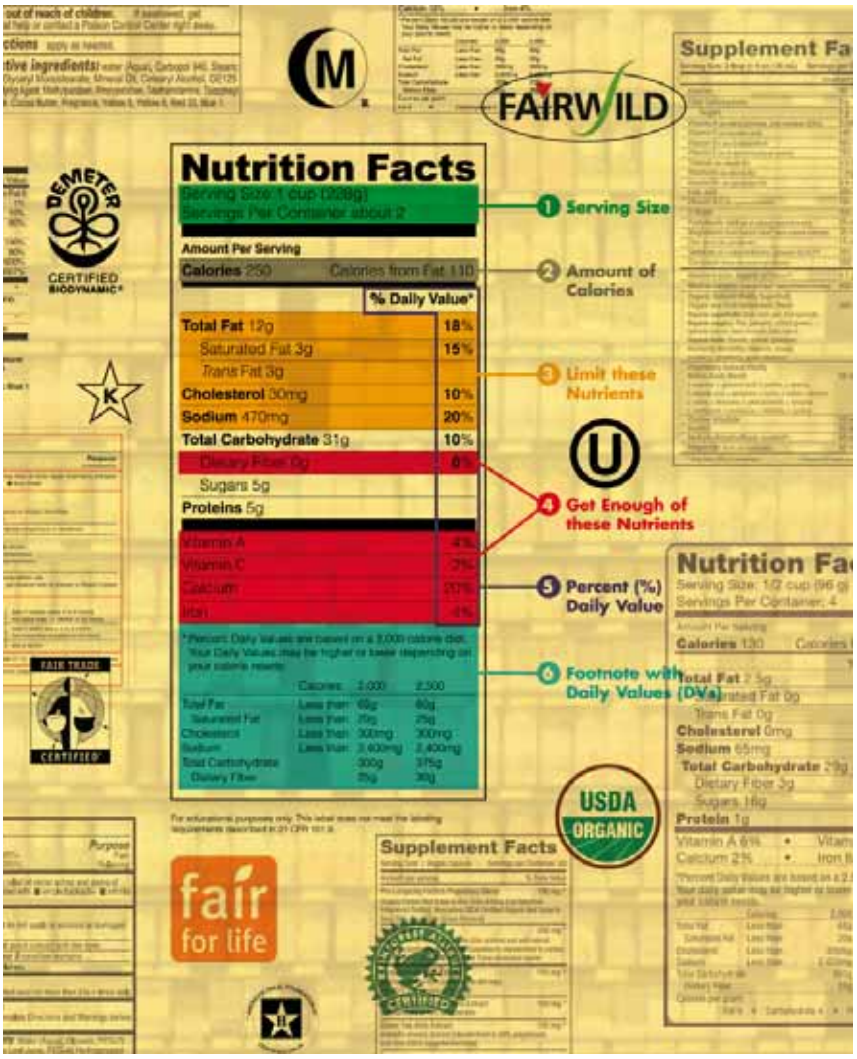
TECHNICAL PAPER

LABELLING OF NATURAL PRODUCTS

THE UNITED STATES MARKET



International Trade Centre

EXPORT IMPACT FOR GOOD

LABELLING OF NATURAL PRODUCTS

THE UNITED STATES MARKET

Abstract for trade information services

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Guide focusing on sustainability certification and labelling requirements of finished natural products in the United States - covers all categories of natural products, namely cosmetics, herbal dietary supplement, health food, and herbal drugs; provides a typology of labels used in the U.S. natural products market and how they fit into a number of different regulatory frameworks; outlines the Fair Packaging and Labeling Act requirements; explains how website content is regulated and highlights the respective jurisdictions; provides information on the labelling requirements of private voluntary certification schemes relevant to natural products.

Descriptors: **Labelling, Certification, Private Standards, Organic Products**.

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English, Spanish (separate editions)

The International Trade Centre (ITC) is the joint agency of the World Trade Organization and the United Nations.

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Sustainability Market Guides

This is part of a series of Sustainability Market Guides produced under ITC's Trade, Climate Change and Environment Programme (TCCEP), financed by the Government of Denmark.

The series aims to guide exporters, civil society and policymakers on trends and practical guidance about the growing market for sustainably produced goods and services.

For further information about this series and the TCCEP, please contact Alexander Kasterine at kasterine@intracen.org.

Contents

Acronyms

ACA	Accredited Certifying Agent
CFR	Code of Federal Regulations
CLAC	Latin American and Caribbean Network of Small Fair Trade Producers
DSP	Dietary Supplement Product
FALCPA	Food Allergen Labeling and Consumer Protection Act of 2004
FDA	Food and Drug Administration (regulates GMPs and labelling)
FD&C Act	Federal Food, Drugs and Cosmetics Act
FLO	FairTrade Labelling Organizations International
FPLA	Fair Packaging and Labeling Act (administered by both FDA and FTC)
FTC	Fair Trade Certified™
FTC	Federal Trade Commission (regulates advertising claims)
FTUSA	Fair Trade USA
FWF	FairWild Foundation
GMP	Good Manufacturing Practices
HPCUS	Homoeopathic Pharmacopoeia Convention of the United States
HPUS	Homoeopathic Pharmacopoeia of the United States
HTSUS	Harmonized Tariff Schedule of the United States
IMO	Institute for Market Ecology
ITC	International Trade Centre
NOP	National Organic Program (regulated by the USDA)
OTC	Over-the-counter Drug Product (sold without a doctor's prescription)
PDP	Principle Display Panel (front facing of product label)
Rx	Prescription Drug Product (sold in pharmacies with a doctor's prescription)
SSO	Standards Setting Organization
UNCTAD	United Nations Conference on Trade and Development
USC	United States Code (Office of the Law Revision Counsel of the U.S. House of Representatives)
USDA	United States Department of Agriculture
WTO	World Trade Organisation

Executive summary

Exporters of natural products from developing countries do not always have easy access to guidance and information on how to meet key market requirements.

Labelling products correctly is an essential requirement to sell natural products in the United States of America consumer market. The type of information that is provided on labels is tightly regulated by the United States Food and Drug Administration (FDA).

Where a product is also certified organic, United States Department of Agriculture's (USDA) regulations must also be taken into consideration alongside the FDA labelling regulations.

Private standards setting organization (SSO) and/or accredited inspection and certification organization will also enforce their own labelling requirements for certified natural products.

This Guide provides easy-to-follow guidance on the basic labelling requirements for each type of finished natural product and sustainability certification. This includes all categories of natural products, namely cosmetics, herbal dietary supplement, health food, and herbal drug. The guide also provides references to more in-depth guidance that is available from governmental agencies as well as inspection and certification organizations.

Section 1 provides a typology of label used in the United States natural products market and how they fit into a number of different regulatory frameworks. These are determined by their

- Composition,
- Dosage form, and
- Intended use(s).

Each framework has its own unique product labelling requirements.

The FDA enforces different labelling regulations for:

- Conventional food products;
- Dietary supplement products;
- Medical food products;
- Non-drug cosmetic products;
- Over-the-counter (OTC) drug products (conventional drugs and homoeopathic drugs); and
- Prescription (Rx) drug products.

The USDA's requirements on organic labelling are also explained.

Section 2 explains the Fair Packaging and Labeling Act (FPLA) that requires labels to disclose net contents (weight), identity of the commodity and the name and place of business. Section 3 explains how website content is regulated and the respective jurisdictions of the FDA and Federal Trade Commission (FTC). Section 4 provides basic information on the labelling requirements of private voluntary certification schemes relevant to natural products. These are of growing importance and increasingly visible in the United States market.

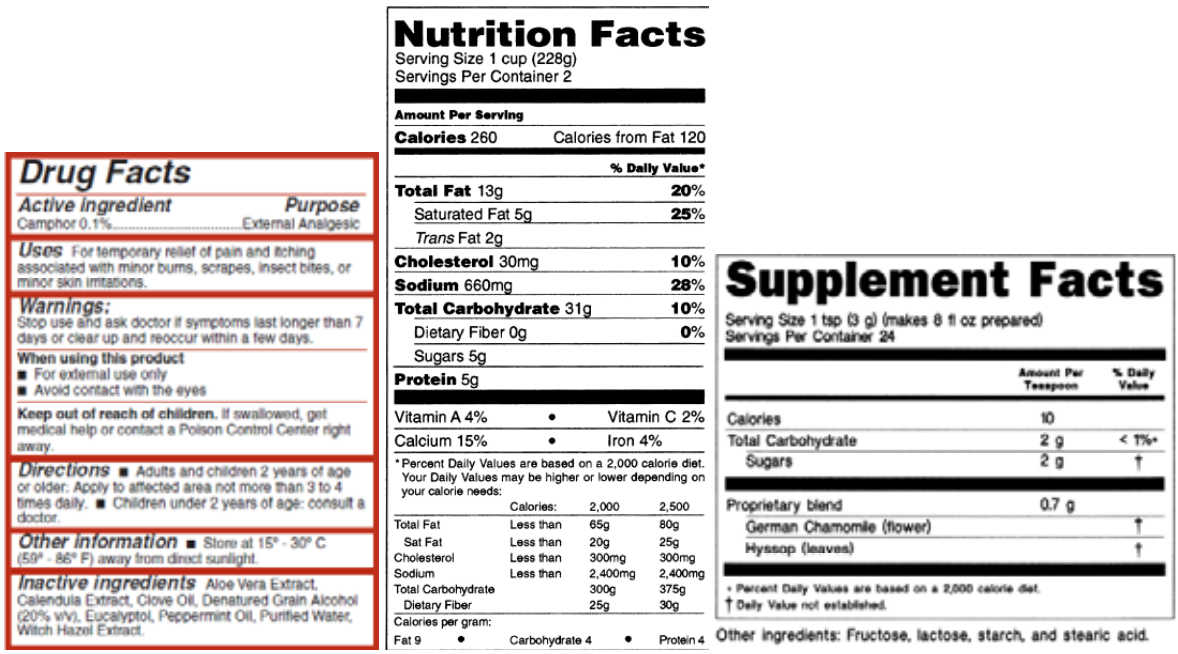
1. Types of labels

In the United States, finished natural products fit into a number of different regulatory frameworks, depending on their composition, dosage form, and intended use(s), each with their own unique product labelling requirements.

The Food and Drug Administration (FDA) enforces different labelling regulations for conventional food products, dietary supplement products, medical food products, non-drug cosmetic products, over-the-counter (OTC) drug products (conventional drugs and homoeopathic drugs) and prescription (Rx) drug products.

For example, the information panel of a dietary supplement product must show a Supplement Facts box, while a food product shows a Nutrition Facts box and an OTC drug product shows a Drug Facts box. Each type of box has its own unique requirements for required statements.

Figure 1 Example of drug facts, nutrition facts and supplement facts for the information panel



Drug Facts

Active ingredient	Purpose
Camphor 0.1%	External Analgesic

Uses For temporary relief of pain and itching associated with minor burns, scrapes, insect bites, or minor skin irritations.

Warnings:
Stop use and ask doctor if symptoms last longer than 7 days or clear up and reoccur within a few days.

When using this product
- For external use only
- Avoid contact with the eyes

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions ■ Adults and children 2 years of age or older: Apply to affected area not more than 3 to 4 times daily. ■ Children under 2 years of age: consult a doctor.

Other information ■ Store at 15° - 30° C (59° - 86° F) away from direct sunlight.

Inactive ingredients Aloe Vera Extract, Calendula Extract, Clove Oil, Denatured Grain Alcohol (20% v/v), Eucalyptol, Peppermint Oil, Purified Water, Witch Hazel Extract.

Nutrition Facts

Serving Size 1 cup (228g)
Servings Per Container 2

Amount Per Serving	
Calories 260	Calories from Fat 120
	% Daily Value*
Total Fat 13g	**20%**
Saturated Fat 5g	**25%**
Trans Fat 2g	
Cholesterol 30mg	**10%**
Sodium 660mg	**28%**
Total Carbohydrate 31g	**10%**
Dietary Fiber 0g	**0%**
Sugars 5g	
Protein 5g	

Vitamin A 4%	•	Vitamin C 2%	
Calcium 15%	•	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

Supplement Facts

Serving Size 1 tsp (3 g) (makes 8 fl oz prepared)
Servings Per Container 24

	Amount Per Teaspoon	% Daily Value
Calories	10	
Total Carbohydrate	2 g	< 1%*
Sugars	2 g	†
Proprietary blend	0.7 g	
German Chamomile (flower)		†
Hyssop (leaves)		†

* Percent Daily Values are based on a 2,000 calorie diet.
† Daily Value not established.

Other ingredients: Fructose, lactose, starch, and stearic acid.

In cases where a product is also certified organic, the National Organic Program (NOP) labelling regulations of the United States Department of Agriculture (USDA) must be taken into consideration alongside the FDA labelling regulations. In such cases, parts of the label are regulated by the FDA and other parts of the label are regulated by the USDA, for example the size, colour and location of the USDA Organic Seal (Figure 2).

Figure 2 USDA Organic Seal

Furthermore, when a natural product is also the subject of other non-legislative or voluntary certification and labelling schemes, the standards setting organization (SSO) and/or accredited inspection and certification organization will enforce its own labelling requirements.

For example, Demeter USA enforces Biodynamic® certified product labelling, Fair Trade USA enforces Fair Trade Certified product labelling, the Institute for Market Ecology (IMO) enforces Fair for Life Social & FairTrade Certified and the FairWild Foundation (FWF) with IMO enforce FairWild Certified product labelling. There are many religious certification agencies for Halal Certified and Kosher Certified products, e.g. Islamic Food and Nutrition Council of America (IFANCA) and OK Kosher Certification, among others.

Figure 3 Example of voluntary labelling marks for ecological certification (Demeter Biodynamic®), religious certification (OK Kosher and IFANCA Halal) and social certification (IMO Fair for Life; FLO FairTrade; FWF FairWild)

This guide provides essential information on the basic labelling requirements for each type of finished natural product (natural cosmetic, herbal dietary supplement, health food, or herbal drug) along with references to more in-depth guidance that is available from governmental agencies as well as inspection and certification organizations.

1.1. FDA labelling requirements for cosmetics (non-drug and drug), drugs (conventional and homoeopathic drugs), foods (conventional foods, dietary supplements and medical foods)

As summarized in section 1, each type of product is subject to a different set of labelling regulations that define the label format and content such as required information (e.g. product name, company name and address, weight, directions for use), and additional statements that can be made (e.g. claim statements), location of content (e.g. information panel), and the type size, font and boldness of certain label information.

The following subsections provide further details and specific examples of labelling requirements for different types of packaged food products (conventional foods, dietary supplements, and medical foods) and OTC drug products (conventional drugs and homoeopathic drugs), some of which are available in Spanish language at the website of the FDA.

1.1.1. Labelling requirements for non-drug cosmetic products

This section discusses the labelling requirements for 'non-drug' cosmetic products.

Cosmetic products marketed in the United States, whether they are manufactured domestically or are imported from abroad, must comply with the labelling requirements of the Federal Food, Drug, and Cosmetic Act (FD&C Act),[1] the Fair Packaging and Labeling Act (FPLA),[2] and the regulations published by the FDA in the Code of Federal Regulations (CFR).[3]

The FD&C Act defines cosmetics by their intended use, as 'articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body...for cleansing,

[1] Food and Drug Administration online reference edition of the Federal Food, Drug, and Cosmetic Act (FD&C Act). Available at: http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/default.htm.

[2] Fair Packaging and Labeling Act. Available at: http://www.fda.gov/RegulatoryInformation/Legislation/ucm148722.htm.

[3] Food and Drug Administration. 'Labeling Regulations Applicable to Cosmetics', *Code of Federal Regulations*, Title 21 (Washington D.C., Government Printing Office, 15 July 2011). Available at: http://www.fda.gov/Cosmetics/CosmeticLabelingLabelClaims/CosmeticLabelingManual/ucm126440.htm.

beautifying, promoting attractiveness, or altering the appearance.' Among the products included in this definition are skin moisturizers, perfumes, lipsticks, fingernail polishes, eye and facial makeup preparations, shampoos, permanent waves, hair colours, toothpastes and deodorants, as well as any material intended for use as a component of a cosmetic product.

Cosmetic products with therapeutic uses or disease treatment claims are drug products (see section 1.1.3 for drug labelling requirements). For example, toothpaste for merely cleaning or whitening the teeth is a 'non-drug' cosmetic while toothpaste that contains fluoride is an 'anti-caries drug product' for preventing cavities.

What labelling information is required on a non-drug cosmetic product?

The **Principal Display Panel (PDP)** is the part of the cosmetic label most likely to be displayed or seen on the store shelf.[4]

The following information must appear on the PDP of a non-drug cosmetic product:

- **An identity statement,** indicating the nature and use of the product, by means of either the common or usual name, a descriptive name, a fanciful name understood by the public, or an illustration representing the intended cosmetic use. The statement of identity must be shown in bold type and be in a size reasonably related to the most prominent printed matter on the PDP.[5]

- **An accurate statement of the net quantity of contents,** in terms of weight, measure, numerical count or a combination of numerical count and weight or measure.[6]

The **Information Panel** is a label panel other than the PDP that can accommodate label information where the consumer is likely to see it. Since the information must be prominent and conspicuous, the bottom of the package is generally not acceptable for placement of required information, such as the cosmetic ingredient declaration.[7]

The following information must appear on the Information Panel of a non-drug cosmetic product.

- **Name and place of business.** This may be the manufacturer, packer, or distributor.[8] **Distributor statement.** If the name and address are not those of the manufacturer, the label must say 'Manufactured for...' or 'Distributed by...'

- **Material facts.** Failure to reveal material facts (e.g. known adverse effects) on the Information Panel is one form of misleading labelling and therefore makes a product misbranded. An example is directions for safe use, if a product could be unsafe if used incorrectly. Other examples of material facts include risk statements (e.g. cautions, contraindications, known side effects, warnings).[9]

- **Warning and Caution statements** (when necessary) must appear on the Information Panel of the cosmetic label prominently and conspicuously as compared to other words, statements, designs, or devices and in **bold type** on contrasting background so that the ordinary person can easily read and understood it. The type size of the letters and/or numbers must not be less than 1/16 inch in height.[10]

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[4] *Ibid.*, 1 April 2011, 21CFR §701.10. Available at: http://www.gpo.gov/fdsys/pkg/CFR-2011-title21-vol7/pdf/CFR-2011-title21-vol7-sec701-10.pdf.

[5] *Ibid.*, 21CFR §701.11. Available at: http://www.gpo.gov/fdsys/pkg/CFR-2011-title21-vol7/pdf/CFR-2011-title21-vol7-sec701-11.pdf.

[6] *Ibid.*, 21CFR §701.13. Available at: http://www.gpo.gov/fdsys/pkg/CFR-2011-title21-vol7/pdf/CFR-2011-title21-vol7-sec701-13.pdf.

[7] Food and Drug Administration, 'Cosmetic labeling and label claims overview' (25 April 2006). Available at: http://www.fda.gov/Cosmetics/CosmeticLabelingLabelClaims/default.htm.

[8] Food and Drug Administration, 'Cosmetic labeling. Name and place of business statement', *Code of Federal Regulations*, 21CFR §701.12 (Washington D.C., Government Printing Office, 1 April 2011). Available at: http://www.gpo.gov/fdsys/pkg/CFR-2011-title21-vol7/pdf/CFR-2011-title21-vol7-sec701-12.pdf.

[9] *Ibid.*, 21CFR §1.21. Available at: http://www.gpo.gov/fdsys/pkg/CFR-2011-title21-vol1/pdf/CFR-2011-title21-vol1-part1.pdf.

[10] *Ibid.*, 21CFR §740.2. Available at: http://www.gpo.gov/fdsys/pkg/CFR-2011-title21-vol7/pdf/CFR-2011-title21-vol7-sec740-2.pdf.

- The **Ingredients** of the product must appear on the Information Panel of the cosmetic label prominently and conspicuously in descending order of predominance (letters must not be less than 1/16 inch in height).[11]

Note: If the cosmetic product is also a drug, its labelling must comply with OTC drug labelling. For example, it would then need to show a 'Drug Facts' box on the Information Panel.

Language: In general, label text must be in English except in the Commonwealth of Puerto Rico where the labelling may be presented in Spanish language (or bilingually with English) or in other United States territories where the predominant language is one other than English. Bilingual labels are permitted in the United States market so long as all of the required elements are provided in both languages (e.g. English and Spanish). Chamorro language could be used on product labels in the American territory of Guam and in the United States Commonwealth of the Northern Mariana Islands. Hawaiian is an official language of the State of Hawaii and could be used there in bilingual labelling with English.

1.1.2. Labelling requirements for food products

The FDA is responsible for assuring that foods sold in the United States are safe, wholesome and properly labelled.

Food products marketed in the United States, whether they are manufactured domestically or are imported from abroad, must comply with the labelling requirements of the FD&C Act,[12] the FPLA,[13] and the regulations written by the FDA as published in the *Code of Federal Regulations* (CFR).

There are different types of food products, each with different labelling requirements, including:

- Conventional food products (including healthy food products eligible for 'health claims' labelling or 'qualified health claims' labelling);
- Dietary supplement products (regulated as a subset of food regulation and eligible for 'health claims,' 'qualified health claims,' or 'structure / function claims' labelling);
- Foods for special dietary use products (e.g. hypoallergenic foods and infant foods);[14] and
- Medical food products (foods which are formulated to be consumed or administered internally (feeding tube) or orally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition with distinctive nutritional requirements).[15]

The following subsections provide further details and specific examples of labelling requirements for conventional foods, dietary supplements, and medical foods, respectively.

1.1.2.1. Labelling requirements for conventional food products

FDA guidance on food labelling is available in Spanish language at:[16]
http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/FoodLabelingGuide/ucm247923.htm

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[11] *Ibid.*, 21CFR §701.3. Available at: http://www.gpo.gov/fdsys/pkg/CFR-2011-title21-vol7/pdf/CFR-2011-title21-vol7-sec701-3.pdf.

[12] Food and Drug Administration online reference edition of the Federal Food, Drug, and Cosmetic Act. Available at: http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/default.htm.

[13] Fair Packaging and Labeling Act. Available at: http://www.fda.gov/RegulatoryInformation/Legislation/ucm148722.htm.

[14] Food and Drug Administration, 'Foods for special dietary use', *Code of Federal Regulations*, Title 21, Part 105 (Washington D.C., Government Printing Office, 1 April 2011). Available at: http://www.gpo.gov/fdsys/pkg/CFR-2011-title21-vol2/pdf/CFR-2011-title21-vol2-part105.pdf.

[15] *Ibid.,* 21CFR §101.9. Available at: http://www.gpo.gov/fdsys/pkg/CFR-2011-title21-vol2/pdf/CFR-2011-title21-vol2-sec101-9.pdf.

[16] Food and Drug Administration, 'Requisitos', *Generales del Etiquetado de Alimentos,* (October 2009). Available at: http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/FoodLabelingGuide/ucm247923.htm.

There are two ways to label food packages and containers:

(a) Place all required label statements on the front label panel (the principal display panel or **PDP**), or

(b) Place certain *specified* label statements on the PDP and other labelling on the **Information Panel** (the label panel immediately to the right of the PDP, as seen by the consumer facing the product).

What labelling information is required on a conventional food product?

The **PDP** is the part of the food label most likely to be displayed or seen on the retail store shelf.[17]

The following information must appear on the PDP of a food product:

- **Statement of identity,** indicating the common or usual name of the food and its form (e.g. whole, slices, diced, etc). The statement of identity must be shown in bold type and be in a size reasonably related to the most prominent printed matter on the PDP.[18]

- **Declaration of net quantity of content,** expressed in the terms of weight, measure, numerical count, or a combination of numerical count and weight or measure. The statement must be in terms of fluid measure if the food is liquid, or in terms of weight if the food is solid, semisolid, or viscous, or a mixture of solid and liquid.[19] The print style must be prominent, conspicuous and easy to read. The letters must not be more than three times as high as they are wide, and lettering must contrast sufficiently with the background to be easy to read.

The **Information Panel** is the label panel immediately to the right of the PDP, as displayed to the consumer. If this panel is not usable, due to package design and construction, (e.g., folded flaps), then the information panel is the next label panel immediately to the right.[20]

'Information panel labelling' refers to the label statements that are generally required to be placed together, without any intervening material, on the information panel, if such labelling does not already appear on the PDP.

The following information must appear on the Information Panel of a food product (unless all essential information already appears on the PDP).

- **Designation of ingredients**: Food ingredients must be listed by their common or usual (American English) name in descending order of predominance by weight on either the Information Panel or the PDP.[21]

- **Name and place of business of manufacturer, packer, or distributor.** If the food product is not manufactured by the business or person whose name appears on the label, the name must be qualified by a phrase that reveals the connection between that company and the product; such as 'Manufactured for ___', 'Distributed by ___', or any other similar wording. [22]

- **Country of origin** statement must be conspicuous. If a United States firm's name and address is declared as the firm responsible for distributing the product, then the country of origin statement

[17] Food and Drug Administration, 'Food labeling. Principle display panel of package form food', *Code of Federal Regulations*, 21CFR §101.1 (Washington D.C., Government Printing Office, 1 April 2011). Available at: http://www.gpo.gov/fdsys/pkg/CFR-2011-title21-vol2/pdf/CFR-2011-title21-vol2-sec101-1.pdf.

[18] *Ibid.*, 21CFR §101.3. Available at: http://www.gpo.gov/fdsys/pkg/CFR-2011-title21-vol2/pdf/CFR-2011-title21-vol2-sec101-3.pdf.

[19] *Ibid.*, 21CFR §101.105. Available at: http://www.gpo.gov/fdsys/pkg/CFR-2011-title21-vol2/pdf/CFR-2011-title21-vol2-sec101-105.pdf.

[20] *Ibid.*, 21CFR §101.2. Available at: http://www.gpo.gov/fdsys/pkg/CFR-2011-title21-vol2/pdf/CFR-2011-title21-vol2-sec101-2.pdf.

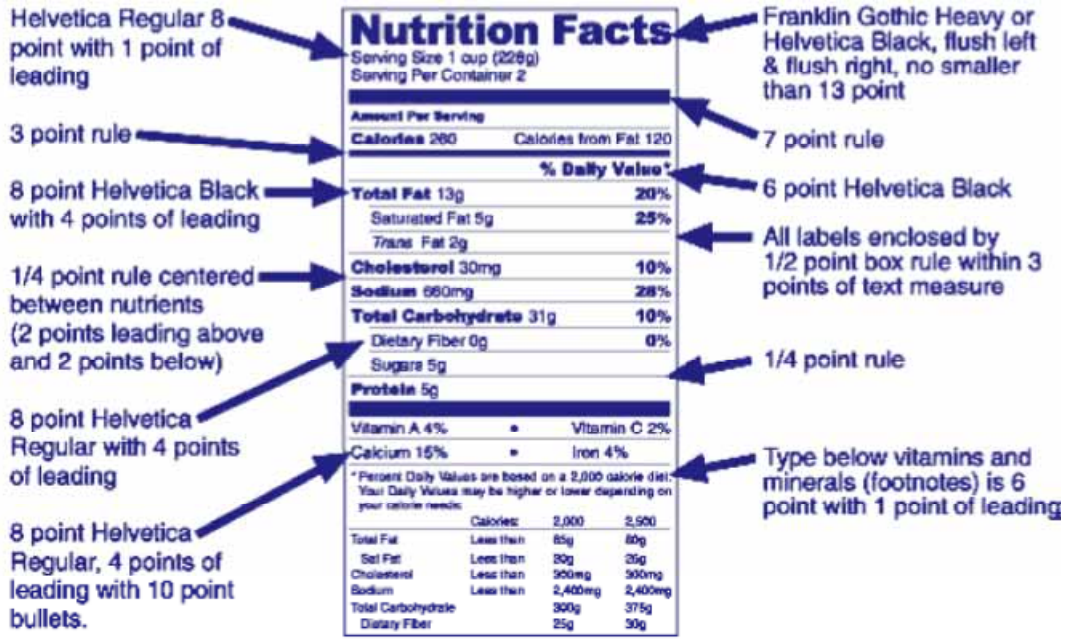
[21] *Ibid.*, 21CFR §101.4. Available at: http://www.gpo.gov/fdsys/pkg/CFR-2011-title21-vol2/pdf/CFR-2011-title21-vol2-sec101-4.pdf.

[22] *Ibid.*, 21CFR §101.5. Available at: http://www.gpo.gov/fdsys/pkg/CFR-2011-title21-vol2/pdf/CFR-2011-title21-vol2-sec101-5.pdf.

must appear in close proximity to the name and address and be at least comparable in size of lettering.[23]

- **Nutrition labelling.** Required nutrition labelling information must appear on the Information Panel in the 'Nutrition Facts' box format that is specified in the regulation 21CFR §101.9, available at: http://www.gpo.gov/fdsys/pkg/CFR-2011-title21-vol2/pdf/CFR-2011-title21-vol2-sec101-9.pdf.[24]

Figure 4 Example of nutrition facts box format requirements specified in 21 CFR §101.9



- **Nutrient content claims** (e.g. 'low fat' or 'good source of fibre') are permitted under certain conditions on labels of food products that meet the requirements. These statements must appear on either the Information Panel or the PDP according to the format specified in the regulation 21CFR §101.13.[25] For example, the type size for a nutrient content claim can be no larger than two times the size of the 'statement of identity' and must not be unduly prominent in type style compared to the statement of identity.

- **Material facts.** Failure to reveal material facts (e.g. known adverse effects) on the Information Panel is one form of misleading labelling and therefore makes a product misbranded. An example is 'directions' for safe use, if a product could be unsafe if used incorrectly. Other examples of material facts include risk statements (e.g. cautions, contraindications, known side effects, warnings).[26]

- **Warning and Caution statements** (when necessary for safe use) must appear on the Information Panel or PDP of the food label prominently and conspicuously.[27] Certain food ingredients require specific statements. For example, food products containing psyllium husk (Plantago ovata Forsk; family Plantaginaceae) that carry an approved soluble fibre health claim statement must also show the following warning statement: **NOTICE**: This food should be eaten with at least a full glass of

[23] Food and Drug Administration, 'Name of Food', *Guidance for Industry: A Food Labeling Guide* (October 2009). Available at: http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/FoodLabelingGuide/ucm247924.htm.

[24] *Ibid.*, 21CFR §101.9. Available at: http://www.gpo.gov/fdsys/pkg/CFR-2011-title21-vol2/pdf/CFR-2011-title21-vol2-sec101-9.pdf.

[25] *Ibid.*, 21CFR §101.13. Available at: http://www.gpo.gov/fdsys/pkg/CFR-2011-title21-vol2/pdf/CFR-2011-title21-vol2-sec101-13.pdf.

[26] *Ibid.*, 21CFR §1.21. Available at: http://www.gpo.gov/fdsys/pkg/CFR-2011-title21-vol1/pdf/CFR-2011-title21-vol1-part1.pdf.

[27] *Ibid.*, 21CFR §101.17. Available at: http://www.gpo.gov/fdsys/pkg/CFR-2011-title21-vol2/pdf/CFR-2011-title21-vol2-sec101-17.pdf.

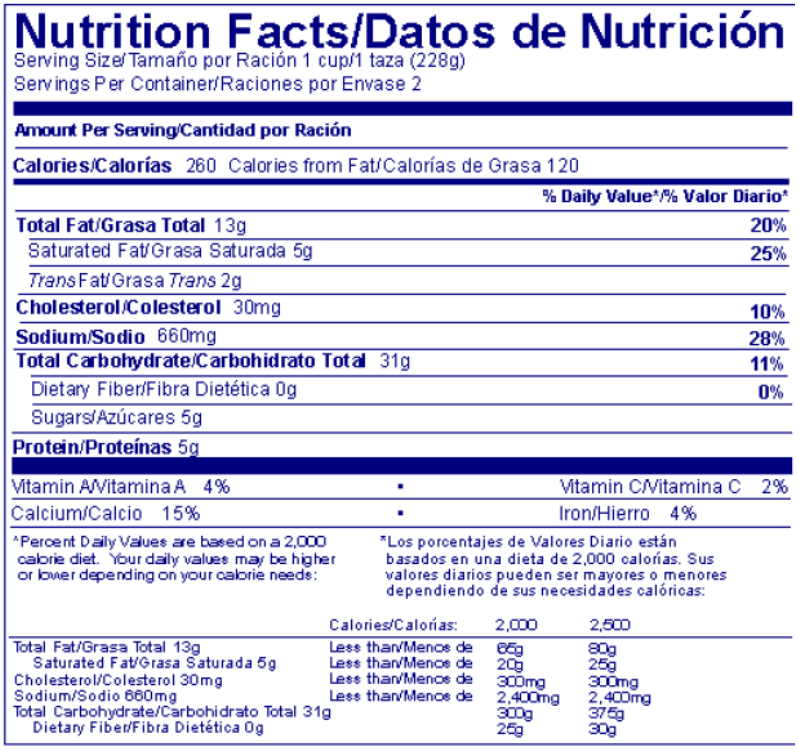
liquid. Eating this product without enough liquid may cause choking. Do not eat this product if you have difficulty in swallowing.

- **Allergy labelling ('Contains statement').**[28] All packaged food products must comply with the food allergen labelling requirements of the 'Food Allergen Labelling and Consumer Protection Act of 2004' (FALCPA). Under FALCPA, major food allergens must be listed on the Information Panel in a 'Contains' statement; for example if the food product contains any ingredients derived from milk, egg, fish, Crustacean shellfish, tree nuts, wheat, peanuts, and/or soybeans. The specific type of Crustacean shellfish (e.g. crab, lobster, or shrimp), fish (e.g. bass, flounder, or cod), or tree nut (e.g. Brazil nut (Bertholletia excelsa) or coconut (Cocos nucifera)) must be declared in the statement. The 'Contains statement' must begin with the word 'Contains' with a capital 'C' followed by the names of the food sources for all major food allergens that either are in the food or are contained in ingredients of the food. For example: **Contains Brazil nuts**. The use of **bolded** text and punctuation within a 'Contains' statement is optional.

Language: In general, label text must be in English except in the Commonwealth of Puerto Rico where the labelling may be presented in Spanish language (or in bilingual labelling) or in other United States territories where the predominant language is one other than English. Bilingual labels are permitted in the United States market so long as all of the required elements are provided in both languages (e.g. English and Spanish). Chamorro language could be used on product labels in the American territory of Guam and in the United States Commonwealth of the Northern Mariana Islands. Hawaiian is an official language of the State of Hawaii and could be used in bilingual labelling with English.

Figure 5 shows an example provided by the FDA for a bilingual (English and Spanish) Nutrition Facts box for the Information Panel of a food product for sale in the United States. Numerical characters that are the same in both languages need not be repeated.

Figure 5 Example of acceptable bilingual (English/Spanish) nutrition facts labelling



Nutrition Facts/Datos de Nutrición

Serving Size/Tamaño por Ración 1 cup/1 taza (228g)
Servings Per Container/Raciones por Envase 2

Amount Per Serving/Cantidad por Ración

Calories/Calorías 260 Calories from Fat/Calorías de Grasa 120

	% Daily Value*/% Valor Diario*
Total Fat/Grasa Total 13g	**20%**
Saturated Fat/Grasa Saturada 5g	**25%**
Trans Fat/Grasa *Trans* 2g	
Cholesterol/Colesterol 30mg	**10%**
Sodium/Sodio 660mg	**28%**
Total Carbohydrate/Carbohidrato Total 31g	**11%**
Dietary Fiber/Fibra Dietética 0g	**0%**
Sugars/Azúcares 5g	
Protein/Proteínas 5g	

Vitamin A/Vitamina A 4%	•	Vitamin C/Vitamina C	2%
Calcium/Calcio 15%	•	Iron/Hierro	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:

*Los porcentajes de Valores Diario están basados en una dieta de 2,000 calorías. Sus valores diarios pueden ser mayores o menores dependiendo de sus necesidades calóricas:

	Calories/Calorías:	2,000	2,500
Total Fat/Grasa Total 13g	Less than/Menos de	65g	80g
Saturated Fat/Grasa Saturada 5g	Less than/Menos de	20g	25g
Cholesterol/Colesterol 30mg	Less than/Menos de	300mg	300mg
Sodium/Sodio 660mg	Less than/Menos de	2,400mg	2,400mg
Total Carbohydrate/Carbohidrato Total 31g		300g	375g
Dietary Fiber/Fibra Dietética 0g		25g	30g

[28] Food and Drug Administration, 'Guidance for Industry: Questions and Answers Regarding Food Allergens, including the Food Allergen Labeling and Consumer Protection Act of 2004 (Edition 4); Final Guidance' (October 2006). Available at: http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/ucm059116.htm.

1.1.2.2. Labelling requirements for dietary supplement products

FDA guidance for industry on dietary supplement product labelling is available in Spanish language at:[29]

http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/DietarySupplements/DietarySupplementlabelingguide/ucm247188.htm

What labelling information is required on a dietary supplement product?

The **PDP** is the part of the dietary supplement label most likely to be displayed or seen on the retail store shelf.[30] The following information must appear on the PDP of a dietary supplement product:

- The **statement of identity** is the common or usual name of the dietary supplement or an appropriately descriptive term. The term 'dietary supplement' must be used as part of the statement of identity, except that the word 'dietary' may be replaced with the name of the dietary ingredient(s) in the product (e.g., cat's claw supplement) or an appropriately descriptive term indicating the type of dietary ingredient(s) in the dietary supplement product (e.g., herbal supplement). The statement of identity must occur as one of the most important features on the PDP. It must appear in bold type and of a type size reasonably related to the most prominent printed matter on the PDP.[31]

- The **net quantity of contents statement** must be located as a distinct item in the bottom 30% of the PDP. The net quantity of contents statement must be expressed in either weight, measure, numerical count or a combination of numerical count and weight or measure. When expressed as a weight or measure, both metric (grams, kilograms, millilitres, or litres) and United States Customary System (ounces, pounds, or fluid ounces) terms must be used.[32] The print style must be prominent, conspicuous and easy to read. The letters must not be more than three times as high as they are wide, and lettering must contrast sufficiently with the background to be easy to read.

The **Information Panel** is the label panel immediately to the right of the PDP, as displayed to the consumer. If this panel is not usable, due to package design and construction, (e.g., folded flaps), then the information panel is the next label panel immediately to the right.[33]

'Information panel labelling' refers to the label statements that are generally required to be placed together, without any intervening material, on the information panel, if such labelling does not already appear on the PDP. The following information must appear on the Information Panel of a dietary supplement product (unless all essential information already appears on the PDP).

- The **Supplement Facts Box** must appear as specified in the regulation 21CFR §101.36 Nutrition labelling of dietary supplements,[34] available at: http://www.gpo.gov/fdsys/pkg/CFR-2011-title21-vol2/pdf/CFR-2011-title21-vol2-sec101-36.pdf

[29] Food and Drug Administration, *Guía para la Industria. Guía de Rotulación de Suplementos Dietéticos* (April 2005). Available at: http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/DietarySupplements/DietarySupplementlabelingguide/ucm247188.htm.

[30] Food and Drug Administration, 'Food labeling. Principle display panel of package form food', *Code of Federal Regulations*, 21CFR §101.1 (Washington D.C., Government Printing Office, 1 April 2011). Available at: http://www.gpo.gov/fdsys/pkg/CFR-2011-title21-vol2/pdf/CFR-2011-title21-vol2-sec101-1.pdf.

[31] *Ibid.*, 21CFR §101.3. Available at: http://www.gpo.gov/fdsys/pkg/CFR-2011-title21-vol2/pdf/CFR-2011-title21-vol2-sec101-3.pdf.

[32] *Ibid.*, 21CFR §101.105. Available at: http://www.gpo.gov/fdsys/pkg/CFR-2011-title21-vol2/pdf/CFR-2011-title21-vol2-sec101-105.pdf.

[33] *Ibid.*, 21CFR §101.2. Available at: http://www.gpo.gov/fdsys/pkg/CFR-2011-title21-vol2/pdf/CFR-2011-title21-vol2-sec101-2.pdf.

[34] *Ibid.*, 21CFR §101.36. Available at: http://www.gpo.gov/fdsys/pkg/CFR-2011-title21-vol2/pdf/CFR-2011-title21-vol2-sec101-36.pdf.

Figure 6 Example of supplement facts box format requirements specified in 21 CFR §101.36

Supplement Facts

Serving Size 1 tsp (3 g) (makes 8 fl oz prepared)
Servings Per Container 24

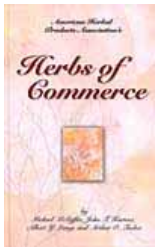
	Amount Per Teaspoon	% Daily Value
Calories	10	
Total Carbohydrate	2 g	< 1%*
Sugars	2 g	†
Proprietary blend	0.7 g	
German Chamomile (flower)		†
Hyssop (leaves)		†

* Percent Daily Values are based on a 2,000 calorie diet.
† Daily Value not established.

Other ingredients: Fructose, lactose, starch, and stearic acid.

- **Designation of ingredients**: The common or usual name of ingredients of dietary supplements that are botanicals (including fungi and algae) must be consistent with the names standardized in the *American Herbal Products Association's Herbs of Commerce*.[35] The part of the plant (e.g., root, leaf) (e.g., 'Cat's claw bark' or 'Cat's claw (bark)') is required except for algae. The name of the part of the plant must be expressed in English (e.g., 'flower' rather than 'flos'). The Latin binomial name of the plant, in parentheses, is only required when the standardized common name does not appear in the *Herbs of Commerce*. When required, the Latin binomial name may be listed before the part of the plant. Any name in Latin must be in accordance with internationally accepted rules on nomenclature, such as those found in the *International Code of Botanical Nomenclature*.[36]

Figure 7 American Herbal Products Association's Herbs of Commerce



- **Name and place of business of manufacturer, packer, or distributor.** The street address, city, state and zip code must be shown if it is not listed in a current city directory or telephone book. If the dietary supplement product is not manufactured by the business or person whose name appears on the label, the name must be qualified by a phrase that reveals the connection between that company and the product; such as 'Manufactured for ___', 'Distributed by ___', or any other similar wording. [37]

- **Country of origin** statement must be conspicuous. If a United States firm's name and address is declared as the firm responsible for distributing the product, then the country of origin statement must appear in close proximity to the name and address and be at least comparable in size of lettering.[38]

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[35] M. McGuffin, J.T. Kartesz, A.Y. Leung, A.O. Tucker, *American Herbal Products Association's Herbs of Commerce*, 2nd Edition, (Silver Spring, Maryland, American Herbal Products Association, 2000).

[36] Food and Drug Administration,.' Food labeling. Food; designation of ingredients' *Code of Federal Regulations*, 21CFR §101.4 (Washington D.C., Government Printing Office, 1 April 2011). Available at: http://www.gpo.gov/fdsys/pkg/CFR-2011-title21-vol2/pdf/CFR-2011-title21-vol2-sec101-4.pdf.

[37] *Ibid.*, 21CFR §101.5. Available at: http://www.gpo.gov/fdsys/pkg/CFR-2011-title21-vol2/pdf/CFR-2011-title21-vol2-sec101-5.pdf.

[38] Food and Drug Administration, 'Name of Food', *Guidance for Industry: A Food Labeling Guide* (October 2009). Available at: http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/FoodLabelingGuide/ucm247924.htm.

- **Material facts.** Failure to reveal material facts (e.g. known adverse effects) on the Information Panel is one form of misleading labelling and therefore makes a product misbranded. An example is 'directions' for safe use, if a product could be unsafe if used incorrectly. Other examples of material facts include risk statements (e.g. cautions, contraindications, known side effects, warnings).[39]

- **Warning and Caution statements** (when necessary for safe use) must appear on the Information Panel or PDP of the dietary supplement label prominently and conspicuously.[40] Certain dietary supplement ingredients require specific statements. For example, the labels of any dietary supplement in solid oral dosage form (e.g., tablets or capsules) that contains iron or iron salts for use as an iron source must show the following statement: **WARNING**: *Accidental overdose of iron-containing products is a leading cause of fatal poisoning in children under 6. Keep this product out of reach of children. In case of accidental overdose, call a doctor or poison control centre immediately*.

- **Allergy labelling ('Contains statement').**[41] All packaged food products (including conventional foods, dietary supplements, infant formula, and medical foods) must comply with the food allergen labelling requirements of the 'Food Allergen Labelling and Consumer Protection Act of 2004' (FALCPA). Under FALCPA, major food allergens must be listed on the Information Panel in a 'Contains' statement; for example if the food product contains any ingredients derived from milk, egg, fish, Crustacean shellfish, tree nuts, wheat, peanuts, and/or soybeans. The specific type of Crustacean shellfish (e.g. crab, lobster, or shrimp), fish (e.g. bass, flounder, or cod), or tree nut (e.g. ginkgo nut (*Ginkgo biloba*) or coconut (*Cocos nucifera*)) must be declared in the statement. The 'Contains statement' must begin with the word 'Contains' with a capital 'C' followed by the names of the food sources for all major food allergens that either are in the food or are contained in ingredients of the food. For example: **Contains ginkgo nuts**. The use of **bolded** text and punctuation within a 'Contains' statement is optional.

- **Language**: Label text must be in **English** except that, for dietary supplements distributed solely in the Commonwealth of Puerto Rico or in a Territory where the predominant language is one other than English, the predominant language may be substituted for English. If a label bears any representation in a **foreign language**, then all mandatory label information must be repeated in each foreign language used on the label.[42]

1.1.2.3. Labelling requirements for medical food products

Medical foods are foods. Therefore the labels of medical food products must contain:

- A **statement of identity** (the common or usual name of the product) (21 CFR 101.3);[43]
- An accurate statement of the **net quantity of contents** (21 CFR 101.105);[44]
- The **name and place of business** of the manufacturer, packer, or distributor (21 CFR 101.5);[45]
- A **complete list of ingredients**, listed by their common or usual name and in descending order of predominance (21 CFR 101.4);[46]

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[39] Food and Drug Administration, 'General labeling requirements. Failure to reveal material facts' *Code of Federal Regulations*, 21CFR §1.21 (Washington D.C., Government Printing Office, 1 April 2011). Available at: http://www.gpo.gov/fdsys/pkg/CFR-2011-title21-vol1/pdf/CFR-2011-title21-vol1-part1.pdf.

[40] *Ibid.*, 21CFR §101.17. Available at: http://www.gpo.gov/fdsys/pkg/CFR-2011-title21-vol2/pdf/CFR-2011-title21-vol2-sec101-17.pdf.

[41] Food and Drug Administration, 'Guidance for Industry: Questions and Answers Regarding Food Allergens, including the Food Allergen Labeling and Consumer Protection Act of 2004 (Edition 4); Final Guidance' (October 2006). Available at: http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/ucm059116.htm.

[42] Food and Drug Administration,.' Food labeling. Food; prominence of required statements', *Code of Federal Regulations*, 21CFR §101.15(c) (Washington D.C., Government Printing Office, 1 April 2011). Available at: http://www.gpo.gov/fdsys/pkg/CFR-2011-title21-vol2/pdf/CFR-2011-title21-vol2-sec101-15.pdf.

[43] *Ibid.*, 21CFR §101.3. Available at: http://www.gpo.gov/fdsys/pkg/CFR-2011-title21-vol2/pdf/CFR-2011-title21-vol2-sec101-3.pdf.

[44] *Ibid.*, 21CFR §101.105. Available at: http://www.gpo.gov/fdsys/pkg/CFR-2011-title21-vol2/pdf/CFR-2011-title21-vol2-sec101-105.pdf.

[45] *Ibid.*, 21CFR §101.5. Available at: http://www.gpo.gov/fdsys/pkg/CFR-2011-title21-vol2/pdf/CFR-2011-title21-vol2-sec101-5.pdf.

[46] *Ibid.*, 21CFR §101.4. Available at: http://www.gpo.gov/fdsys/pkg/CFR-2011-title21-vol2/pdf/CFR-2011-title21-vol2-sec101-4.pdf.

- In plain language, the food source name of the **major allergens,** i.e. milk, eggs, fish (e.g., bass, flounder, cod), crustacean shellfish (e.g., crab, lobster, or shrimp), tree nuts (e.g., almonds, pecans, or walnuts), wheat, peanuts, and soybeans. [47]

All words, statements, and other information required to appear on a label or labelling of a medical food:

- Must appear with **prominence and conspicuousness** (21 CFR 101.15): and
- Be in **English** except that, for medical foods distributed solely in the Commonwealth of Puerto Rico or in a Territory where the predominant language is one other than English, the predominant language may be substituted for English. If a label bears any representation in a **foreign language**, then all mandatory label information must be repeated in each foreign language used on the label (21 CFR 101.15(c)).[48]

Medical foods also must be labelled in conformance with: the **PDP** requirements (21 CFR 101.1);[49] the **Information Panel** requirements (21 CFR.101.2);[50] and the **misbranding of food** requirements (21 CFR 101.18).[51]

1.1.3. Labelling requirements for drug products

While most natural botanical products in the United States market are labelled and marketed as dietary supplement products (DSPs), healthy food products or non-drug cosmetic products, some are labelled as listed over-the-counter (OTC) drug products for human use including some conventional drug products composed of botanical active ingredients (e.g. Capsicum Oleoresin or Cocoa Butter). There are also some prescription drug products (Rx) composed of botanical active ingredients.

Additionally, there is a wide range of homoeopathic drug products composed of infinitesimal dilutions of tinctures of botanical origin.

This section provides basic information on the labelling requirements for conventional botanical drug products and homoeopathic botanical drug products.

1.1.3.1. Labelling requirements for conventional drug products

In the United States, there are a few botanical substances that may be used as active ingredients of OTC drug products for human use (e.g. Camphor, Capsicum Oleoresin, Cocoa Butter, Elm Bark, Ipecac Syrup, Psyllium Seed Husk, Senna Leaf or Pod, and Witch Hazel).

The labelling requirements for these botanical drugs are basically the same as for any conventional drug product. The specific labelling text for each type of drug product is provided in its respective labelling standards monograph. The overall format and content requirements for OTC drug labelling are available at:[52]
http://www.gpo.gov/fdsys/pkg/CFR-2011-title21-vol4/pdf/CFR-2011-title21-vol4-sec201-66.pdf

The general labelling requirements for an OTC drug product are the following:

- **Principal Display Panel (PDP)**: The labelling must comply with the PDP provision under 21 CFR 201.60.

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[47] Food and Drug Administration, 'Guidance for Industry: Questions and Answers Regarding Food Allergens, including the Food Allergen Labeling and Consumer Protection Act of 2004 (Edition 4); Final Guidance' (October 2006). Available at: http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodLabelingNutrition/ucm059116.htm

[48] Food and Drug Administration, 'Food labeling. Food; prominence of required statements', *Code of Federal Regulations*, Title 21CFR §101.15(c) (Washington D.C., Government Printing Office, 1 April 2011). Available at: http://www.gpo.gov/fdsys/pkg/CFR-2011-title21-vol2/pdf/CFR-2011-title21-vol2-sec101-15.pdf.

[49] *Ibid.*, 21CFR §101.1. Available at: http://www.gpo.gov/fdsys/pkg/CFR-2011-title21-vol2/pdf/CFR-2011-title21-vol2-sec101-1.pdf.

[50] *Ibid.*, 21CFR §101.2. Available at: http://www.gpo.gov/fdsys/pkg/CFR-2011-title21-vol2/pdf/CFR-2011-title21-vol2-sec101-2.pdf.

[51] *Ibid.*, 21CFR §101.18. Available at: http://www.gpo.gov/fdsys/pkg/CFR-2011-title21-vol2/pdf/CFR-2011-title21-vol2-sec101-18.pdf.

[52] *Ibid.*, 21CFR §201.66. Available at: http://www.gpo.gov/fdsys/pkg/CFR-2011-title21-vol4/pdf/CFR-2011-title21-vol4-sec201-66.pdf.

- **Name and Place of Business**: The label must bear conspicuously the name and place of business of the manufacturer, packer, or distributor in conformance with 21 CFR 201.1.

- **Directions for Use**: Each drug product must bear adequate directions for use as per 21CFR §201.5.

- The **National Drug Code (NDC)** number is requested but not required to appear on all drug labels as per 21 CFR 201.2. If the NDC number is shown on a drug label, it must appear prominently in the top third of the principal display panel (PDP) of the label on the immediate container and of any outside container or wrapper as per 21 CFR § 207.35(b)(3).

- An **Expiration date** must appear on the immediate container and also the outer package, if any, unless it is easily legible through such outer package. However, when single-dose containers are packed in individual cartons, the expiration date may properly appear on the individual carton instead of the immediate product container (21 CFR §201.17).

- The **Lot Number** on the label of a drug should be capable of yielding the complete manufacturing history of the package (21 CFR §201.18).

- **Statement of Identity**: The label must contain a statement of identity in bold type as described in 21CFR §201.61. It must use the 'established name' of drug product and a statement of general pharmacological category(ies) or the principal intended actions corresponding to its monograph.

- Declaration of **Net Quantity of Contents**: The label must bear a declaration of the net quantity of contents expressed in the terms of weight, measure, numerical count, or a combination or numerical count and weight, measure, or size, as per 21CFR §201.62.

- **Pregnancy / Breastfeeding Warnings**: The labels of all OTC drug products that are intended for systemic absorption, unless specifically exempted, must contain a general warning under the heading 'Warning' (or 'Warnings' if it appears with additional warning statements) as follows: 'If pregnant or breast-feeding, ask a health professional before use.' (21CFR §201.63).

- **Language:** The label must be in the English language as per 21CFR 201.15(c)(1), although it is permissible for industry to include foreign language in the labelling, so long as all required text occurs in both languages (e.g. English and Spanish.

1.1.3.2. Labelling requirements for homoeopathic drug products

Homoeopathic medicines are drug products. Some are labelled and marketed for OTC human use and some are available by doctor's prescription (Rx) only. As such, OTC homeopathic drug products are subject to the same labelling requirements as for conventional drug products (See section 1.1.3.1).

The names of the active ingredients however must correspond to their respective monographs published in the Homoeopathic Pharmacopoeia of the United States (HPUS), which is the official compendium of standards for homoeopathic medicines marketed in the United States. If a drug product is labelled and offered for sale as a homoeopathic drug, it is subject to the provisions of the HPU and not to those of the United States Pharmacopoeia (USP).[53]

The initials 'HPUS' on the label of a drug product assures that legal standards of strength, quality, purity and packaging exist for the drug product within the package. The active ingredients are official Homeopathic Drug Products and are found in the current edition of the HPUS. The standards which must be met in order to append 'HPUS' to a substance or a product are established by the Homeopathic Pharmacopeia Convention of the United States (HPCUS).[54]

[53] Drugs and Devices, Title 21 Part 351 Adulterated drugs and devices, *United States Code,* 21USC §351 (2010). Available at: http://www.gpo.gov/fdsys/pkg/USCODE-2010-title21/pdf/USCODE-2010-title21-chap9-subchapV-partA-sec351.pdf.

[54] Homoeopathic Pharmacopoeia Convention of the United States, 'Overview: the legal status since 1897'. Available at: http://www.hpus.com/overview.php.

Figure 8 Example of an herbal homoeopathic drug product label

The FDA provides information on the conditions under which homoeopathic drugs may be marketed in the United States including the following general labelling requirements for OTC homoeopathic drug products:[55]

- **Principal Display Panel (PDP)**: The labelling must comply with the PDP provision under 21 CFR 201.60.
- **Statement of Identity**: The label shall contain a statement of identity as described in 21 CFR 201.61.
- Declaration of **Net Quantity of Contents**: The label shall conform to the provisions for declaring net quantity of contents under 21 CFR 201.62.
- **Indications for Use**: The labelling must bear at least one major OTC indication for use, stated in terms likely to be understood by lay persons.
- **Warnings**: OTC homeopathic drugs intended for systemic absorption, unless specifically exempted, must bear a warning statement in conformance with 21 CFR 201.63(a). Other warnings, such as those for indications conforming to those in OTC drug final regulations, are required as appropriate.
- **Name and Place of Business**: Each product must bear the name and place of business of the manufacturer, packer, or distributor in conformance with 21 CFR 201.1.
- **Directions for Use**: Each drug product must bear adequate directions for use in conformance with 21 CFR 201.5.

[55] Food and Drug Administration, 'Sec. 400.400 Conditions under which homeopathic drugs may be marketed', *FDA Compliance Policy Guide* (January 2010). Available at: http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm074360.htm.

- **Statement of Ingredients**: Ingredient information shall appear in accord with 21 CFR 201.10. Labelling must bear a statement of the quantity and amount of ingredient(s) in the product in conformance with 21 CFR 201.10, expressed in homeopathic terms, e.g., lx, 2x.

- **Documentation** must be provided to support that those products or ingredients which are not recognized officially in the HPUS, an addendum to it, or its supplements are generally recognized as homeopathic products or ingredients.

- **Established Name**: The product must be in conformance with Section 502(e)(1) of the Act and must bear an established name in accord with Section 502(e)(3) of the Act and 21 CFR 201.10. Many homeopathic products bear Latin names which correspond to listings in the HPUS. The industry is required to translate these names from Latin to their common English names. It is permissible for industry to include in the labelling both English and Latin names.

- **Container Size - Labelling Exemption**: For those products packaged in containers too small to accommodate a label bearing the required information, the labelling requirements may be met by placing information on the carton or outer container, or in a leaflet with the package, as designated in 21 CFR 201.10(i) for OTC drugs. However, as a minimum, each product must also bear a label containing a statement of identity and potency, and the name and place of business of the manufacturer, packer, or distributor.

- **Language:** The label and labelling must be in the English language as described and provided for under 21 CFR 201.15(c)(1), although it is permissible for industry to include foreign language in the labelling, as well.

1.2. USDA labelling requirements for certified organic products

Whether a health food product, herbal dietary supplement product, natural cosmetic product, or herbal drug product, the USDA is the regulatory agency responsible for certified organic agricultural products and their labelling.

Products produced in a foreign country and exported for sale in the United States must be certified and labelled according to the USDA National Organic Program (NOP) regulations.[56] The entire NOP regulations are available to download at:

http://www.gpo.gov/fdsys/pkg/CFR-2011-title7-vol3/pdf/CFR-2011-title7-vol3-subtitleB-chapI-subchapM.pdf

The term, 'organic,' may only be used on labels of finished products or ingredients that have been produced and handled in accordance with the USDA-NOP regulations published in the *Code of Federal Regulations*, Title 7, Part 205 (7CFR §205: Subpart D - Labels, Labeling and Market Information).[57]

For Peru, there is one Accredited Certifying Agent (ACA) for the USDA NOP:

	Bio Latina Certificadora
Address:	Av. Alfredo Benavides 330, Ofic. 203, Miraflores, Lima 18
Telephone:	(51 1) 209 03 00
Fax:	(51 1) 209 03 00 Anexo 20
Contact:	Roxana Priego Flores
E-mail:	central@biolatina.com.pe
Website:	http://www.biolatina.com

The USDA also publishes a regularly updated '*Program Handbook: Guidance and Instructions for Accredited Certifying Agents & Certified Operations*.'[58] The purpose of the Program Handbook is to provide

[56] United States Department of Agriculture, 'Organic Foods Production Act Provisions', *Code of Federal Regulations*, 7CFR §205 (1 January 2011). Available at: http://www.gpo.gov/fdsys/pkg/CFR-2011-title7-vol3/pdf/CFR-2011-title7-vol3-subtitleB-chapI-subchapM.pdf.

[57] *Ibid.,* subpart D. Available at: http://www.gpo.gov/fdsys/pkg/CFR-2011-title7-vol3/pdf/CFR-2011-title7-vol3-part205-subpartD.pdf.

those who own, manage, or certify organic operations with guidance and instructions that can assist them in complying with the NOP regulations. The Handbook includes three types of documents:

(a) **Guidance**, which provides interpretations of NOP statutory or regulatory requirements;

(b) **Instructions**, which informs certifying agents and certified operations about best practices for conducting business related to certification, accreditation, international activities, and compliance and enforcement; and

(c) **Policy memos**, which provide formal communication to public audiences on NOP policy regarding a specific regulatory requirement.

The 224-page Winter 2011 edition of the *Program Handbook* can be downloaded at:

http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5088939

2. Fair Packaging and Labeling Act (FPLA)

The Fair Packaging and Labeling Act (FPLA)[59] directs both the Federal Trade Commission (FTC) and the FDA to issue regulations requiring that all 'consumer commodities' (e.g. cosmetic, dietary supplement, drug, and food products) be labelled to disclose:

- **Net contents** (the net quantity of contents in terms of weight, measure, or numerical count (measurement must be in both metric (e.g. grams) and inch/pound (e.g. ounce) units).
- **Identity of commodity** (a statement identifying the commodity, e.g. cat's claw bark herbal dietary supplement); and
- **Name and place of business** of the product's manufacturer, packer, or distributor.

The FDA administers the FPLA with respect to foods (conventional foods and dietary supplements), drugs (conventional drugs and homoeopathic drugs), cosmetics, and medical devices. The FTC administers the FPLA with respect to other 'consumer commodities' that are consumed or expended in the household.

The FPLA authorizes additional regulations where necessary to prevent consumer deception (or to facilitate value comparisons), for example with respect to descriptions of the ingredients or characterization of the package sizes.

3. Website content: advertising or labelling or both?

Concerning advertising of dietary supplement products (DSPs), the role of the FTC is to enforce laws outlawing 'unfair or deceptive acts or practices' and to ensure that consumers get accurate information so that they can make informed decisions about DSPs.

The FTC and the FDA work together under a long-standing liaison agreement governing the division of responsibilities between the two agencies.

As applied to DSPs, the FDA has primary responsibility for claims on product labelling, including packaging, inserts, and other promotional materials distributed at the point of sale. The FTC has primary responsibility for claims in advertising, including print and broadcast ads, infomercials, catalogues, and

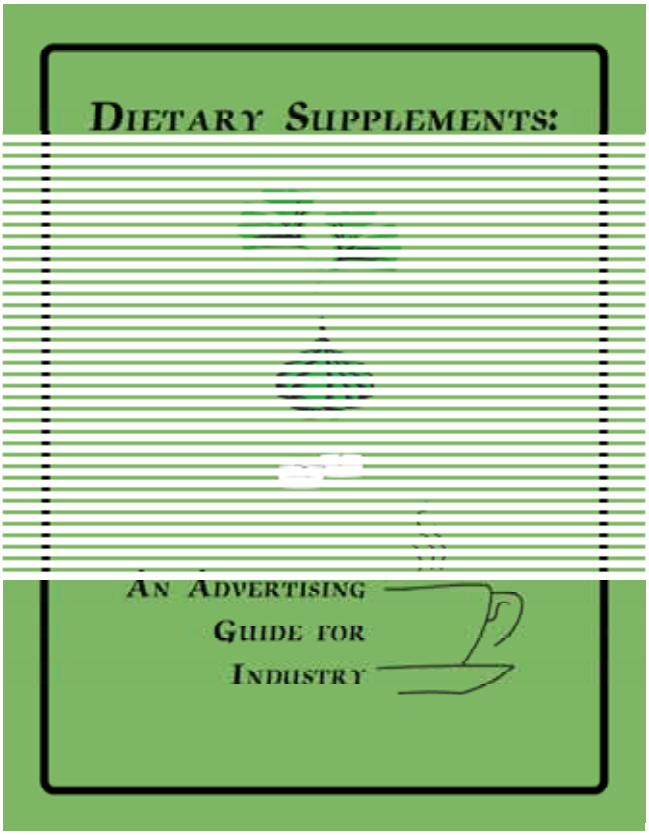
[58] United States Department of Agriculture. 'Program Handbook: Guidance and Instructions for Accredited Certifying Agents & Certified Operations' (2011). Available at:
http://www.ams.usda.gov/AMSv1.0/ams.fetchTemplateData.do?template=TemplateR&navID=ProgramHandbookNOPNationalOrganicProgramHome&rightNav1=ProgramHandbookNOPNationalOrganicProgramHome&topNav=&leftNav=NationalOrganicProgram&page=NOPProgramHandbook&resultType=&acct=noppub.

[59] Federal Trade Commission, The Fair Packaging and Labeling Act Home Page, 15 U.S.C. §§ 1451-1461. Available at: http://www.ftc.gov/os/statutes/fplajump.shtm.

similar direct marketing materials. Marketing on the Internet is subject to regulation in the same fashion as promotions through any other media. Because of their shared jurisdiction, the two agencies work closely to ensure that their enforcement efforts are consistent to the fullest extent feasible.

The FTC has published guidelines for the advertising of DSPs (including website content) entitled 'Dietary Supplements: an Advertising Guide for Industry,' which is available at the FTC's website at: http://business.ftc.gov/documents/bus09-dietary-supplements-advertising-guide-industry.pdf

Figure 9 Dietary supplements: an advertising guide for industry



The FTC has also developed its *Green Guides* for the use of environmental benefit claim statements,[60] e.g. biodegradable, compostable, photodegradable, recyclable, recycled content, refillable, and reusable.

The FTC *Green Guides* apply to environmental claims included in labelling, advertising, promotional materials and all other forms of marketing, whether asserted directly or by implication, through words, symbols, emblems, logos, depictions, product brand names, or through any other means, including marketing through digital or electronic means, such as the Internet or electronic mail. The guides apply to any claim about the environmental attributes of a product, package or service in connection with the sale, offering for sale, or marketing of such product, package or service for personal, family or household use, or for commercial, institutional or industrial use.

The *Green Guides* are available at the FTC's website at: http://www.ftc.gov/bcp/grnrule/guides980427.htm

[60] Federal Trade Commission, Guides for the Use of Environmental Marketing Claims (Green Guides). Available at: http://www.ftc.gov/bcp/grnrule/guides980427.htm.

Figure 10 FTC Eco in the market green guides review

4. Labelling requirements for finished products with certifications

While some labelling requirements for products with certifications are legislatively mandated, for example certified organic products are subject to the National Organic Program (NOP) regulations, many others are voluntary schemes that are administered and enforced by independent standards setting organizations (SSOs) and the corresponding accredited inspection and certification organizations.

This chapter will provide basic information on the labelling requirements of voluntary certification schemes[61], relevant to the labelling and marketing of biodiversity products, that are of growing importance and increasingly visible in the United States natural products trade. These include labelling requirements for finished products with ecological certification (e.g. Demeter Biodynamic®), religious certification (e.g. Halal and/or Kosher), and social certification (e.g. FLO FairTrade or FWF FairWild).

4.1. Labelling requirements for finished products with ecological certification

This section provides information on labelling requirements for finished products with ecological certification including Demeter Biodynamic® certified products and NOP organic certified products.

There are also other standards that include modules with ecological criteria and performance indicators for products composed of botanical ingredients of sustainable agriculture farms or sustainable wild collection operations. For example, Section 4.3 of this report provides labelling information for products that are certified against social sustainability standards that also require compliance with certain ecological sustainability standards. These include standards such as the Institute for Market Ecology (IMO) Fair For Life and the FairWild Foundation (FWF) FairWild Standard, among others.

4.1.1. Demeter Biodynamic® labelling

Demeter USA is a non-profit American chapter of Demeter International, the world's only certifier of Biodynamic farms and products.

Biodynamic® agriculture goes beyond organic, envisioning the farm as a self-contained and self-sustaining organism. In an effort to keep the farm, the farmer, the consumer, and the earth healthy, farmers avoid chemical pesticides and fertilizers, utilize compost and cover crops, and set aside a minimum of 10% of their total acreage for biodiversity. The entire farm, versus a particular crop, must be certified, and farms are inspected annually.

In order for a finished product to bear the Demeter logo it must be made with certified Biodynamic® ingredients and meet strict processing standards to ensure the purest possible product.

The International Demeter Standards for Processing [62] is available in Spanish language at: http://demeter.net/standards/st_processing_s.pdf

[61] See www.standardsmap.org – an ITC online tool comparing different sustainability certifications.

[62] Demeter International, 'Normas internacionales de elaboración para el use de Demeter Biodynamica y comerciales relacionadas' (June 2010). Available at: http://demeter.net/standards/st_processing_s.pdf.

The standards for labelling of Demeter products are also available in Spanish language at: http://demeter.net/standards/st_labelling_s.pdf

Figure 11 General labelling of products consisting of Demeter ingredients

4.1.2. NOP organic labelling

Information on the labelling of NOP certified organic products is provided in Spanish language at the website of 'Bio Latina Certificadora', an Accredited Certifying Agent (ACA) for the USDA NOP in Peru: http://www.biolatina.com.

The organic labelling rules are included in the Spanish translation of the NOP available at: http://www.biolatina.com/doc_bl/normas200311/GNP-USA-200311.pdf.

Figure 12 Spanish translation of NOP organic labelling rules

4.2. Labelling requirements for finished products with religious certification

Religious certifications for natural ingredients and finished natural products in the United States market are of increasing importance. Many of the major botanical ingredient suppliers and an increasing number of finished products are beginning to display both Halal and Kosher certification logos on the labelling.

In many cases, ingredient suppliers are marketing botanicals with multiple certifications (e.g. ecological, religious and social) in order to reach the broadest possible audiences. For example, figure 13 is an advertisement of the Martin Bauer Group, one of the largest suppliers of botanical ingredients globally,

showing an image of chamomile flowers (*Matricaria recutita*) with religious certification seals (halal and kosher) as well as fairtrade and organic seals.[63]

This section provides links to information on the certification bodies and their labelling guidance for Halal and/or Kosher certified finished products.

Figure 13 Martin Bauer Group advertisement showing Halal, Kosher, Fairtrade and Organic seals

4.2.1. Halal labelling

Halal is an Arabic word meaning 'lawful' or 'permitted'. The opposite of halal is haram, which means 'unlawful' or 'prohibited.' When it comes to food and consumables, halal is the dietary standard of Muslims. The market for halal-certified products is huge and growing. It includes the 1.4 billion Muslims worldwide and many millions of health-conscious non-Muslims who choose to eat halal-certified products.

The Islamic Food and Nutrition Council of America (IFANCA) signed a Memorandum of Understanding (MoU) with Halal Peru to provide halal certification services to South American companies. The cooperation became effective 10 August 2011. Halal Peru was born out of a need to provide Latin American companies viable access to global markets, where halal is a necessary regulatory and compliance issue for food, beverage, pharmaceutical and cosmetic goods. Halal Peru will work with IFANCA's halal certification experts to provide halal certification services for companies interested in competing in global markets where consumers are looking for products with religious certification.[64]

Information on halal certification and product labelling in the United States is available from certification organizations including:

American Halal Foundation (AHF): http://www.halalfoundation.org/certProcess.htm

Islamic Food And Nutrition Council of America (IFANCA): http://www.ifanca.org/procedure

Figure 14 Halal certified logos for product labels in the United States market

4.2.2. Kosher labelling

The word kosher is an adaptation of the Hebrew word meaning 'fit' or 'proper.' It refers to foodstuffs that meet the dietary requirements of Jewish Law. The kosher symbol on a label represents more than a product that conforms to religious standards. It is viewed as a mark of quality and an added safeguard.

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[63] Martin Bauer Group, Organic, Kosher and Halal with Peace of Mind. Available at: http://www.martin-bauer-group.com/en/active-phytopharmaceutical-ingredients-nutritional-supplementsfinzelberg/quality-and-safety/botanicals-and-procurement/botanicals-with-a-seal-of-quality.html.

[64] IFANCA and Halal Peru Sign MoU to provide Halal Certification Services in South America (24 August 2011). Available at: http://ifanca.wordpress.com/2011/08/24/ifanca%C2%AE-and-halal-peru-sign-mou-to-provide-halal-certification-services-in-south-america

Kosher foods, although based on one of the world's oldest dietary laws, are among the fastest growing current trends in food processing. The United States is an epicentre for kosher foods because it is home to 40% of the world's Jewish population, roughly 5.2 million consumers. What makes the American kosher market particularly profitable is that kosher foods are increasingly attractive to the non-Jewish population, who now make up the leading and fastest-growing consumer base for kosher products. This increase in popularity has provided the United States kosher market with a value of US$12.5 billion in 2008. It is predicted that this value will increase to US$13 billion by 2013.[65]

Spanish language kosher certification and labelling information is available from Kosher Peru: http://www.kosher.pe/certificacion-kosher.html

Information on kosher certification and product labelling in the United States is available from certification organizations including:

Kof-K:	http://www.kof-k.org/industrialcontent.php
Kosher Supervision of America (KSA):	http://www.ksakosher.com/application.html
OK Kosher:	http://www.ok.org/Content.asp?ID=19
Orthodox Union (OU):	http://www.oukosher.org/index.php/prolearn/certification_guide
Star-K:	http://www.star-k.org/industry.htm

Figure 15 Kosher certified logos for product labels in the United States market

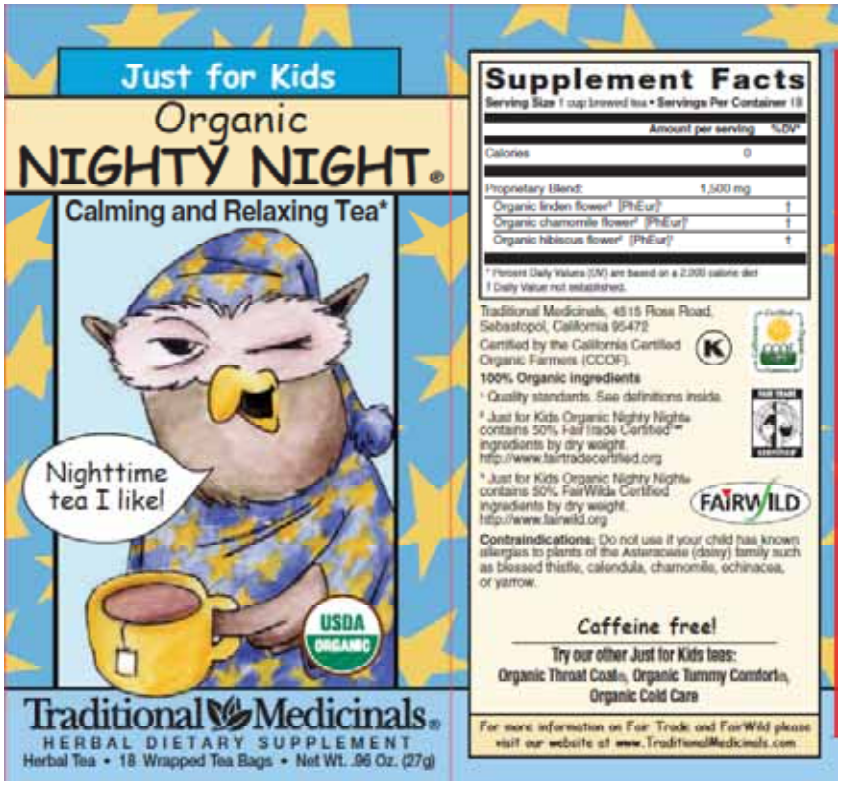
4.3. Labelling requirements for finished products with social certification

The market for natural ingredients and finished natural products that bear some type of social certification continues to grow in the United States. More and more major brands are making commitments to using certified ingredients in their products. This section provides basic information on these standards and their labelling requirements. The most visible certification schemes so far in the United States market include:

- **Fair for Life Certified** - products marketed by Dr. Bronner's Magic Soaps (Cosmetics, Soap Products), Eco Teas (Teas), Equal Exchange (Coffee, Chocolate, Sugar), and Guayaki Sustainable Rainforest Products (Teas), among others;
- **Fair Trade Certified** – products marketed by Avon Products (Body Creams), Badger Company (Cocoa Butter Lip Balms), Ben & Jerry's (Ice Cream), Choice Organic Teas, Frontier Natural Products Cooperative (Teas and Spices), Glory Bee (Honey), Green & Black's (Chocolates), Honest Tea, Numi Organic Tea, Stash Tea, and Traditional Medicinals (Herbal Teas), among many others.
- **FairWild Certified** - products marketed by Traditional Medicinals (Herbal Teas).
- **Rainforest Alliance Certified** – products marketed by Alba Botanics (Skin and Hair Care Products), Endangered Species Chocolates, Lipton Pure Leaf (Tea), Naked Juice (Fruit Juice), Newman's Own Organics (Chocolates), and Whole Foods Market (Bananas, Chocolate, Coffee, Tea), among many others.

[65] Agriculture and Agri-Food Canada (AAFC), United States Kosher Food Market Brief (August 2010). Available at: http://www.ats.agr.gc.ca/amr/4975-eng.htm.

Figure 16 Dietary supplement label showing FairTrade, FairWild, Organic and Kosher seals



4.3.1. Fair Trade USA labelling

A 501 (c) (3) non-profit organization, Fair Trade USA (FTUSA) (formerly 'TransFair USA') is the leading third-party certifier of Fair Trade products in the United States. Up until recently, FTUSA had been a member of Fairtrade International (FLO). Although FLO and FTUSA share a belief in the importance of empowering producers and workers around the world to improve their lives through better terms of trade, FTUSA has decided to resign its membership from FLO effective 31 December 31 2011 due to differing perspectives on how best to achieve their common mission.

There are already a significant number of Peruvian producers and traders exporting products that are Fair Trade Certified through the FLO system including bananas, cane sugar, cocoa, coffee, fresh fruits (coconuts, lemons, mangos, oranges, papayas, passion fruit, pineapples), fruit juices, gold, nuts and oilseeds (Brazil nuts), and seed cotton.[66]

Although the labelling and logo use requirements through FTUSA will soon change due to its resignation from FLO, the current Fair Trade Certified Label and Language Use Guide[67] is available at: http://transfairusa.org/sites/default/files/uploads/Label%20Use%20Guide.pdf

There is an FLO Producer Network with an office in Lima, Peru: 'Coordinadora Latinoamericana y del Caribe de Pequeños Productores de Comercio Justo' (CLAC), Jr. Ramón Dagnino Nº 369, Jesús María (Lima 11), Lima, Perú; Tel: +51 424 3753; Web: http://clac-comerciojusto.org.

[66] FairTrade International, Product Standards for small producers. Available at: http://www.fairtrade.net/product_standards_smallproducers.0.html.

[67] Fair Trade USA, TransFair USA Label and Language Use Guide (February 2009). Available at: http://transfairusa.org/sites/default/files/uploads/Label%20Use%20Guide.pdf.

Figure 17 Fair Trade USA Label and Language Use Guide

Figure 18 Cosmetic product label with Organic and Fair Trade certified cocoa butter from Peru

4.3.2. FWF FairWild labelling

The FairWild Foundation (FWF) promotes sustainable, fair and value-added management and supply chain development of wild-collected natural ingredients and products thereof**.** The FairWild Standard assesses the harvest and trade of wild plants against various ecological, social and economic requirements. Use of the FairWild Standard helps support efforts to ensure plants are managed, harvested and traded in a way that maintains populations in the wild and benefits rural producers. FairWild

Certification means that buyers know they are supporting fair trading – the products are legally and sustainably sourced, and the benefits are felt by all those involved right down to the local communities harvesting the wild plants.

Branding guidelines for use of the FairWild trademark and trademark utilization agreements for labelling are available in English and German languages at: http://www.fairwild.org/labelling-documents

The FairWild Standard is available in many languages including Armenian, Azeri, Bosnian, Chinese, English, French, Georgian, German, Japanese, Polish, Portuguese, Russian, and Spanish.[68]

4.3.3. IMO Fair for Life labelling

'Fair for Life' is a brand neutral third party certification programme for social accountability and fair trade in agricultural, manufacturing and trading operations. The programme complements existing fair trade certification systems. The 'Fair for Life' - Social & FairTrade Certification Programme[69] offers operators of socially responsible projects a solution for objective inspection and certification by a highly qualified external verifier. It combines strict social and fair trade standards with adaptability to local conditions.

The 'Fair for Life' - Social & FairTrade certified by IMO certification seal guarantees that the production complies at all stages with the social responsibility as well as fairtrade criteria of the 'Fair for Life' Social & FairTrade Certification Programme.

The 'For Life' - Social Responsibility certified by IMO seal guarantees that production complies at all stages with the social responsibility criteria of the fair for life Social & FairTrade Certification Programme.

The seal is only awarded to products which fulfil the programme´s control requirements along the entire production and trade chain. Depending on the operation type and actual activity different control requirements apply.

The Fair for Life Social & FairTrade Programme Standard is available to download at:
http://www.fairforlife.net/logicio/pmws/indexDOM.php?client_id=fairforlife&page_id=download&lang_iso639=en

The labelling and control criteria for products labelled as Fair For Life Fairtrade Certified is available at:
http://www.fairforlife.net/logicio/client/fairforlife/file/FFL_2011__1_Labelling_and_Control.pdf

For Processors, Packers and Wholesalers a specific labelling guide is available at:
http://www.fairforlife.net/logicio/client/fairforlife/file/Labelling_Guide_Fairforlife_Handlers_2010-001.pdf

[68] FairWild Foundation, FairWild Standard Documents. Available at: http://www.fairwild.org/documents

[69] Bio-Foundation Switzerland, Fair for Life Social & Fairtrade Certification Programme Version 2011. Available at: http://www.fairforlife.net/logicio/client/fairforlife/file/FFL_2011__0_Programme.pdf.

Figure 19 Bar of soap with Fair for Life certified label

4.3.4. Rainforest Alliance labelling

According to the Rainforest Alliance: 'The Rainforest Alliance Certified™ seal assures consumers that the product they are purchasing has been grown and harvested using environmentally and socially responsible practices. Farms and forestlands that meet the rigorous, third-party standards of the Sustainable Agriculture Network or the Forest Stewardship Council are awarded the Rainforest Alliance Certified™ seal.' Businesses that source products grown on certified farms and farms that meet the Sustainable Agriculture Network (SAN) Standard may apply to use the Rainforest Alliance Certified™ seal on their finished product labels.

Product labelling guidelines for use of the Rainforest Alliance Certified™ seal are available at: http://www.rainforest-alliance.org/sites/default/files/site-documents/marketing/seal-guidelines-agriculture.pdf.

Figure 20 Rainforest Alliance Certified™ use of seal guidelines

Street address
International Trade Centre
54-56 Rue de Montbrillant
1202 Geneva, Switzerland

P: +41 22 730 0111
F: +41 22 733 4439
E: itcreg@intracen.org
www.intracen.org

Postal address
International Trade Centre
Palais des Nations
1211 Geneva 10, Switzerland