STATE OF CALIFORNIA DEPARTMENT OF FOOD AND AGRICULTURE MARKETING BRANCH



GUIDELINES ON ADVERTISING, PROMOTION AND COMMUNICATIONS FOR COMMODITY MARKETING PROGRAMS

EFFECTIVE NOVEMBER 1, 2015

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CALIFORNIA DEPARTMENT OF FOOD AND AGRICULTURE GUIDELINES ON ADVERTISING, PROMOTION AND COMMUNICATIONS BY CALIFORNIA COMMODITY MARKETING PROGRAMS

The Department of Food and Agriculture (hereinafter referred to as "Department") is responsible for oversight of commodity marketing programs (boards, councils and commissions) established pursuant to Divisions 21 and 22 of the California Food and Agricultural Code. While the form of departmental oversight varies for these programs, the guidelines apply to all.

STANDARD

In order to be in the public interest, the Secretary has determined that communication content¹ created by California commodity marketing programs (hereinafter referred to as "programs") will meet the following standards:

- 1. Be consistent with their statutory authority and obligations.
- 2. Be truthful and not misleading.
- 3. Not disparage other agricultural commodities or food products pursuant to the following:
 - a. Disparagement is any statement or depiction, that denigrates, discredits, or criticizes another commodity or product (whether generic or branded).
 - b. Comparisons of one commodity or food product with another are allowed provided that the comparison is factual, and not misleading.
 - c. Comparisons may extol the positive attributes of a commodity, but cannot emphasize the negative attributes of a competing commodity. For example: ("Our product has more Vitamin C than their product" is allowed provided it is a factually accurate comparison and supporting documentation is on file. Stating that "The competing product is low in Vitamin C" is not allowed.)
- 4. Be appropriate for all audiences (in good taste, respectful of people and all classes of people, and appropriate for a governmental entity to communicate),
 - a. In the case of wine and distilled spirits, while the target audience and messaging are directed at adults (at least 21 years of age), the commercial or promotional material must be appropriate for all viewers.

¹ Materials prepared for TV, radio, outdoor print and/or website as well as materials prepared for marketing mass release and product correspondence.

California Department of Food and Agriculture Guidelines on Advertising, Promotion and Communications Effective November 1, 2015

- 5. Nutrition, health or structure function claims that expressly or implicitly link the consumption of a food substance to the risk of a disease or a health related condition must: Comply with Federal Trade Commission (FTC) Standards and Guidelines (reference www.ftc.gov/public-statements/1983/03/ftc-policy-statement-regarding-advertising-substantiation) and comply with the Food and Drug Administration (FDA) Standards and Guidelines (reference www.fda.gov/Food/IngredientsPackagingLabeling/LabelingNutrition/ucm111447.htm).
- 6. Communications intended for an international audience do not require compliance with USDA/AMS, FTC or FDA law or regulations. Instead these communications should be:
 - a. Truthful
 - b. In good taste
 - c. Not disparaging
 - d. Consistent with program statutory authority and obligations.
 - e. In compliance with the local law, custom and generally accepted standards for the destination country.

DEPARTMENT REVIEW

Major advertising strategies for television, radio, print, outdoor and websites must either (1) be presented to and approved by boards of directors at board meetings or by a committee delegated that authority by a board when the CDFA liaison is present or (2) reviewed with the CDFA liaison assigned to the program. Programs shall maintain substantiation for all content in a readily accessible format. The Department shall annually review content substantiation.

ENGAGEMENT OF CRISIS MANAGEMENT PLANS

Situations arise in which urgent communications with the public are warranted to ensure accurate information is provided. For this reason, most programs have developed crisis-management plans that are triggered to ensure urgent issues are addressed swiftly. The Department recognizes that such plans are in the public interest. The Department shall be kept apprised of the program's actions under such plans and that any communications material developed or relevant information that is gathered should be shared with the Department's Public Affairs office.

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RETENTION OF DOCUMENTATION

All documentation supporting advertising and promotion messaging should be retained for a period of five (5) years consistent with the statute of limitations specified in the U.S. Food and Drug Act. Documentation may be maintained in electronic form. It will be sufficient if the agency or program maintains a system for documentation of claims made that includes review and approved by legal counsel with expertise in FTC and FDA Standards and Guidelines.

ADDITIONAL RESOURCE

Guidelines prepared by USDA/AMS for use by Federal Marketing Order boards and committees are attached. As they clarify a number of issues related to advertising and communication, CDFA is providing them as a valuable resource in terms of complying with these guidelines.

Attachment

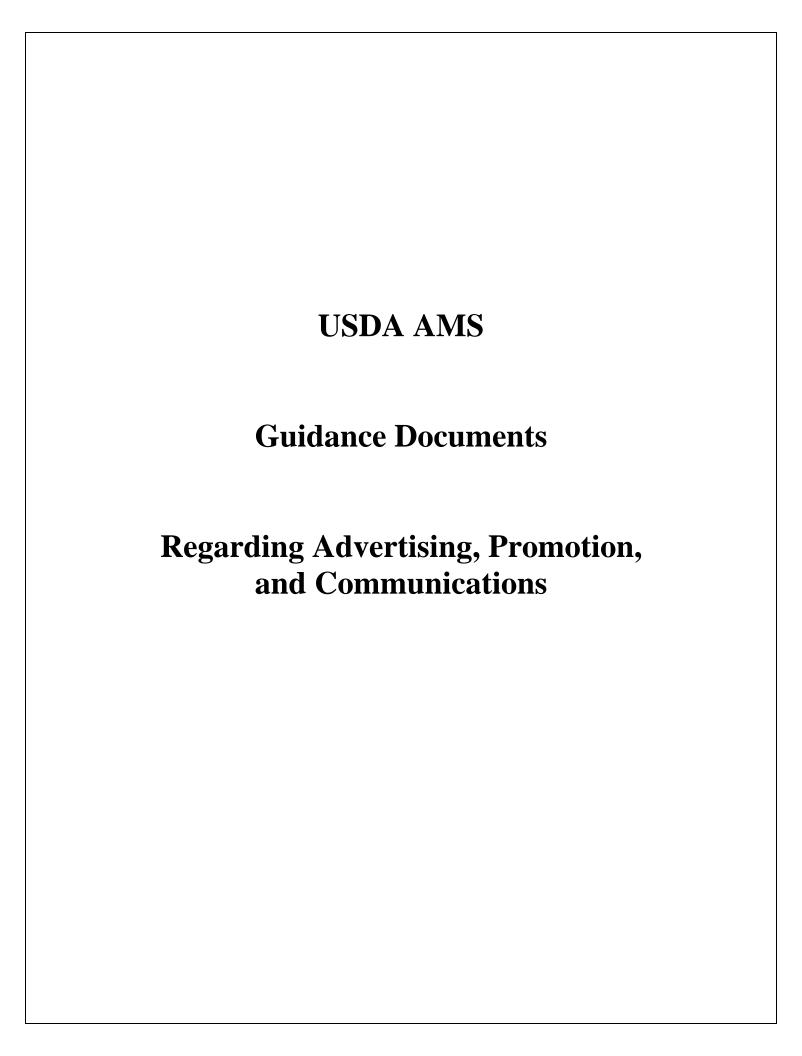


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Guidelines for Committee/Board Advertising, Promotional Material,

Web Sites, and Other Publications

These Guidelines are for the use of Fruit and Vegetable Programs, Agricultural Marketing Service (AMS) and its marketing order committees and research and promotion boards to provide a framework for the review of advertising and promotional materials (all media), internet sites, press releases, articles for magazines and industry newsletters. The overview of review criteria and key points shown below is intended to serve as a checklist. For definitions, guidance, examples of statements that are approved or that would require change, and additional technical guidance for the criteria, please see the Appendix. Questions should be referred to the designated AMS representative, as AMS is responsible for the final approval of all materials.

	Criteria for Advertising, Promotion, and Other Material	Key Points
A.	Use only true statements and depictions and conform with Federal Trade Commission (FTC) guidelines for advertising, internet, and other marketing materials	 Use no false, misleading or deceptive statements. Identify all expressed and implied claims; Committees and boards cannot suggest claims that they could not make directly. Claims must be adequately supported. Net impression is key.
В.	Use only health, nutrient and structure function claims that conform with Food and Drug Administration (FDA) standards The FDA has primary responsibility for claims on product labeling, including packaging, inserts, and other promotional materials distributed at the point of sale. The FTC works closely with FDA to align health and nutrition messages.	 Nutrient content claims must be accurate – e.g., terms such as "good source of" or "excellent source of" must be supported with data from the National Nutrient Database or FDA's Guidelines for Voluntary Nutrition Labeling or Raw Fruits and vegetables. Claims for nutrients for which there is not established daily value (e.g. antioxidants) must be limited to stating that the product contains the nutrient, provided that the net impression of the material is not misleading. Nutrient or health claims for commodities that contain more than specified amounts of saturated fat, cholesterol, or sodium may be used if the amount of the risk-increasing nutrient in the food product is disclosed. All health claims, and implied health claims, must be approved by FDA, or include adequate disclaimers. No medical claims (i.e., commodity cannot be portrayed as a "drug" with a therapeutic effect) are allowed.
C.	Do not disparage any commodity or competing product	 No statement or depiction is permitted that disparages another commodity or product. Any comparison to another commodity or product must be non-disparaging and limited to the presentation of fact-based information or data.
D.	Use only appropriate speech and depictions and conform to USDA and other federal policies and all applicable statutes and regulations.	 All statements or depictions must be appropriate for all audiences and be appropriate for the Secretary of Agriculture and other USDA employees to make. Do not attempt to influence government policy or action or use political issues or images. Boards and committees cannot unlawfully use other organizations' trademarks, copyrights, or logos.

APPENDIX

A.		only true statements and depictions and conform			
	with 1	th Federal Trade Commission (FTC) guidelines			
	for ac	advertising, internet, and other marketing			
	mater	materials			
1. Defi	A deceptive ad or other promotional material is one that contains a misrepresentation or omission that "is likely to mislead consumers acting reasonably under the circumstances to their detriment."				
but r by al (Wh		a. Identify all claims. Do not focus just on individual phrases or statements, but rather consider the ad as a whole, assessing the "net impression" conveyed by all elements of the ad, including the text, product name, and depictions. (When necessary, copy tests or other evidence of how consumers actually interpret an ad, can be valuable.)			
implied by		b. An advertiser is equally responsible for the accuracy of claims suggested or implied by the ad. Committees and boards cannot suggest claims that they could not make directly.			
		c. Committees and boards should disclose information relevant to the limited applicability of an advertised benefit.			
		d. When the disclosure of qualifying information is necessary to prevent an ad from being deceptive, that information should be presented clearly and prominently, so that it is actually noticed and understood by consumers (e.g., in a readable font and position within the ad).			
		e. Without appropriate scientific evidence to back up the underlying claim, committees and boards should not make claims either through consumer or expert endorsements that would be deceptive or could not be substantiated if made directly. It is not enough that a testimonial represents the honest opinion of the endorser.			
		Consumers should have access to information about emerging areas of science so that they can have confidence in the accuracy of information presented in advertising. All claims should be supported with competent and reliable scientific evidence. FTC defines such evidence as "tests, analysis, research, studies or other evidence based on the expertise of professionals in the relevant area, that have been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results." However, health and nutrition claims must conform to FDA requirements as discussed in Part B.			

A. Use only true statements and depictions and conform with Federal Trade Commission (FTC) guidelines for advertising, internet, and other marketing materials.

3. Examples of statements that are approved

Ads for peanuts [or other nuts] can extol their benefits as part of a healthy lifestyle, but the ads must disclose the total fat content per servings (see Section B).

"For a tasty treat, try _____."

4. Examples that would require change

"Scientists Now Agree!" in discussing the product's benefit. This statement likely conveys to consumers that the state of science supporting the benefit has reached the level of scientific consensus. Unless the advertiser possesses this level of evidence, the claim is not substantiated. (Health and nutrition claims must conform to FDA requirements as discussed in Part B.)

"My bad cholesterol dropped significantly by eating an ounce a day of _____." Testimonials are not permitted. Also, all implied claims are subject to FDA requirements.

"The Washington Post reports significant benefits . . ." Consumers need full and balanced information to evaluate a claim. Thus, without appropriate scientific or other evidence to back up the underlying claim, the selective use of newspaper articles, abstracts of scientific studies, or other "third party literature" to promote a particular brand or product can be misleading on how consumers interpret an advertisement.

5. Additional technical guidance

"Advertising and Marketing on the Internet: Rules of the Road" FTC: www.ftc.gov/bcp/conline/pubs/buspubs/ruleroad.htm

"FTC Guides Concerning Use of Endorsements and Testimonials in Advertising" FTC: www.ftc.gov/bcp/guides/endorse.htm

"Enforcement Policy Statement on Food Advertising" May 1994, FTC: www.ftc.gov/bcp/policystmt/ad-food.htm

"Dietary Supplements: An Advertising Guide for Industry" 1998, FTC: www.ftc.gov/bcp/conline/pubs/buspubs/dietsupp.htm

"Generic Copy Test of Food Health Claims in Advertising: November 1998, FTC: www.ftc.gov/os/1998/11/netfood.pdf

B. Health, nutrient and structure function claims should conform with Food and Drug Administration (FDA) standards

1. Definitions

Claims that can be used on food and dietary supplement labels fall into three categories: health claims, nutrient content claims, and structure/function claims.

<u>Health Claims</u> describe a relationship between a food, food component, or dietary supplement ingredient, and reducing risk of a disease or health-related condition.

- a. Nutrition Labeling Education Act (NLEA) Authorized Health Claims.
 FDA authorizes these types of health claims based on an extensive review of the scientific
- b. Health claims based on authoritative statements are as a result of a successful submission to FDA of a health claim based on an "authoritative statement" from a scientific body of the U.S. Government or the National Academy of Sciences.
- c. Qualified health claims [are allowed] . . . when there is emerging evidence for a relationship between a food, food component, or dietary supplement and reduced risk of a disease or health-related condition. In this case, the evidence is not well enough established to meet the significant scientific agreement standard required for FDA to issue an authorizing regulation. Qualifying language is included as part of the claim to indicated that the evidence supporting the claim is limited.

<u>Nutrient content claims</u> are claims on a food product that directly or by implication characterize the level of a nutrient in the food (e.g., "low fat" or "high in oat bran.")

<u>Structure/function claims</u> describe the role of a nutrient or dietary ingredient intended to affect normal structure of function in humans, for example, "calcium builds strong bones." In addition, they may characterize the means by which a nutrient or dietary ingredient acts to maintain such structure or function, for example, "fiber maintains bowel regularity," or "antioxidants maintain cell integrity," or they may describe general well-being from consumption of a nutrient or dietary ingredient.

Structure/function claims may also describe a benefit related to a nutrient deficiency disease (like vitamin C and scurvy), as long as the statement also tells how widespread such a disease is in the United States.

B. Health, nutrient and structure function claims should conform with Food and Drug Administration (FDA) standards

2. Guidance

Nutrient or health claims for commodities that contain more than 13 grams of fat, more than 4 grams of saturated fat, more than 60 milligrams of cholesterol, or more than 480 milligrams of sodium (disqualifying levels of risk-increasing nutrients) may be used if the amount of the risk-increasing nutrient in the food product is disclosed.

Based on information in the National Nutrient Database or other approved databases (e.g., FDA's Guidelines for Voluntary Nutrition Labeling of Raw Fruits and Vegetables), a product may be called a <u>source or a good source</u> (or similar language) of a nutrient if a recommended amount customarily consumed (RACC) serving contains 10 to 19 percent of the daily value of the nutrient.

A product may be called an excellent source (or similar language – e.g., "packed with") if a RACC serving contains 20 percent or more of the daily value for the nutrient. Between two percent and ten percent of the daily value may be listed on the nutrition facts label and mentioned in a list of total number of nutrients in the product, but the food may not be promoted as a source of the nutrient or imply that, because it contains said nutrient, it may have an effect on health status.

A statement about a nutrient for which there is no established daily value may be used so long as the claim specifies only the amount of the nutrient per serving and does not imply that there is a lot or a little of that nutrient in the product. Such a claim might be "x grams of omega-3 fatty acids."

Implied health claims will be treated the same as health claims that must be approved by FDA. Implied health claims include illustrations (such as the heart symbol or the depiction of a medical professional) and third-party endorsements and testimonials (including quotations from religious documents).

The words "cures", "mitigates", "treats", or "prevents" even if modified by "may" are not permitted, because these words redefine the substance as a "drug" with a therapeutic effect under FDA regulations. This includes the phrase "lowers cholesterol".

A product may be called "healthy" or any derivative of the term healthy if a RACC serving is low fat (3 grams or less), low in saturated fat (1 gram or less and 15 percent or less calories from saturated fat), low in cholesterol (20 milligrams or less), and low in sodium (140 milligrams or less), and contains at least 10 percent of the daily reference value for one of the following: Vitamin A, Vitamin C, calcium, iron, protein, or fiber, except for raw and canned or frozen single ingredient fruits and vegetables and enriched cereal-grain products that conform to a standard of identity.

B. Health, nutrient and structure function claims should conform with Food and Drug Administration (FDA) standards

"Mangos are a healthy, deep orange fruit that provide high amounts of 3. Examples vitamins A and C." of statements that are "Tomatoes contain Lycopene" approved. "Research shows that tomatoes may help prevent certain cancers." The claim 4. Examples that would is in conflict with FDA's November 2005 official statement require (www.cfsan.fda.gov/~dms/qhclyco2.html) change is a nutritious food." (Nutritious can be used in reference to the diet as a whole, not an individual food.) 5. Additional National Nutrient Database for Standard Reference: technical www.nal.usda.gov/fnic/foodcomp/data/index.html guidance FDA's Guidelines for Voluntary Nutritional Labeling of Raw Fruits and Vegetables – Table C: www.cfsan.fda.gov/~acrobat/fr060817.pdf Dietary Reference Intakes and Recommended Dietary Allowances: www.nal.usda.gov/fnic/dga/rda/pdf Food Labeling and Nutrition: www.cfsan.fda.gov/~dms/lab-hlth.html Label Claims: www.cfsan.fda.gov/~dms/lab-hlth.html Reference amounts customarily consumed (RACC): www.cfsan.fda.gov/~lrd/CF101-12.HTML

C. Do not product		e any con	nmodit	y or co	ompetin	ng
1. Definitions	A disparagement is any statement or depiction that denigrates, discredits, or criticizes another commodity or product.					
2. Guidance No statement or depiction can be used that disparages another comproduct. Moreover, any comparison to another commodity or product limited to the presentation of information or data that has a support factual basis, is truthful and non-deceptive, and provides a source important information to consumers for the purpose of assisting the making rational purchase decisions.			product is portable rce of			
3. Examples of statements that are approved	atements that supporting data)				oducts are	
			-	I a	~	
		Fresh	Butter, Salted	Sour	Cheddar	Mayonnaise
	Portion	Avocados 2 Tbsp. or 2-	2 Tbsp.	Cream 2 Tbsp.	Cheese 1 Slice	with Salt 2 Tbsp.
	(1 ounce)	3 Thin Slices	2 10sp.	2 10sp.	1 Slice	2 10sp.
	Calories	50	204	60	114	109
	Total Fat (g)	4.6	23	6	9.4	9.4
	Sat Fat (g)	0.6	14.6	3.7	6	1.4
	Cholesterol (mg)	0	61	13	30	7
	Sodium (mg)	2	164	15	176	199
*Source: USDA National Nutrient Database for Standard Reference, Release 18 (2005)						
4. Examples that would require change	ould require			ation)		
"Peanuts taste better than walnuts or almonds in a salad."						

	1			
D.		only appropriate speech and depictions and orm to USDA and other Federal policies and all		
	*			
1 D	applicable statutes and regulations			
1. Dei	1. Definitions Government speech is any communication of committees and boards that requires USDA approval.			
2. Gu	 As Government speech, all statements and depictions must be appropriate all audiences. In addition, statements must be appropriate for the Se of Agriculture and other USDA employees to make. For example, statements and descriptions, including the use of innuendo or double meaning, that are offensive or otherwise not appropriate for all audic cannot be used. All statements and depictions must conform to USDA's prohibitions discrimination on the basis of race, color, national origin, age. Disable where applicable, sex, marital status, familial status, parental status, sexual orientation, genetic information, political beliefs, reprisal, or all or a part of an individual's income is derived from any public ass program. Boards and committees cannot unlawfully use other organizations' trademarks, copyrights, or logos. Boards and committees cannot attempt to influence government polaction or use political issues or images. Must be in full conformity with Executive orders and directives, off websites, memoranda, regulations and procedures published in the Grederal Regulations, correspondence, and official written or oral states. 			
4. Exathat we require change	re	"Encourage your Representative to support the proposed Farm Bill". During a Presidential campaign, USDA disapproved a milk mustache campaign that featured a picture of both major candidates – each with a milk mustache, because of its political nature. The woman purchasing a tomato is described as a "love machine."		
5. For addition technic guidan	onal ical	Consult AMS representative.		

FTC AND FDA GUIDANCE ON "SOURCE", "GOOD SOURCE", "CONTAINS", "PROVIDES"

GOOD SOURCE: A product may be called a source or a good source (or similar

language) of a nutrient if a Referenced Amount Customarily Consumed (RACC) serving contains 10-19% or more of the daily

value for the nutrient.

EXCELLENT SOURCE: A product may be called an excellent source (or similar language)

if a RACC serving contains 20 percent or more of the daily value

for the nutrient.

LOW FAT: A product may be called low fat if a RACC serving contains 3

grams or less of fat.

LOW IN SATURATED FAT: A product may be called low in saturated fat if a RACC serving

contains 1 gram or less of saturated fat.

LOW IN CHOLESTEROL: A product may be called low in cholesterol if a RACC serving

contains 20 milligrams or less of cholesterol.

LOW IN SODIUM: A product may be called low in sodium if a RACC serving

contains 140 milligrams or less of sodium.

LOW CALORIE: A product may be called low calorie if a RACC serving contains

40 or fewer calories.

HEALTHY: A product may be called healthy or any derivative of the term

healthy if a RACC serving is low fat, low sodium, and low

cholesterol and contains at least 10 percent of the daily reference value for one of the following: Vitamin A, Vitamin C, calcium,

iron, protein, or fiber.

1. Comparative Nutrient Content Claims

FDA's regulations also establish definitions for comparative terms that characterize the nutrient content of a labeled food relative to that of a comparison or "reference" food. These definitions require that a food bearing a comparative term meet specified minimum percentage differences in the relevant nutrient. For example, the regulations permit use of the terms "less" and "reduced" only where there is a minimum 25 percent difference in the relevant nutrient. In addition, comparative claims must disclose the reference food, the percentage difference in the nutrient between the labeled and reference food (e.g., "50 percent less fat than our regular cheese"), and quantitative information regarding the absolute amount of the nutrient in the labeled and reference foods (e.g., "fat reduced from 6 g. to 3 g. per serving").

Comparative nutrient content claims that comply with FDA's regulations will generally comply with Section 5. The Commission will scrutinize carefully comparative nutrient content claims that characterize nutrient differences in ways that do not comply with FDA's regulations. However, a comparative advertising claim that is accurately qualified to identify the nature of the nutrient difference and to eliminate misleading implications may comply with Section 5, even if the nutrient difference does not meet FDA's prescribed differences for purposes of labeling.

In examining comparative claims, several principles are likely to be applied by the Commission. First, comparative claims should make clear the basis for the comparison. Claims should identify the reference food to which the product is being compared to so that the appropriate comparison is clear to consumers. Second, consistent with the position it has taken on the use of descriptors, the commission believes that advertisers using unqualified comparative terms must meet FDA's minimum percentage difference requirements for those claims. For example, if an ad represents that a food has "less fat than Brand X," without indicating the percentage or absolute difference in fat, the Commission will rely on FDA's 25% minimum difference requirement in determining whether the claim is deceptive.

Third, comparative claims should not overstate the significance of a nutrient difference. For this reason, some comparative claims may need to be qualified in a manner sufficient to ensure that consumers are not misled regarding the significance of the nutrient difference. For example, a simple statement of percentage difference for a food that contains only a small amount of a nutrient, such as "our crackers have one-third less fat that Brand X," may suggest that the nutrient difference is greater in a absolute sense than it actually is. This type of claim may need further qualification to prevent the claim from creating a misleading impression (e.g., "one third less fat than Brand X —theirs has 3 g., ours has 2 g.").

Even where nutrient differences are substantial in an absolute sense, careful qualification may be necessary for products that despite such absolute reductions, still contain appreciable amounts of a nutrient, to ensure that consumers are not misled regarding the absolute level of the nutrient. Thus, a claim such as "20% less fat in our frozen entrée compared to Brand X," regarding a product that nevertheless contains a significant amount of fat, may need to identify the quantitative amount of fat in the advertised food and the reference food (e.g., "20% less fat thatn Brand X – Brand X has 25 g. fat, ours has 20 g. fat"), particularly in situations where consumers are not likely to be aware that the item is generally high in fat.

2. Synonyms for Nutrient Claims

In addition to authorizing the use of only a limited set of defined nutrient content terms on food labels, FDA's regulations authorize the use of only certain synonyms for these defined terms. The impetus behind Congress's requirement that FDA limit defined terms and synonyms may be found in the educational and public health goals of the NLEA – to promote consumer understanding of the meaning of the terms through a limited lexicon that will allow consumers to make informed dietary choices.

The Commission will examine advertising to ensure that claims that characterize the level of a nutrient, including those using synonyms that are not provided for in FDA's regulations, are consistent with FDA definitions. Commission precedent establishes that an advertisement that can reasonably be interpreted in a misleading way is deceptive, even though other, non-misleading interpretations may be equally possible. Thus, when express or implied claims suggest that a food product meets the standard for use of an FDA-defined term, advertisers should ensure that the food actually meets the relevant FDA standard. For example, depending on the context of an ad, use of the phrases "packed with" or "lots of" to describe the level of fiber in a food could convey to some reasonable consumers that the food is "high" in fiber. Because FDA's regulations define the terms "good source" and "high" with respect to fiber, consumers are likely to be misled if a "high fiber" claim is implied by an ad for a food that is only a "good source" of fiber.

For FDA updates on communications guidance changes, AMS receives those from Janet Tenney, the AMS Nutritionist.

For FTC updates on communication guidance changes, the FTC website is check periodically by the AMS staff and information is pulled from the site.

The following is FTC's website address: www.ftc.gov

For advertising and marketing information: http://business.ftc.gov/advertising-and-marketing

USDA AMS

Guidelines for Communication of Research

Human Clinical, Animal, and In Vitro

USDA AMS Guidelines for Communication of Research

The following guidelines relate to the communication of research, including audience/market research, emerging and preliminary Human Clinical Research, and Animal and In Vitro Studies. They reflect standards for communicating study findings to a broad array of audiences, including health professionals industry, food service, trade, consumers, and media. Note: Other types of research, such as production, environmental or other scientific studies typically intended for an agricultural audience are not subject to these guidelines for communications.

Definition of and Guidelines for Audience/Market Research

Audience research may be conducted for internal purposes to understand target audience attitudes and usage and to measure results of marketing programs. Research questionnaires and summaries of results for the industry are not subject to AMS review. However, when market audience research is repurposed for use in delivering marketing communications messages to external target audiences, those market research-based messages are subject to the review process described above.

Definition of Emerging and Preliminary Research/Science

Emerging research/science by definition is any evidence that lacks significant scientific agreement. It is science or research published in peer-reviewed journal(s), for which there is some scientific evidence that supports the possible link between consumption of a product in reasonable proportion and a health benefit. Not every new study is considered emerging research.

According to the FDA Food Advisory Committee and Emerging Science Work Group, "Emerging Science" is: "one or more research findings pertaining to a food substance's consumption by humans that are judged, by a panel of appropriately qualified experts, to indicate, after consideration of all valid reports pertaining to the substance, that the general population, or some specific segment of the population, will possibly achieve a significant health benefit(s) without significant adverse effects when the substance is consumed in a reasonable amount over a reasonable period."

Preliminary research is defined as a study that is not yet completed, but has strong indicators of a finding or findings. Interim research results would need to follow the guidance of animal or in-vitro research below, as it pertains to hypothesis and not final results.

Definition of Significant Scientific Agreement and Qualified Health Claims

Research meeting significant scientific agreement (SSA) is research in which the strength of the total body of scientific evidence supports the health claim being made. According to FDA, SSA occurs well after the stage of emerging science where data and information permit a valid inference.

Credible research for a qualified health claim is when there is scientific evidence that supports the health claim but such evidence does not meet the SSA standard. Health claims based on such research should include qualifying language that reflects the level of scientific support with specificity and accuracy.

Resource document: FDA Guidance for Industry Evidence-Based Review System for the Scientific Evaluation of Health Claims.

 $\underline{www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/ucmo7332.htm}$

Communication of Human Clinical Trials/Studies

- Communication should be factual and consistent with findings and conclusions sections of the study.
- Communication should not overstate the findings and/or the body of scientific evidence. This includes the titles, headings, and sub-headings.
- Findings should be discussed in the proper context relating to the body of scientific evidence; and should refrain from including words or phrases that overstate the study or its findings. When applicable, statement(s) should be included that findings are not conclusive.
- Communication of a single study should not imply the findings should result in a change in behavior since these are preliminary and not conclusive findings.
- The report should not draw conclusions from the findings of the study if it is emerging research. Boards should not draw conclusions based on this study. Limit statements to the findings of the study. For example: The results of the study suggest . . .
- Communication should disclose study limitations and other factors that affect study results. This includes unique characteristics of study participants.
- The findings of study should not be applied to the general population if study participants are not representative of the general population.
- Appropriate qualifiers should be included in the communication. Such qualifiers should reflect those noted in the study and the body of the scientific evidence.
- Quotes from researchers must be consistent with the science on the issue and findings of the study. Do not allow quotes to expand to the general population based on a limited study.
- Provide PubMed or other available link for readers to obtain study. Provide reference information for study and other studies noted in release.

Communication of Animal and In Vitro Studies

- Communication should be consistent with the standards for human clinical studies.
- Communication should note the type of study (animal or in vitro).
- Communication should not imply a change in human behavior based on this research.
- For animal and in vitro studies, it should be noted that the results are indicators that are used as background and to formulate hypotheses for other studies.

Reporting Emerging or Preliminary Research: Presentation Guidelines

Communications of animal and/or in vitro and/or preliminary human trial studies should include "disclaimers and qualifying statements."

Disclose relevant information about the study: Information should be placed as near as possible
to the discussion of the finding(s) and should be prominently placed in the communication.
Disclaimers at the bottom of a communication piece or as footnotes are not considered
prominently placed. This placement could vary depending on the type of communication. For
example:

- One-page Information Sheet of several studies of various chronic diseases. It may be appropriate to place disclaimers and qualifying statements at the top of the communication.
- Press Releases: Prominent placement in the body of the communication as near as possible to the discussion of the study finding(s) is appropriate.
- Statement(s) should be included that findings of the study should only be considered as a
 hypothesis and not conclusive. Communication should state that the study is a basis for
 formulating hypotheses for additional studies particularly, human clinical studies.
- State that additional research studies, including clinical studies, are needed and why such studies are needed. For example: to fully understand the effect on humans; to see what the effect would be on humans; because effects on humans are unknown; and/or findings are not conclusive as to the effects on humans.

Resource Document: Improving Public Understanding: Guidelines for Communicating Emerging Science on Nutrition, Food Safety, and Health www.ific.org/publications/brochures/guidelinesbroch.cfm

EXTRACT FROM FDA WEBSITE:

Guidance for Industry: Food Labeling; Nutrient Content Claims; Definition for "High Potency" and Definition for "Antioxidant" for Use in Nutrient Content Claims for Dietary Supplements and Conventional Foods; Small Entity Compliance Guide

Antioxidant nutrient content claims

- 1. Is an antioxidant claim a nutrient content claim?
 - **Yes.** A claim that describes the level of antioxidant nutrients present in a food is a nutrient content claim and may be used on the label or in the labeling of a food when the conditions of use in the regulation are met (21 CFR 101.54(g)).
- Can I make an antioxidant nutrient content claim for any ingredient in a food?
 No. An antioxidant nutrient content claim can only be made for nutrients for which there is an RDI established in 21 CFR 101.9 (21 CFR 101.54(g)(1)).
- 3. Does the claim apply to all nutrients listed in 21 CFR 101.9?
 - **No.** The nutrient that is the subject of the claim must have recognized antioxidant activity. That is, there must be scientific evidence that after it is eaten and absorbed from the gastrointestinal tract, the substance participates in physiological, biochemical, or cellular processes that inactivate free radicals or prevent free radical-initiated chemical reactions (21 CFR 101.54(g)(2)).
- 4. How much of the nutrient must be present in each serving in order to use the antioxidant nutrient content claim?
 - The antioxidant nutrient must meet the requirements for nutrient content claims in 21 CFR 101.54(b), (c), or (e) for "High" claims, "Good source" claims, and "More" claims, respectively. For example, to use a "high" claim, the food would have to contain 20% or more of the Daily Reference Value (DRV) or RDI per serving. For a "good source" claim, the food would have to contain between 10-19% of the DRV or RDI per serving (21 CFR 101.54(g)(3)).
- 5. What special requirements apply to an antioxidant nutrient content claim for beta-carotene? Beta-carotene may be the subject of an antioxidant claim when the level of vitamin A present as beta-carotene in the food using the claim is sufficient to qualify for the claim. For example, if the claim is "good source of antioxidant beta-carotene," then at least 10% of the RDI for vitamin A must be present as beta-carotene per serving (21 CFR 101.54(g)(3)).
- 6. Does the label claim have to include the name of the nutrient that is an antioxidant, or can the claim simply say "antioxidants?"

The names of the nutrients that are the antioxidants must appear in the claim. For example, "high in antioxidant vitamins C and E."

Alternatively, when used as part of a nutrient content claim, the term "antioxidant" or "antioxidants" (such as "high in antioxidants"), may be linked by a symbol (such as an asterisk) that refers to the same symbol that appears elsewhere on the same panel of a product label followed by the name or names of the nutrients with the recognized antioxidant activity. If this is done, the list of nutrients must appear in letters of a type size height no smaller than the larger of one half of the type size of the largest nutrient content claim or 1/16 inch (21 CFR 101.54(g)(4)).

Appendix B:

Draft Lexicon and Defined Terms

Last Amended 8/7/12

Appendix B: Draft Lexicon and Defined Terms

As referenced in the main document, this appendix includes words and phrases that are marketing related but currently undefined from a regulatory perspective, followed by a listing of terms that FDA has currently defined and additional guidance on terms from AMS.

** The fact that the word or phrase is listed here does NOT mean that it is automatically approved for use. Each marketing term and phrase will be individually evaluated based on the context in which it is used.

Unregulated Terms

The following marketing terms have not been defined from a regulatory perspective. This is NOT an exhaustive or all-inclusive list, and these terms may not apply to all commodities. Starred items are clarified below in the AMS Guidance for Specific Terms section.

Unregulated Terms			
A must for any diet	High-quality plant protein		
Alternative	Low carb		
As wholesome as it gets	More flavor for everyone		
Bursting with	Nourishing		
Chock full of	Power packed		
Crispy	Real		
Crunchy	Robust		
Delicious	Satisfying		
Deliciously packed with nutrients*	Sensational		
Delightful	Sizzling		
Good stuff	Sumptuous		
Good-for-you	Super food		
Goodness	Super fruit		
Goodness of	Tasty		
Health benefits	Ultimate		
Healthy naturals	Wholesome		
Heart-warming			

FDA Defined Terms

Good Source or similar language (10 to 19 percent of DV for nutrient)

Excellent Source or similar language (20 percent or more of DV for the nutrient)

Healthy – A product may be called "healthy" or any derivative of that term if a RACC serving is low fat (3 grams or less), low in saturated fat (1 gram or less and 15 percent or less calories from saturated fat), low in cholesterol (20 milligrams or less), and low in sodium (140 milligrams or less), and contains at least 10 percent of the daily reference value for one of the following: Vitamin A, Vitamin C, calcium, iron, protein, or fiber, except for raw and canned or frozen single ingredient fruits or vegetables and enriched cereal-grain products that conform to a standard of identity.

Defined Terms Continued

Calories:

- Calorie free: fewer than 5 calories per serving
- **Low calorie**: 40 calories or less per serving and if the serving is 30 g or less or 2 tablespoons or less, per 50 g of the food

Cholesterol:

- Cholesterol free: less than 2 milligrams (mg) of cholesterol and 2 g or less of saturated fat per serving
- Low cholesterol: 20 mg or less per serving and if the serving is 30 g or less or 2 tablespoons or less per 50 g of the food

Fat:

- Fat free: less than 0.5 g of fat per serving
- Saturated fat free: less than 0.5 g per serving and the level of trans fatty acids does not exceed 1 percent of the total fat
- Low fat: 3 g or less per serving, and if the serving is 30 g or less or 2 tablespoons or less, per 50 g of the food
- Low saturated fat: 1 g or less per serving and not more than 15 percent of calories from saturated fatty acids

Sodium:

- Sodium free: less than 5 mg per serving
- **Very low sodium**: 350 mg or less per serving or, if the serving is 30 g or less or 2 tablespoons or less, 35 mg or less per 50 g of the food
- Low sodium: 140 mg or less per serving and, if the serving is 30 g or less or 2 tablespoons or less, per 50 g of the food

Other Defined Terms

Fresh – implies that the food is unprocessed, means that the food is in its raw state and has not been frozen or subjected to any form of thermal processing or any other form of preservation.

Provisions and restrictions include:

- (1) The following do not preclude the food from use of the term "fresh":
 - The addition of approved waxes or coating;
 - The post-harvest use of approved pesticides;
 - The application of a mild chlorine wash or milk acid wash on produce; or
 - The treatment of raw foods with ionizing radiation not to exceed the maximum dose of 1 kiloGray,
- (2) A food meeting the definition in the paragraph in above section that is refrigerated is not precluded from use of "fresh" as provided by this section.

However, the use of the term "fresh" is not subject to the requirements if the term does not suggest or imply that a food is unprocessed or unpreserved. For example, the term "fresh" used to describe pasteurized whole milk is not subject to the definition because the term does not imply that the food is unprocessed (consumers commonly understand that milk is nearly always pasteurized). However, the term "fresh" to describe pasta sauce that has been pasteurized or that contains pasteurized ingredients would be subject to the definition because the term implies that the food is not processed or preserved.

AMS Guidance for Specific Terms

Bad fat (may be used to indicate saturated and trans fats)

Good fat (may be used for unsaturated fats (monounsaturated and polyunsaturated)

Packed with (similar language to excellent source of stated nutrient)

Bursting with (implies excellent source of stated nutrient)

Chock full of (implies excellent source of stated nutrient)

Packed with plenty of nutrients (product should be an excellent source of at least 2 nutrients)

Deliciously packed with nutrients (product should be an excellent source of at least 2 nutrients)

Power packed (Context in which phrase is used will be considered: For example, the term "power-packed" in the phrase "power-packed protein" describes the nutrient and does not imply that the food is an excellent source of protein. As another example, the phrase "product x has y grams of power-packed protein" is also approvable. Although the total amount of protein is stated, there is no implication that the food is an excellent source of protein.

Premier source of (similar language for excellent source of stated nutrient)

Natural; All natural; Natural goodness; Naturally good for you – FDA General Guidance: Product does not contain added color, artificial flavors, or synthetic substances. This term is not defined by FDA.

Nutrient Dense; Nutritionally dense. Nutrient Dense Foods – The Dietary Guidelines defines it as: Those foods and beverages that provide vitamins, minerals, and other substances that may have positive health effects, with relatively few calories. Nutrient-dense foods and beverages are lean or low in solid fats, and minimize or exclude added solid fats, sugars, starches, and sodium. Ideally, they also are in forms that retain naturally occurring components, such as dietary fiber. All vegetables, fruits, whole grains, seafood, eggs, beans and peas, unsalted nuts and seeds, fat-free and low-fat milk and milk products, and lean meats and poultry – when prepared without solid fats or added sugars – are nutrient dense foods. The term and similar terms should be used as defined.

Nutrient rich – The term "rich" is defined as a synonym for excellent source. Therefore, the term nutrient rich should be used to indicate that a food is an excellent source of at least two nutrients. "Nutrient-rich foods are defined as foods that provide substantial amounts of vitamins, minerals, and other nutrients with relatively few calories. These foods include colorful fruits and vegetables; whole, fortified and fiber-rich grain foods; fat-free and low-fat dairy products; and lean meats, poultry, fish, eggs, beans and nuts." (Source USDA HSMRS Practical Nutrition Lesson Plan)

Antioxidants – vitamin E, vitamin C and selenium. These antioxidants have established daily values so nutrient content claims for good and/or excellent source are allowed. For antioxidants and/or nutrients for which there is not established DV, the amount of the nutrient per serving must be reference when making a nutrient content claim.

Nutritious – there are no FDA guidelines for it but the statement must be truthful and not misleading

Potassium:

- High-potassium: 700 mg or more per serving
 - o Good source of potassium: 350 mg to 665 mg per serving

Calcium:

- High-calcium: 200 mg or more per serving
 - o Good source of calcium: 100 mg to 190 mg per serving