

Food Safety and Inspection Service Guidance on the Labeling of Omega Fatty Acid Claims on Meat, Poultry and Egg Products

September 2016

**FRONT
EXAMPLE**
Tromiktus



FULLY COOKED
Chicken Nuggets

BREADED NUGGET SHAPED CHICKEN BREAST PATTIE WITH RIB MEAT



KEEP FROZEN

NET WT. 5 LB 80 OZ (2.26kg)

250 milligrams of
Omega-3 Fatty Acids
per serving from flax
seed in breading.

This guideline is designed to help industry determine:

- Which Omega fatty acids statements are permitted on the labeling of their products; and
- What are the criteria for the use of statements related to Omega fatty acids.

**BACK
EXAMPLE**

Nutrition Facts	
Serving Size 5 pieces (88g)	
Servings Per Container: About 25	
Amount Per Serving	
Calories 230	Calories from Fat 120
%Daily Value*	
Total Fat 13g	20%
Saturated Fat 3g	15%
Trans Fat 0g	
Cholesterol 40mg	13%
Sodium 480mg	20%
Potassium 0mg	0%
Total Carbohydrate 14g	5%
Dietary Fiber 3g	16%
Sugars 0g	
Protein 12g	24%
Vitamin A 0%	Vitamin C 0%
Calcium 0%	Iron 4%
* Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs:	
	Calories 2,000 2,500
Total Fat	Less Than 65g 80g
Sat Fat	Less Than 20g 25g
Cholesterol	Less Than 300mg 300mg
Sodium	Less Than 2,400mg 2,400mg
Total Carbohydrate	300g 375g
Dietary Fiber	25g 30g
Calories per gram:	
Fat 9 • Carbohydrate 4 • Protein 4	

INGREDIENTS: Chicken breast with rib meat, wheat flour, milled flax seed, contains 2% or less of the following: brown sugar, paprika, dried garlic, corn flour, salt. Breading set in vegetable oil.

CONTAINS: Wheat.

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FSIS Compliance Guidance for Label Approval

Table of Contents

Preface.....	3
Key Points Reference Chart.....	5
Omega Fatty Acid Claims on the Labeling of Meat, Poultry and Egg Products.....	6
Label Examples.....	8
Additional Resources	9

Preface

What is the purpose of this Compliance Guideline?

The purpose of this compliance guideline is to help industry determine which statements are permitted on the labeling of their products and the criteria for their use.

The Food Safety and Inspection Service (FSIS) ensures that the labeling of meat, poultry and egg products is truthful and not misleading.

FSIS considers labeling bearing any reference to Omega fatty acids to be a special statement or claim. The regulations require establishments to submit all labels bearing special statements or claims to the Agency's Labeling and Program Delivery Staff for evaluation and approval before use. However, once a label with a statement on Omega fatty acids is approved, there are many types of changes to the label that are generically approved and don't require submission to the Agency for approval prior to use (for example, change in net weight, label color, vignettes, cooking instructions, and the addition of information that is not considered a special statement or claim). The key for making the change generically is that the change cannot affect the special statement or claim (see slide 40 on the following PowerPoint Presentation [Generic Label Approval](#)).

Who is this guideline designed for?

This guidance is for establishments that are designing or modifying meat, poultry or egg product labels with statements related to Omega fatty acids.

What changes have been made to the guidance from the last version?

FSIS previously issued guidance on omega fatty acids claims on July 11, 2007. FSIS has updated the guideline to include further details and explanations on the different types of claims and a key-points reference chart.

How can I comment on this guideline?

FSIS is seeking comments on this guideline as part of its efforts to continuously assess and improve the effectiveness of policy documents. All interested persons may submit comments regarding any aspect of this document, including but not limited to: content, readability, applicability, and accessibility. The comment period will be 60 days and the Agency will update the document in response to the comments.

Comments may be submitted by either of the following methods:

Federal eRulemaking Portal Online submission at [regulations.gov](http://www.regulations.gov): This Web site provides the ability to type short comments directly into the comment field on this Web page or attach a file for lengthier comments. Go to <http://www.regulations.gov> and follow the online instructions at that site for submitting comments.

Mail, including - CD-ROMs, and hand- or courier-delivered items: Send to Docket Clerk, U.S. Department of Agriculture (USDA), FSIS, Patriots Plaza 3, 1400 Independence Avenue SW, Mailstop 3782, 8-163A, Washington, DC 20250-3700.

All items submitted by mail or electronic mail must include the Agency name, FSIS, and document title: **Food Safety and Inspection Service Statement of Labeling Guideline on Omega Fatty Acid Claims April 2016**. Comments received will be made available for public inspection and posted without change, including any personal information, to <http://www.regulations.gov>.

Although FSIS is requesting comments on the guidance and may update it in response to comments, the guidance reflects FSIS's current position, and establishments may start using it now.

What if I still have questions after I read this guideline?

If the desired information cannot be found within the Compliance Guidance, FSIS recommends that users search the publicly posted Questions & Answers (Q&As) in the [askFSIS](#) database or submit questions through [askFSIS](#). Documenting the questions helps FSIS improve and refine present and future versions of the Compliance Guidance and associated issuances.

When submitting a question, use the **Submit a Question** tab, and enter the following information in the fields provided:

Subject Field: Enter **FSIS Labeling Guideline on Omega Fatty Acid Claims April 2016**

Question Field: Enter question with as much detail as possible

Product Field: Select **Labeling** from the drop-down menu

Category Field: Select **Labeling Regulations, Policies and Claims** from the drop-down menu

Policy Arena: Select **Domestic (U.S.) only** from the drop-down menu

When all fields are complete, press **Continue**.

KEY-POINTS REFERENCE CHART

Claim Type	Permitted	Examples	Criteria and Requirements for Approval
FACTUAL STATEMENTS (fatty acid content from naturally occurring food sources)	Yes (requires FSIS approval under 9CFR 412.1)	- “X grams of Omega-3 Fatty Acids per serving from canola oil” - “X milligrams of Omega-3 Fatty Acids per serving from flax seed in breeding”	1) Omega fatty acid content cannot come from fortification; 2) Include the nutrition facts panel on label ; 3) Provide data to support Omega fatty acid content; <i>plus</i> 4) Name the food(s) responsible for the omega fatty acid content.
FACTUAL STATEMENTS (fatty acid content from raising animals with naturally occurring foods added to feed)	Yes (requires FSIS approval under 9CFR 412.1)	- “X milligrams of CLA (Conjugated Linoleic Acid) per serving” - “X grams of Omega-3 Fatty Acids per serving”	1) Omega fatty acid content cannot come from fortification; 2) Include the nutrition facts panel on label; 3) Provide data to support Omega fatty acid content; <i>plus</i> 4) Provide feed formulation and animal raising documentation.
LEVEL CHARACTERIZATION	No	- “Good Source of Omega-3 Fatty Acids” - “More than X grams of Omega-3 Fatty Acids”	These statements are not permitted because there are no defined claims for Omega fatty acids.
COMPANY/BRAND NAMES (Trademarked company/brand name associated with omega fatty acids)	Yes (in signature line only; requires FSIS approval under 9CFR 412.1)	- “Omega 3 Company”	Signature line is placed on information panel and is not given undue prominence.
TRADEMARKED SYMBOLS/LOGOS (Trademarked symbols/logos associated with omega fatty acids)	No		These symbols and similar logos are not permitted because there are no defined claims or synonyms for Omega fatty acids

Omega Fatty Acid Claims on the Labeling of Meat, Poultry and Egg Products

TYPES OF OMEGA FATTY ACIDS

This guidance document applies to making factual statements for Omega-3 fatty acids, Omega-6 fatty acids, and Omega-9 fatty acids. It is also applicable for statements that identify specific Omega fatty acids by name, for example, Alpha-Linolenic Acid (ALA), which is a specific omega-3 fatty acid or Conjugated Linoleic Acid (CLA), which is a specific Omega-6 fatty acid.

FACTUAL STATEMENTS

FSIS permits factual statements on the labeling of meat, poultry, and egg products that declare the amount of Omega fatty acids per serving, provided:

- 1) Establishments obtain sketch approval through FSIS, LPDS for Labeling that includes Omega fatty acid statements or any reference (direct or implied) to omega fatty acids;
- 2) The product is not fortified to provide the Omega fatty acid content,
- 3) The labeling bears a nutrition facts panel in compliance with 9 CFR 317.309, 381.409, or 590.411(e) to identify the serving size of the product,
- 4) Data documenting the Omega fatty acid content per labeled serving is provided with the label application submitted to LPDS for approval, and
- 5) The labeling includes a statement identifying the type and amount of Omega fatty acid(s) per serving and the common or usual name of the food source(s)¹ from which the Omega fatty acids are obtained (for example, “X milligrams of Omega-3 Fatty Acids per serving from flax seed in breading”).

NOTE: [See label example 1](#)

When the level of Omega fatty acids is integral in the animal tissue as a result of specialized diets fed to animals, for example, grass fed cattle or raising chickens on a feed formulated with flaxseeds or other whole food sources¹ with naturally occurring (indigenous) Omega fatty acids, the same criteria above apply except that the food source¹ of the Omega fatty acid does not need to be declared on the labeling. For example, grass fed beef might include the statement “Xmg of Omega-6 fatty acids per serving.” In this situation, documentation to support the specialized feeding formula and raising plan for the animal will also need to be included as part of the label application submitted for approval.

When making statements about specific Omega fatty acids, use the full fatty acid name with the statement not just the abbreviation, for example, “Xmg Conjugated Linoleic Acid (CLA) per serving”, (on grass fed beef) or prominently link the abbreviated name to the full name with an asterisk or other symbol on the same label panel as the statement.

¹ Commonly used food sources with naturally occurring (indigenous) Omega fatty acids include: fish oil, canola oil, flaxseeds, and walnuts. When adding omega fatty acid sources to animal feeds the food sources would also include plant material such as grass.

For example, “Xmg of CLA* per serving” displayed on same panel as “*Conjugated Linoleic Acid.”

Grams and milligrams

The amount of the Omega fatty acids per serving on the label may be expressed either as the number of milligrams per serving or the number of grams per serving. The number of grams may be declared to the nearest one thousandth gram, for example, “0.125 grams Omega-3 fatty acids per serving from flax seed.”

NOTE: See label example 2

LEVEL CHARACTERIZATION STATEMENTS

FSIS will not approve statements that declare or imply that the product is a good or excellent source of Omega fatty acids per serving. The nutrition labeling regulations in Title 9, Code of Federal Regulations (9 CFR), Subpart B, Section 317.313(b), for red meat products, Subpart Y, Sections 381.413(b), for poultry products, and Title 21 CFR Subpart A, Section 101.13(b) clearly state that “A claim which, expressly or by implication, characterizes the level of a nutrient (nutrient content claim) of the type required in nutrition labeling ..., may not be made on a label or in labeling of that product unless the claim is made in accordance with the applicable provisions in this subpart.” Therefore, without regulations defining such claims, the use of statements with expressed Omega-3 fatty acid claims, including, but not limited to “Good Source of Omega-3 Fatty Acids” and “Excellent Source of Omega-3 Fatty Acids,” cannot be approved.

Likewise, labeling for meat, poultry, and egg products that bear claims that imply that the level of Omega fatty acids in a product is high or place significance on a specific level of Omega Fatty Acids, including, but not limited to “Contains X grams of Omega-3 Fatty Acids,” “More than X grams of Omega-6 Fatty Acids” and “Fortified with X grams of Omega-9 Fatty Acids,” “With...”, “Provides...”, “Packed with...”, etc., cannot be approved.

TRADEMARKS, AND COMPANY NAMES

Trademarked company brand names, trademarked symbols or phrases, and statements included in ad-copy on labeling that declare or imply that the product is a good or excellent source of Omega fatty acids per serving, or declare or imply a particular level of Omega fatty acids per serving using a similar wording a level of Omega fatty acids in a product cannot be approved. One exception, is that the company name may be labeled as part of the signature line for compliance with 9 CFR 317.2(g), 381.122, and 590.411 (c) (2) provided the signature line is only displayed on the information panel in normal size font so that it is not given undue prominence which would cause the use of the company name to be a false or misleading.

For additional information about FSIS labeling policies and programs, including Generic Label Approval, please review the FSIS Web Site at: <http://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/labeling/> or contact the Labeling and Program Delivery Staff at (301) 504-0878 or (301) 504-0879.

Label Example 1

Marco's Nation

250 milligrams of Omega-3 Fatty Acids per serving from canola oil.

FULLY COOKED

Beef Patty

Ingredients: Beef, water, canola oil, contains 2% or less of salt, sugar, beef stock, corn syrup, flavoring, sodium phosphate, yeast extract, modified food starch.

Keep Frozen

Net Wt. 18 oz (1 lb 2 oz)

Nutrition Facts

Serving Size 1 patty (84g)
Servings Per Container: 6

Amount Per Serving		
Calories 230	Calories from Fat 170	
		%Daily Value*
Total Fat 19g		29%
Saturated Fat 6g		30%
Trans Fat 0.5g		
Cholesterol 60mg		20%
Sodium 450mg		19%
Potassium 0mg		0%
Total Carbohydrate 0g		0%
Dietary Fiber 0g		0%
Sugars 0g		
Protein 15g		
Vitamin A 0%	•	Vitamin C 0%
Calcium 0%	•	Iron 8%

* Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs:

	Calories	2,000	2,500
Total Fat	Less Than	65g	80g
Sat Fat	Less Than	20g	25g
Cholesterol	Less Than	300mg	300mg
Sodium	Less Than	2,400mg	2,400mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g

Calories per gram:
Fat 9 • Carbohydrate 4 • Protein 4

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Label Example 2



Serving suggestion

Fully Cooked Corned Beef Brisket

Cured with: water, salt, spices, sodium erythorbate, sodium nitrite.

Keep Frozen

Net Wt. 18 oz (1 lb 2 oz)

Nutrition Facts

Serving Size 3 oz (84g)
Servings Per Container: 6

Amount Per Serving		
Calories 210	Calories from Fat 140	
		%Daily Value*
Total Fat 16g		25%
Saturated Fat 5g		25%
Trans Fat 0g		
Cholesterol 85mg		28%
Sodium 830mg		35%
Potassium 125mg		4%
Total Carbohydrate 0g		0%
Dietary Fiber 0g		0%
Sugars 0g		
Protein 15g		
Vitamin A 0%	•	Vitamin C 0%
Calcium 0%	•	Iron 10%

* Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs:

	Calories	2,000	2,500
Total Fat	Less Than	65g	80g
Sat Fat	Less Than	20g	25g
Cholesterol	Less Than	300mg	300mg
Sodium	Less Than	2,400mg	2,400mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g

Calories per gram:
Fat 9 • Carbohydrate 4 • Protein 4

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A photograph of three call center workers wearing headsets, smiling and looking towards the right. The image is part of a promotional graphic for a help desk.

SMALL PLANT HELP DESK
A resource for small and very small plants
Est. 12-17-2010

Knowledgeable, USDA-FSIS specialists from the Outreach and Partnership Division are available weekdays 8:00 AM to 4:00 PM EST to give you personal assistance on matters relating to the regulation of meat, poultry, and processed egg products. We can also be reached by email at info@source@fsis.usda.gov.

Call Toll-Free 1-877-374-7435

A graphic with a dark green background. At the top is the text 'askFSIS' in white. Below it is the USDA logo, which consists of the letters 'USDA' in blue above a green stylized landscape. Below the logo is a close-up photograph of a person's eyes, looking upwards. At the bottom of the graphic is the text 'a policy-related question' in white.

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