

SUPPORTING STATEMENT

A. Justification

1. Circumstances Making the Collection of Information Necessary

The Food and Drug Administration (FDA) has the responsibility to protect public health by assuring the safety and security of our nation's food supply and by assuring that foods are effectively labeled. In addition, the FDA is responsible for advancing public health by helping the public to get the accurate, science-based information they need to use foods to improve health. As a member agency, the FDA supports the Department of Health and Human Services policies related to infant and child health, nutrition, and obesity prevention.

FDA conducts research and educational and public information programs relating to food safety pursuant to its broad statutory authority, set forth in section 903(b)(2) of the Federal Food, Drug, and Cosmetic Act (FFDCA) (21 U.S.C. 393 (b)(2)), to protect the public health by ensuring that foods are "safe, wholesome, sanitary, and properly labeled," and in section 903(d)(2)(C) (21 U.S.C. 393 (d)(2)(C)), to conduct research relating to foods, drugs, cosmetics and devices in carrying out the act.

The Nutrition Labeling and Education Act requires almost all packaged foods to bear nutrition labeling in the form of the Nutrition Facts label. The law also allows manufacturers to provide other nutrition information on labels in the form of various types of statements, including claims, as long as such statements comply with the regulatory limits that govern the use of each type of statement. There are three types of claims that the food industry can voluntarily use on food labels: (1) health claims, (2) nutrient content claims (e.g., "Low fat"), and (3) structure/function claims (e.g., "Calcium builds strong bones."). Although the different types of claims are regulated differently, they all must be truthful and not misleading (Ref. 1).

With the increased public interest in identifying healthier foods, U.S. food processors have been adding nutritional information in the form of nutrition symbols to food labels in addition to claims. Examples of nutrition symbols that have been or are suggested include nutrient-specific disclosures (e.g., "Guideline Daily Amounts") (Ref. 2), calorie declarations (Ref. 3), summary product ratings (e.g., "Smart Spot") (Ref. 4), and hybrid summary indicators with nutrient-specific disclosures (e.g., "Sensible Solution: Good Source of Calcium, Good Sources of 8 Vitamins and Minerals") (Ref. 5). Claims related to non-nutritional product characteristics are also used in food labeling. The claims may feature, among other things, statements about how foods are grown or made (e.g., "Organic" and "All Natural") or absence of a substance (e.g., "Gluten-free").

Many consumers use claims and the Nutrition Facts label in food choice decisions (Refs. 6-8). While some products carry only a single labeling statement (e.g., either one claim or one symbol) on their packages, many products carry two or more labeling statements. In addition, on the same package, the attributes of one statement may differ from those of other statements in terms of featured nutrient, type of claim, framing of statement, nature of statement, and presentation of statement. For example, a package may display one or more statements such as symbols relating to nutrition content, statements in words relating to the presence of certain nutrients, statements in words relating to the absence of other nutrients, statements in words describing the health benefits of consuming foods containing or not containing certain nutrients, and statements in words describing how the product was produced. Moreover, all of those symbols and statements are distributed in various places on the package in different font sizes and colors.

There exists a large body of literature on the impacts of different types of labeling statements on consumer perceptions and choices of products (Refs. 9-10). The majority of the research, including the consumer research that the agency has previously conducted (Refs. 11-12), has focused on single labeling statements by eliciting study participants' reactions to variants of a given statement. An advantage of this research approach is that it helps isolate the effects of individual statements and avoid potential confounding effects caused by the presence of other statements. A disadvantage of this research approach, however, is that it does not necessarily reflect the labels consumers see in the marketplace. In particular, the existing literature provides little information about how the coexistence of two or more different labeling statements affects product perceptions and choices. This information, however, is critical for understanding the roles played by labeling statements in dietary decisions.

Research suggests consumer product perceptions and purchase decisions can be influenced by labeling statements and different labeling statements may have different influences (Refs. 9-12). Therefore, the FDA, as part of its effort to promote public health, proposes to use this study to explore consumer responses to food labels that bear multiple labeling statements. Specifically, the study plans to examine: (1) consumer responses to food labels that exhibit various combinations of the number and type of statements; (2) whether and how consumer responses to one label characteristic may be affected by the other characteristic (i.e., the interactions between different characteristics of labeling statements); and (3) whether and how labeling statements affect the use of the Nutrition Facts label.

2. Purpose and Use of the Information Collection

The data collection is intended to provide answers to the three research objectives stated in the previous section. The study will use an experimental design and statistically test differences in participants' responses to a variety of mockup food labels. All label images will be mockups resembling food labels that may be found in the marketplace. Images will show product identity (e.g., snack bar), but not any real or fictitious brand name.

The study will ask its participants to view label images and answer questions about their perceptions and reactions related to the viewed product and label. Product perceptions

(i.e., healthfulness, potential health benefits, levels of nutrients and substances, taste, and purchase intention) and label perceptions (e.g., helpfulness and credibility) will constitute the measures of responses in the experiment. To help understand the data, the survey will also collect information about participants' background, such as familiarity with and consumption, purchase, and perception of the categories of food included in the study; awareness and knowledge of nutrients; dietary interests; motivation regarding label use and health literacy; and health status and demographic characteristics.

The study will provide interested participants access to the Nutrition Facts label, but not together with a product image. The study will record whether participants use the NF label when answering product perception questions and test whether the use differs between different label conditions.

The food labels will vary in:

1. the number of statements:

- 1.1 none (which will only show the Nutrition Facts label of a product on the front of the label, with a size covering approximately less than a fifth of the front surface),
- 1.2 one statement,
- 1.3 two statements, or
- 1.4 three statements;

2. the type of statement:

2.1 text-content-claim

- 2.1.1 "Low Sodium"—chips (yes/no),
 - 2.1.2 "High Fiber"—cereal (yes/no),
 - 2.1.3 "Low Fat"—snack bar (yes/no),
- (the claim-food pairings have been chosen based on observations of content claims featured on actual products; the pairings will be fixed in the study);

2.2 text-structure/function-claim

- 2.2.1 "Supports cardiovascular functioning" (yes/no),
- 2.2.2 "Supports the immune system" (yes/no);

2.3 text-process-claim

- 2.3.1 "100% Natural" (yes/no),

2.4 graphic-icon

- 2.4.1 basic Facts-Up-Front icon (yes/no),
- 2.4.2 basic-plus-two Facts-Up-Front icon (yes/no),
- 2.4.3 Institute of Medicine icon (yes/no);

(the basic FUF icon shows the amounts and percent Daily Values, when applicable, of calories, saturated fat, sodium and sugars; the basic plus two FUF also shows the amounts and percent Daily Values, when applicable, of two of potassium, fiber, protein, vitamin A, vitamin C, vitamin D, calcium, and iron; the IOM icon is one of the three design concepts proposed by the IOM (Refs. 13-14).

The no-statement label (see 1.1 above) has been chosen to serve as the control in the experimental study. The product and label perceptions of this label condition will indicate the inferences participants would make when they are cued by the Nutrition Facts label to pay attention to the nutritional characteristics of a product while still subject to the influences of other images on the front of the label, such as the picture of the product and product identity. On all other labels, participants are provided different degrees of cue by different labeling statements but the same label image for a given product. Statistical tests between inferences from the control label and inferences from other labels will then suggest the incremental effects of labeling statements.

The experimental conditions included in the study are but a small set of examples of the products and labeling statements that are available in the marketplace or have been proposed. Due to resource limitations, we have decided to keep the scope of the study at a manageable level. Furthermore, we do not plan to vary the content-claim-product pairings, the location of a statement on the label, or the nutritional characteristics of a product. We recognize that these are additional factors that may influence consumer responses to labeling. The agency will consider extending the study in the future to include other variations, to focus on certain variations, or both.

To answer the research questions, the study plans to test the following null hypotheses:

Hypothesis 1a: There is no difference in product perceptions (i.e., healthfulness, potential health benefits, levels of nutrients and substances, and taste) or label perceptions (i.e., helpfulness and credibility) between labels that differ in (1) presence or absence of any statement; or (2) the number of statements, if any statement is present (one, two, or three).

Hypothesis 1b: Among labels that display at least one statement, there is no difference in product or label perceptions between labels that differ in the number of statements.

Hypothesis 1c: Among labels that display at least one statement, there is no difference in product or label perceptions between the four types of statement.

Hypothesis 1d: Among labels that display a text-structure/function-claim, there is no difference in product or label perceptions between the two structure/function claims.

Hypothesis 1e: Among labels that display a graphic-icon, there is no difference in product or label perceptions between the three icons.

Hypothesis 1f: Among labels that display a graphic-icon, there is no difference in product or label perceptions between the two FUF icons.

Hypothesis 1g: Among labels that display a graphic-icon, there is no difference in product or label perceptions between the basic-FUF icon and the IOM icon.

Hypothesis 1h: Among labels that display a graphic-icon, there is no difference in product or label perceptions between the basic-plus-two-FUF icon and the IOM icon.

Hypothesis 2a: There are no two-way interaction effects in product or label perceptions between labels that display at least two statements and differ in the: (1) number of statements and featured nutrient and product; (2) number of statements and type of statement; (3) number of statements and nature of featured product attribute; (4) featured nutrient and product and type of statement; (5) featured nutrient and product and nature of featured product attribute; (6) type of statement and nature of featured product attribute; (7) type of graphic-icon and type of other statement(s) on the label; or (8) type of graphic-icon and nature of featured product attribute.

Hypothesis 2b: For a given text-structure/function claim, there are no two-way interaction effects in product or label perceptions between labels that also display the other text claims in the: (1) featured nutrient; or (2) nature of featured product attribute.

Hypothesis 3: There are no three-way interaction effects on product or label perceptions between labels that display at least three statements and differ in the: (1) number of statements, featured nutrient and product, and type of statement; or (2) number of statements, featured nutrient and product, and nature of featured product attribute; or (3) number of statements, type of statement, and nature of featured product attribute.

Hypothesis 4: There is no difference in the proportion of participants who choose to view the Nutrition Facts label while answering product perception questions between labels that differ in (1) presence or absence of any statement; (2) the number of statements, if any statement is present (one, two, or three); or (3) the nature of featured product attribute.

The study will use a convenience sample of self-selected members of an established online consumer panel, rather than a probability-based sample with known probability of the general population. Hence, the study is not intended to or will yield nationally representative population estimates. Even if the results are not nationally representative, the study design would provide valid and quantitative estimates of differences in consumer responses caused by variations between different labels.

The study is part of the agency's continuing effort to enable consumers to make informed dietary choices and construct healthful diets. Results of the study will be used primarily to enrich the agency's understanding of how multiple claims and other labeling statements on food packages may affect how consumers perceive a product or a label, which may in turn affect their dietary choices. In particular, are certain types of statements more influential on consumer responses? Are consumer effects of nutrition-related statements influenced by non-nutrition statements? Are textual or graphic statements more influential on consumer responses? Does a larger number of statements dilute the effects of individual statements? Would there be any differential effects between the FUF icons and the concepts proposed by the IOM? The understanding will help the agency identify and develop future research to clarify this study's observations

and to provide further information about how consumers are affected by specific labeling statements. The understanding also can be used as an input in the agency's deliberation of possible measures to help consumers make better dietary choices.

3. Use of Improved Information Technology and Burden Reduction

The proposed information collection will recruit respondents and conduct experiments via the Internet. The Internet mode of data collection is more appropriate than other modes, e.g., telephone or in-person, because of its advantages in respondent burden, cost, administration, speed, and absence of interviewer effects. Web-based data collections also minimize possible data entry errors and expedite the timeliness of data processing. Compared to face-to-face interviews and mailed surveys, web-based surveys are less intrusive and less costly.

4. Efforts to Identify Duplication and Use of Similar Information

The proposed experimental study is not duplicative of existing information. As previously noted, although prior research has examined the effects of different types of labeling statements on consumer perceptions and product choices (Refs. 9-10), the majority of the research, including research previously conducted by the agency (Refs. 11-12), has focused on consumer reactions to single labeling statements. Thus, the existing literature provides little information about how the coexistence of two or more different labeling statements affects product perceptions and choices. This information, however, is critical for understanding the roles played by labeling statements in dietary decisions.

5. Impact on Small Businesses or Other Small Entities

No small businesses will be involved in this collection.

6. Consequences of Collecting the Information Less Frequently

This is a one-time data collection. Without this study, FDA will not have the needed information to understand consumer responses to food labels that display multiple labeling statements. The information from this study will help the Agency to explore potential areas of concern to better understand where we might want to focus research in the future and also help define the dimensions of future research on select topics. In addition, the results will be used to provide a background for understanding issues of importance to the Agency's program offices.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances for this collection of information.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

In the Federal Register of April 13, 2011 (76 FR 20675), FDA published a 60-day notice requesting public comment on the proposed collection of information. The Agency received four responses to the notice. One of the responses was outside of the scope of the proposed collection of information described in the 60-day notice and is not

addressed here. The remaining three responses contained multiple comments. These comments, and the Agency's responses, are discussed in the following paragraphs.

(Comment 1) Two comments suggested that FDA provide mock stimuli for public comment prior to initiating the study.

(Response 1) We appreciate the suggestion for the Agency to provide the experimental stimuli for public comment prior to initiating the study. Per the PRA, a copy of the proposed experimental stimuli is provided in the appendix of the supporting document.

(Comment 2) One comment suggested that the study include questions to probe how non-misleading nutrient content, health, and structure/function claims may improve consumers' understanding of a product's nutritional attributes.

(Response 2) We agree and have included measures to assess how participants' understanding of a product's nutritional attributes may be affected by non-misleading claims.

(Comment 3) Two comments expressed concerns about four questions proposed in the draft questionnaire. Two of the questions of concern asked if participants had ever heard or read that certain foods (unnamed) may help lower the risk of seven different types of health problems, such as cancer, diabetes, and others. The third and fourth questions of concern asked whether specific nutrients (e.g., calcium, potassium, etc.) or a particular food product, respectively, might help reduce the risk of the same health problems asked about in the other two questions. Both comments suggested that such questions would demonstrate that "consumers misinterpret structure function claims as health claims," and argued that such a demonstration would be inconsistent with the stated purpose of the information collection.

(Response 3) FDA does not agree that the proposed questions on participants' prior knowledge of foods' health benefits and inferences from reading a label would bias the study toward health claims rather than structure/function claims. Since label inferences can be affected by what consumers already know or believe about a food, the prior knowledge questions are included to help understand study participants' reactions to labeling statements. The question about perceived health benefits of a product is one of the most important measures of label inferences. The agency's previous research has shown that consumer inferences of the health benefits of a product do not necessarily vary between types of labeling statements (i.e., health claims, structure/function claims, and nutrient content claims). Hence, this question is not expected to produce erroneous data with respect to inferences about structure/function claims.

(Comment 4) One comment suggested that FDA consider including an experimental condition in which participants would view a label bearing up to three different labeling statements, because consumers are routinely exposed to this amount of information on food packages. In the originally proposed design, FDA included label manipulations involving only up to two different labeling statements.

(Response 4) We agree with the comment and have revised the study to include experimental conditions containing up to three labeling statements on a label.

(Comment 5) One comment suggested including an assessment of how the various labeling statements affect whether participants intend to purchase the product or not.

(Response 5) As we proposed in the draft questionnaire, we will include a question about purchase intention.

(Comment 6) One commenter noted that prior research has shown that the appearance of packaging and statements on the front of the package can increase the likelihood of consumers using the Nutrition Facts label.

(Response 6) FDA agrees that information about consumers' use of the Nutrition Facts label is important and plans to record and analyze how likely the study's participants are to consult the Nutrition Facts label when viewing claims and other statements on the front label of a product.

(Comment 7) One comment questioned the relevance of asking participants to rate the safety or trustworthiness of a product based on the label information they view.

(Response 7) Although the label content of a product may not be intended to influence consumer assumptions regarding the safety of a product, prior research has demonstrated that such influence may occur (Ref. 15). Therefore, it would be useful to understand whether similar reactions happen in a multi-claim context. Nevertheless, the products that the proposed study plans to include (breakfast cereal, chips, and snack bar) are generally not associated with safety issues that may lead to foodborne illness or other safety hazards. Therefore, the study will omit the proposed question on perceived product safety. On the other hand, the agency has determined that it is still important and relevant to elicit study participants' perceptions of the trustworthiness of various labeling statements (not foods, as stated in the comment), especially when these statements feature different nutrients or product benefits. Thus, the study will keep the proposed question on perceived trustworthiness of the label.

(Comment 8) One comment suggested that the study ask about participants' interest in nutrients for which there is concern of inadequate intake among Americans. The comment recommended replacing Vitamin D and omega-3 fatty acids for Vitamins A and C, as proposed in the previous draft questionnaire.

(Comment 9) We agree with the comment and have incorporated the suggestion in the revised questionnaire.

(Comment 10) One comment suggested that a plausible distractor or wrong choice be included in the question about the nutrients participants try to limit or increase in their diet to test the validity of the responses.

(Response 10) We disagree with the comment. Our previous surveys indicate respondents can provide valid responses to these questions (for example, Ref. 16). Furthermore, we are concerned that the validity of the responses would suffer if a distractor or wrong choice is included, because participants may be confused by the presence of such options in the question.

In addition to eliciting comments with the 60-day Federal Register notice, we requested feedback from several academic researchers who have conducted research related to nutrition labeling and claims. The following researchers responded to our request and provided their comments. We have carefully considered the input from these experts and incorporated their suggestions where appropriate and necessary.

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9. Explanation of Any Payment or Gift to Respondents

We will recruit members on the Knowledge Networks' KnowledgePanel to participate in the study. Knowledge Networks (KN) provides non-specific survey incentives in order to maintain a high degree of panel loyalty and to prevent attrition from the panel. For the households that are provided Internet appliances and an Internet connection by KN, their "panel loyalty" incentive is the hardware and Internet service that KN provides free of charge. For households using their own personal computers and Internet service for survey participation, KN enrolls the panelists into a points program that is analogous to a

“frequent flyer” program, in that respondents are credited with points in proportion to their regular participation in surveys. Panelists receive cash-equivalent checks approximately every four to six months in amounts reflecting their level of participation in the panel, which commonly results in distributions in the range of \$4 to \$6 per month.

We plan to conduct nine cognitive interviews. Participants will be paid \$50 for a 60-minute interview.

10. Assurance of Confidentiality Provided to Respondents

All data will be kept private to the extent permitted by law. The study instrument will include a statement explaining this to respondents.

No personally identifiable information will be sent to FDA. All information that can identify individual respondents will be kept by the independent contractor that is separate from the data provided to FDA. The information will be kept in a secured fashion that will not permit unauthorized access. These methods will all be approved by FDA’s Institutional Review Board (Research Involving Human Subjects Committee) prior to collecting any information.

KN will collect the study data and follow its standard confidentiality and privacy policy, as described below:

“Survey responses are confidential, with identifying information never revealed without respondent approval. When surveys are assigned to KnowledgePanel Members, they receive notice in their password protected e-mail account that the survey is available for completion. Surveys are self-administered and accessible any time of day for a designated period. Participants can complete a survey only once. Members may leave the panel at any time, and receipt of the laptop and Internet service is not contingent on completion of any particular survey.

All KN panelists, when joining the panel, are given a copy of the Privacy and Term of Use Policy. The privacy terms are also available electronically at all times to panelists via the Panel Member website. The Privacy and Terms of Use Policy is posted at <http://www.knowledgenetworks.com/company/privacy.html>.”

In addition, all electronic data will be maintained in a manner that is consistent with the Department of Health and Human Services ADP Systems Security Policy as described in DHHS ADP Systems Manual, Part 6, chapters 6-30 and 6-35. All data will also be maintained in consistency with the FDA Privacy Act System of Records #09-10-0009 (Special Studies and Surveys on FDA Regulated Products).

11. Justification for Sensitive Questions

The study will ask respondents their height, weight, perceived health, perceived weight status, special diets, and status and risk perception of chronic illnesses. This information is needed for two purposes. First, we are interested in investigating how these personal characteristics affect respondents’ nutrition- and health-related perceptions, attitudes and

behaviors. Second, as personal characteristics may explain some of the variations in respondents’ perceptions, attitudes and behaviors, the study will examine these variations by controlling for personal characteristics.

The agency’s experience with these questions suggests that the overwhelming majority of respondents feel comfortable providing this information. For example, in the Experimental Study of Health Claims on Food Packages (OMB Control No. 0910-0565), the item non-response rates due to refusal were <1% for height, perceived weight status, special diets, and status and risk perception of chronic illnesses. Only the question of weight had a higher non-response rate of 6%.

As an additional precaution, the experimental study will include an explanation preceding the health status questions that reminds participants that they may decline to respond to any particular question.

12. Estimates of Annualized Burden Hours and Costs

12a. Annualized Hour Burden Estimate

To help design and refine the questionnaire, FDA plans to conduct cognitive interviews by screening 72 panelists in order to obtain 9 participants in the interviews. Each screening is expected to take 5 minutes (0.083 hour) and each cognitive interview is expected to take one hour. The total for cognitive interview activities is 15 hours (6 hours + 9 hours). Subsequently, we plan to conduct pretests of the questionnaire before it is administered in the study. We expect that 1,600 invitations, each taking 2 minutes (0.033 hour), will need to be sent to panelists to have 200 of them complete a 15-minute (0.25 hour) pretest. The total for the pretest activities is 106 hours (53 hours + 50 hours). For the survey, we estimate that 32,000 invitations, each taking 2 minutes (0.033 hour) to complete, will need to be sent to the consumer panel to have 4,000 of its members complete a 15-minute (0.25 hour) questionnaire. The total for the survey activities is 2,056 hours (1,056 hours + 1,000 hours). Thus, the total estimated burden is 2,174 hours. FDA’s burden estimate is based on prior experience with research that is similar to this proposed study.

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden¹

Portion of Study	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Cognitive interview screener	72	1	72	0.083 (5 min.)	6
Cognitive interview	9	1	9	1	9
Pretest invitation	1,600	1	1,600	0.033 (2 min.)	53

Pretest	200	1	200	0.25 (15 min.)	50
Survey invitation	32,000	1	32,000	0.033 (2 min.)	1056
Survey	4,000	1	4,000	0.25 (15 min.)	1,000
Total					2,174

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

12b. Annualized Cost Burden Estimate

The annualized cost to all respondents for the hour burden for the collection of information is \$17,116 (1,052 x \$16.27) at \$16.27 per hour (the 2010 median wage rate in the U.S.) See http://www.bls.gov/oes/current/oes_nat.htm#00-0000.

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/Capital Costs

There are no capital, start-up, operating or maintenance costs associated with this information collection.

14. Annualized Cost to the Federal Government

The estimated total cost to the Federal Government for this information collection \$300,000. This includes the value of a task order to execute the collection of information and the value of a Full-Time-Employee to develop, monitor and analyze the data collection.

15. Explanation for Program Changes or Adjustments

This is a new information collection.

16. Plans for Tabulation and Publication and Project Time Schedule

We plan to complete data collection and analysis within two years from the date of OMB approval. The planned schedule for the project is shown in Table 2.

The purpose of tabulation is to quantitatively analyze the data and summarize findings to meet the informational needs. Commonly accepted statistical techniques such as descriptive analysis, analysis-of-covariance (ANCOVA), and the generalized linear model will be used to analyze the experimental data.

Table 2. Project Schedule

Date	Activity
Within 1 day following OMB approval	Notification to contractor to proceed with data collection
Within 45 days following OMB approval	Completion of data

Within 75 days following OMB approval	Completion of data delivery by the contractor
Within 135 days following OMB approval	Completion of preliminary analyses
Within 180 days following OMB approval	Beginning of review, clearance, and dissemination of preliminary findings

FDA will disseminate the results of this study strictly following FDA's "Guidelines for Ensuring the Quality of Information Disseminated to the Public." In describing the data collected and results of the analysis, FDA will clearly acknowledge that the experimental data does not provide nationally representative population estimates such as consumer attitudes, knowledge, or behaviors but provides valid and quantitative estimates of differences across experimental conditions.

The dissemination may include internal briefings and reports, presentations and articles at trade and academic conferences, in professional journals, and posting on FDA Web site.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

The OMB approval and expiration date will be displayed on all materials associated with the study. No exemption is requested.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

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