL COST SAVINGS, OPTION 2

	Savings from Avoiding a Label on the PDP		Savings from Avoiding a Label on the Information Panel		Total Cost Savings	
	12-month compliance	36-month compliance	12-month compliance	36-month compliance	12-month compliance	6-month compliance
Mean estimate	\$11,032,000	\$2,888,000	0	0	\$11,032,000	\$2,888,000
Low estimate (5th percentile)	\$5,125,000	\$1,352,000	0	\$5,125,000	\$1,352,000	
High estimate (95th percentile)	\$18,658,000	\$4,732,000	\$365,000	\$112,000	\$19,022,000	\$4,844,000

The mean, low, and high estimates of the cost savings are reported in table 2 of this document. Low estimates are where there is a 5 percent probability of being higher than the true value. High estimates are where there is a 95 percent probability of being higher than the true value. The distribution of the cost savings is truncated at zero, since no firms would print the safe handling statement on the information panel if the savings were negative. The total cost savings from option two are estimated to range from \$5.1 to \$19 million, with a mean of \$11 million assuming a 12-month compliance period, and from \$1.4 to \$4.8 million, with a mean of \$2.9 million, assuming a 36-month compliance period.

After inventories of the labeled egg cartons have been depleted, it can reasonably be expected that firms would again decide on which panel to print the safe handling statement for a new batch of egg cartons. There could be additional savings from the proposed flexibility if firms at that later date would choose to print the safe handling statement on the inside lid rather than either the PDP or information panel. However, in this analysis we assume that all cost savings from the proposed flexibility result from the initial decision on the placement of the safe handling statement. This assumption is justified because it is likely that adjustment costs from changing the earlier decision

on the placement of the safe handling statement are greater than any savings that could result from a labeling change at that later date. Once a firm has decided on which panel to print the safe handling statement and has incurred the labor and capital costs of that decision, the costs of changing that decision at a later date are assumed to be greater than any potential benefit from doing so. Finally, as explained previously in this document, the placement of the safe handling statement on the inside lid could result in a larger number of consumers reading it than under the existing regulation. Although this possibility is not quantified in the analysis, it may be considered as an additional benefit from the proposed flexibility. We request comments on this possibility.

The proposed option: Allow the Safe Handling Statement to Be Placed on the Inside Lid Without a Referral Statement if the Words “Keep Refrigerated” are Placed on the PDP or Information Panel

The proposed option allows firms to print the safe handling statement on the inside lid but does not require a referral if the words “Keep Refrigerated” are placed on the PDP or information panel.

c. Costs of the proposed option: potential reduction in the numbers of consumers reached—FDA estimates that the costs of the proposed option are likely to be zero. We assume that the costs of this option arise from changes in the number of consumers who read the safe handling statement. The number of consumers who would read the safe handling statement on the inside lid under the proposed option is assumed to be about the same as the number who read it under the existing regulation. The reasons for this assumption are:

1. The consumer practice of looking inside the egg carton either at the time of purchase or at a time before consumption and

2. The potential for more space on the inside lid of egg cartons because of the relatively large surface area there.

Because all consumers look inside the egg carton at some time before consumption, FDA assumes that the costs of the proposed option are the same as those from option two. In addition, as explained in option two, because of the potential for larger font sizes and less text density on the inside lid, the safe handling statement located there may actually be read by more consumers than the same statement placed on the outside of the carton, as is currently required by the shell egg labeling regulation. We request comments on this possibility.

d. Benefits of the proposed option: no required referral statement if the words “Keep Refrigerated” appear on the PDP or information panel—FDA performed Monte Carlo simulations of the total cost savings for the proposed option by modifying the distributional assumptions in option two, to incorporate additional potential cost savings of not requiring a referral statement. The results are reported in table 3 of this document, which contains the mean, low, and high estimates of the cost savings.

TABLE 3.—TOTAL COST SAVINGS, PROPOSED OPTION

	Savings from Avoiding a Label on the PDP		Savings from Avoiding a Label on the Information Panel		Total Cost Savings	
	12-month compliance	36-month compliance	12-month compliance	36-month compliance	12-month compliance	6-month compliance
Mean estimate	\$14,843,000	\$3,886,000	0	0	\$14,843,000	\$3,886,000
Low estimate (5th percentile)	\$8,039,000	\$2,175,000	0	0	\$8,039,000	\$2,175,000
High estimate (95th percentile)	\$23,192,000	\$6,192,000	\$1,453,000	\$389,000	\$24,645,000	\$6,582,000

The distribution of the cost savings is truncated at zero, since no firms would print the safe handling statement on the information panel if the savings were negative. Consequently, the cost savings for the mean and lower estimates of cost savings for firms that would otherwise print the safe handling statement on the information panel are reported to be zero. Only the high estimate of

cost savings (95 percent), for firms that would otherwise print the safe handling statement on the information panel, is reported to be positive.

The range of cost savings from the proposed option is estimated to be between \$8 and \$24.6 million, with a mean of \$14.8 million assuming a 12-month compliance period, and between \$2.2 and \$6.6 million, with a mean of \$3.9 million, assuming a 36-month compliance period. As in the analysis for option two, we assume that there are no additional cost savings from proposed flexibility after the initial cost savings, because the adjustment costs from changing the earlier decision on the placement of the safe handling statement are probably greater than any savings from a labeling change.

Comparing the Benefits of Option Two With Those of the Proposed Option

A comparison of the estimates of the total costs savings reported for option two with those reported for the proposed option indicates the potential for substantial cost savings from the proposed option. The larger cost savings from the proposed option compared with option two reflects the lower cost from not requiring a referral statement on an outside panel in the proposed option, as well as the cost savings from a larger share of the industry choosing the inside lid statement under the proposed option (i.e., S2 would be larger under the proposed option than under option two). The results from the comparison are reported in table 4 of this document. The cost savings from the proposed option compared with option two range from \$0 to \$11.5 million, with a mean of \$3.8 million assuming a 12-month compliance period, and from \$0 to \$3.3 million, with a mean of \$1 million assuming a 36-month compliance period.

TABLE 4.—SAVINGS FROM THE PROPOSED OPTION COMPARED WITH OPTION 2

	Savings from Avoiding a Label on the PDP		Savings from Avoiding a Label on the Information Panel		Total Cost Savings	
	12-month compliance	36-month compliance	12-month compliance	36-month compliance	12-month compliance	6-month compliance
Mean estimate	\$3,811,000	\$998,000	0	0	\$3,811,000	\$998,002
Low estimate (5th percentile)	0	0	0	0	0	0

TABLE 4.—SAVINGS FROM THE PROPOSED OPTION COMPARED WITH OPTION 2—Continued

	Savings from Avoiding a Label on the PDP		Savings from Avoiding a Label on the Information Panel		Total Cost Savings	
	12-month compliance	36-month compliance	12-month compliance	36-month compliance	12-month compliance	6-month compliance
High estimate (95th percentile)	\$10,308,100	\$2,977,000	\$1,180,000	\$306,000	\$11,488,000	\$3,282,000

Note: The values reported here are computed by assuming a joint distribution of the difference in cost savings between option 2 and the proposed option. Consequently, a value reported here may be different from that which would be obtained by simply subtracting a value reported in table 2 of this document from the appropriate value reported in table 3 of this document.

Summary of Costs and Benefits

FDA estimates the costs and benefits for three regulatory options for flexibility in the placement of the safe handling statement on egg cartons. The regulatory options considered were: (1) No new regulatory action, (2) allowing flexibility in the placement of the safe handling statement to include the inside lid, accompanied by a referral statement on an outside panel if the words “Keep Refrigerated” are placed on the PDP or information panel, and the proposed option, allowing flexibility in the placement of the safe handling statement to include the inside lid but without requiring the referral statement if the words “Keep Refrigerated” are placed on the PDP or information panel. The analysis concludes that the costs of the proposed flexibility, measured as the public health effects of a decrease in the number of consumers that would read the safe handling statement, are zero for both option two and the proposed option. Because all consumers open egg cartons before consumption, we assume the same number of consumers will notice the safe handling statement on the inside lid as would notice statement on the outside of the carton, because of the greater potential for larger font sizes and lower text density on the inside lid. If this is true, there would be no additional benefit from the required referral statement on an outside panel under option two. However, we requested comments on these assumptions.

The benefits from the options considered are measured as the cost savings from allowing firms the flexibility of printing the safe handling statement on

the inside lid. Option two requires an accompanying referral statement on an outside panel and the words “Keep Refrigerated” to be placed on the PDP or information panel, while the proposed option does not require a referral statement but does require the words “Keep Refrigerated” to be placed on the PDP or information panel. The estimated cost savings from option two range from \$4.7 to \$20 million, with a mean of \$11 million. The estimated cost savings from the proposed option range from \$8 to \$25 million, with a mean of \$15 million. The estimated cost savings from the proposed option range from \$8 and \$24.6 million, with a mean of \$14.8 million assuming a 12-month compliance period, and between \$2.2 and \$6.6 million, with a mean of \$3.8 million assuming a 36-month compliance period. The estimated savings from the proposed option compared with option two range between \$0 and \$11.5 million, with a mean of \$3.8 million assuming a 12-month compliance period, and between \$0 and \$3.3 million, with a mean of \$1 million assuming a 36-month compliance period.

B. Initial Regulatory Flexibility Analysis

FDA has examined the economic implications of this proposed rule as required by the Regulatory Flexibility Act (5 U.S.C. 601–612). If a rule has a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze regulatory options that would lessen the economic effect of the rule on small entities. The proposed rule provides additional options for placing the safe handling statement on egg cartons. No small business would be forced to use this option, so the proposed rule imposes no costs on small businesses. For those small businesses choosing the option, the proposed rule reduces labeling costs. FDA certifies that this

proposed rule, if it becomes final, would not have a significant economic impact on a substantial number of small entities.

C. Unfunded Mandates

Title II of the Unfunded Mandates Reform Act of 1995 (Public Law 104–4) requires cost-benefit and other analyses before any rulemaking if the rule would include a “Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any 1 year.” The current inflation-adjusted statutory threshold is \$115 million. FDA has determined that this proposed rule does not constitute a significant rule under the Unfunded Mandates Reform Act.

D. Small Business Regulatory Enforcement Fairness Act

The Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104–121) defines a major rule for the purpose of congressional review as having caused or being likely to cause one or more of the following: An annual effect on the economy of \$100 million; a major increase in costs or prices; significant adverse effects on competition, employment, productivity, or innovation; or significant adverse effects on the ability of U.S.-based enterprises to compete with foreign-based enterprises in domestic or export markets. In accordance with the Small Business Regulatory Enforcement Fairness Act, the Office of Management and Budget (OMB) has determined that this proposed rule, when final, will not be a major rule for the purpose of congressional review.

IV. Analysis of Environmental Impact

The agency has determined under 21 CFR 25.30(k) that this action is of a type that does not individually or cumulatively have a significant effect on

the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

V. Paperwork Reduction Act of 1995

FDA tentatively concludes that this proposed rule contains no collection of information. Therefore, clearance by OMB under the Paperwork Reduction Act of 1995 is not required.

VI. Federalism

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule would have a preemptive effect on State law. Section 4(a) of the Executive order requires agencies to “construe * * * a Federal Statute to preempt State law only where the statute contains an express preemption provision, or there is some other clear evidence that the Congress intended preemption of State law, or where the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute.”

To ensure the safety of eggs for all consumers in this country, not only must there be minimum national standards, but enforcement of these standards must be uniform across the country. However, because State and local public health officials are the primary enforcement officials in retail establishments, FDA has recognized that it must rely on these officials to provide the bulk of the enforcement of these regulations. FDA thus believes that it is critical for these regulations to establish uniform minimum standards. If less stringent State or local refrigeration and labeling requirements are not preempted, enforcement of those less stringent requirements—which are not sufficient to protect the public health—will interfere with the cooperative enforcement of the Federal egg refrigeration and labeling requirements. FDA believes that the

cooperative enforcement approach utilized in FDA's egg labeling regulation is critical to effective implementation of this important food safety requirement.

Thus, although Congress did not expressly preempt State law in this area, FDA finds preemption is needed because State and local laws that are less stringent than the Federal requirements will significantly interfere with the important public health goals of these regulations.

FDA believes that preemption of State and local labeling requirements that are the same as or more stringent than the requirements of this proposed regulation would not be necessary, as enforcement of such State and local requirements would not interfere with the food safety goals of this regulation. Further, it is likely that any states that enacted similar labeling requirements to those in FDA's rule would change those requirements to be consistent with any changes made by FDA as a result of this rulemaking. Accordingly, the preemptive effect of this rule would be limited to State or local requirements that are not as stringent as the requirements of this regulation. Requirements that are the same as or more stringent than FDA's requirement would remain in effect.

Further, section 4(e) of the Executive order provides that "when an agency proposes to act through adjudication or rulemaking to preempt State law, the agency shall provide all affected State and local officials notice and an opportunity for appropriate participation in the proceedings." We are providing an opportunity for State and local officials to comment on FDA's proposed change to FDA's shell egg labeling regulation in this rulemaking. For the reasons set forth previously in this document, the agency believes that it has complied with all of the applicable requirements under the Executive

order. In conclusion, FDA has determined that the preemptive effects of this proposed rule would be consistent with Executive Order 13132.

VII. Proposed Effective Date

FDA is proposing that any final rule that may be issued based upon this proposal become effective 30 days after its publication in the **Federal Register**.

VIII. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IX. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. United Egg Producers letter, Carlton Lofgren, Chairman, Al Pope, President, Ken Klippen, Vice President for Government Relations, and Randy Green, Senior Government Relations Representative, to Dr. Christine Lewis, FDA, March 2, 2001.
2. Foam Packaging, Inc. letter, Ray B. English, President, to Felicia Satchell, FDA, January 25, 2001.
3. Tuominen, R., "Why Do Some Yellow Page Advertisements Capture Attention Better Than Others?," *Acta Odontologica Scandinavica*, 59: 79-82, 2001.
4. Dietrich, D.A., "Enhancing Label Readability for Over-the-Counter Pharmaceuticals by Elderly Consumers," *Journal of Safety Research*, 27: 132, 1996.

5. RTI International, “FDA Labeling Cost Model, Final Report,” prepared by Mary Muth, Erica Gledhill, and Shawn Karns, RTI. Prepared for Amber Jessup, FDA/Center for Food Safety and Applied Nutrition, April 2002.

List of Subjects in 21 CFR Part 101

Food labeling, Nutrition, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 101 be amended as follows:

PART 101—FOOD LABELING

1. The authority citation for 21 CFR part 101 continues to read as follows:

Authority: 15 U.S.C. 1453, 1454, 1455; 21 U.S.C. 321, 331, 342, 343, 348, 371; 42 U.S.C. 243, 264, 271.

2. Section 101.17 is amended by revising paragraph (h)(2) to read as follows:

§ 101.17 Food labeling warning, notice, and safe handling statements.

* * * * *

(h) * * *

(2) The label statement required by paragraph (h)(1) of this section shall appear prominently and conspicuously, with the words “SAFE HANDLING INSTRUCTIONS” in bold type, on the principal display panel, the information panel, or on the inside of the lid of egg cartons. If this statement appears on

the inside of the lid, the words “Keep Refrigerated” must appear on the principal display panel or information panel.

* * * * *

Dated: October 12, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05-????? Filed ??-??-05; 8:45 am]

BILLING CODE 4160-01-S