Almost all food labeling regulations are enforced by the US Food and Drug Administration (FDA). One exception is the Country of Origin Marking Requirement that is enforced by the U.S. Customs Service, but even that regulation can be enforced by the FDA.

The major focus on food labeling in the United States today is on nutrition. Olive oil companies must comply with regulations on:
- Nutritional labeling
- Net weight declarations
- Metric declarations
- Country of origin marking requirements
- Labeling in two languages
- Product descriptions

### Nutritional Labeling Regulations

Nutritional Labeling Regulations became effective August 6, 1994.

### Nutrient Declarations

21 CFR Section 101.9 sets out and explains all the nutrients that need to be declared on the food label, as well as those that may be declared. There are a few exemptions for products that have no significant food value, i.e. less than 5 calories per serving and for products in very small containers. For the latter, there must be a telephone number or an address on the label that the consumer can contact for nutritional information.

FDA specified the following nutrients must be declared on a label: calories, total fat, saturated fat, trans fat cholesterol, sodium, total carbohydrate, dietary fiber, sugars, protein, vitamin A, vitamin C, calcium and iron. However when a product, such as olive oil, contains insignificant amounts* of seven or more of these nutrients, only the following nutrients must be declared: total calories – calories from total fat – saturated fat – trans fat – total carbohydrate – protein – sodium, and nutrients present in more than insignificant amounts.

*An “insignificant amount” is defined as an amount that allows a declaration of zero in nutritional labeling, except that for total carbohydrates, dietary fiber, and protein, it shall be an amount that allows a declaration of “less than one gram.”

Additionally, the serving size and the number of servings per container must be declared. The serving size is declared in a common household measure and in grams or milliliters (if product is fluid). For olive oil the serving size would be 1 tablespoon (15 mL).

When a company decides to add a declaration to the simplified format, such as “monounsaturated fat”, then the statement “Not a significant source of…” must be added, as shown on the next page.

Calories must be expressed to the nearest 5-calorie increment up to and including 50 calories, and in 10-calorie increments above 50 calories. Amounts less than 5 calories may be expressed as zero (0).

In determining Caloric Content, one may calculate calories by using specific Atwater factors (i.e., the Atwater method) given in Table 13 “Energy Value of Foods-Basis and Derivation,” by A.L. Merrill and B.K. Watt, USDA Handbook No. 74. This book is available from: Division of Nutrition, Center for Food Safety & Applied Nutrition (HFF-260), FDA, 5100 Paint Branch Parkway, College Park, MD 20740-3835.

Calories from Fat must be expressed to the nearest 5-calorie increment up to and including 50 calories, and in 10-calorie increments above 50 calories. Amounts less than 5 calories may be expressed as zero (0).

Calories from saturated fat are not required. This declaration is voluntary.

Total Fat (total lipid fatty acids expressed as triglycerides) must be declared in grams to the nearest ½ gram increments below 5 grams and to the nearest gram increment above 5 grams. Under ½ gram may be expressed as zero (0).

Saturated fat (sum of all fatty acids containing no double bonds) may be declared as 0 if there is less than ½ gram per serving.

Trans Fatty Acid: As of Jan. 1, 2006, all food product labels will be required to declare the amount of trans fatty acids in the product. Please note that FDA has not yet set a daily recommended value for trans fatty acids.
Polyunsaturated fat is a voluntary declaration unless there is a declaration for monounsaturated fat, or a statement is made about fatty acids or cholesterol on the label.

Monounsaturated fat is also a voluntary declaration, unless there is a declaration of polyunsaturated fat, or a statement is made about fatty acids or cholesterol on the label.

Cholesterol need not be declared if there is less than 2 milligrams per serving. If it is not declared, a footnote is required stating: “Not a significant source of cholesterol”. For 2-5 milligrams, the declaration must be: “less than 5 milligrams.” When more than 5 milligrams, the declaration must be to the nearest 5-milligram increment. Alternatively, if the cholesterol is less than 2 milligrams per serving, it can be declared as zero.

Sodium must be declared. Under 5 milligrams per serving, the declaration is zero. Between 5 and 140 milligrams the declaration is the nearest 5 gram increment. Over 140 milligrams the declaration is the nearest 10 gram increment.

Carbohydrate or Total Carbohydrate must be declared to the nearest gram. Under ½ gram, the declaration is zero.

Protein must be declared to the nearest gram. Under ½ gram, the declaration is zero. Under 1 gram may be declared as “Less than 1 gram.”

Footnotes: Most olive oil companies include information on their labels on polyunsaturated fat, monounsaturated fat, and cholesterol. Therefore, they have to include the following footnotes on their label:

“Not a significant source of dietary fiber, sugars, vitamin A, vitamin C, calcium, and iron.”

“%Percent Daily Values are based on a 2,000 calorie diet.”

Format for Nutritional Label

There are two illustrations below indicating the format for the nutritional label for olive oil.

In the first illustration, the percentage of daily value is based on the actual amount of each nutrient before rounding. The percentage of daily value for total fat is 21%. This percentage is based on the actual fat in a tablespoon, namely, 13.6 grams.

In the second illustration the percentage of daily value for total fat is 22% which is based on the amount declared on the label, i.e. 14 grams.

FDA states that “The percent shall be calculated by dividing either the amount declared on the label for each nutrient or the actual amount of each nutrient (i.e., before rounding) by the Daily Recommended Value (DRV) for the nutrient.”

The Daily Recommended Value for total fat is 65 grams, and for saturated fat, it is 20 grams. When one di-

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Illustration 1.

<table>
<thead>
<tr>
<th>Nutrition Facts</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serving Size 1 Tbsp (15mL)</td>
</tr>
<tr>
<td>Servings Per Container</td>
</tr>
<tr>
<td>Amount Per Serving</td>
</tr>
<tr>
<td>Calories 120</td>
</tr>
<tr>
<td>% Daily Value</td>
</tr>
<tr>
<td>Total Fat</td>
</tr>
<tr>
<td>Saturated Fat</td>
</tr>
<tr>
<td>Trans Fat</td>
</tr>
<tr>
<td>Polyunsaturated Fat</td>
</tr>
<tr>
<td>Monounsaturated Fat</td>
</tr>
<tr>
<td>Cholesterol</td>
</tr>
<tr>
<td>Sodium</td>
</tr>
<tr>
<td>Total Carbohydrate</td>
</tr>
<tr>
<td>Protein</td>
</tr>
</tbody>
</table>

Not a significant source of dietary fiber, sugars, vitamin A, vitamin C, calcium and iron.

*Percent Daily Values are based on a 2,000 calorie diet.

Illustration 2.

<table>
<thead>
<tr>
<th>Nutrition Facts</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serving Size 1 Tbsp (15mL)</td>
</tr>
<tr>
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<tr>
<td>Amount Per Serving</td>
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<tr>
<td>Calories 120</td>
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<tr>
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<tr>
<td>Total Fat</td>
</tr>
<tr>
<td>Saturated Fat</td>
</tr>
<tr>
<td>Trans Fat</td>
</tr>
<tr>
<td>Polyunsaturated Fat</td>
</tr>
<tr>
<td>Monounsaturated Fat</td>
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</tr>
<tr>
<td>Total Carbohydrate</td>
</tr>
<tr>
<td>Protein</td>
</tr>
</tbody>
</table>

Not a significant source of dietary fiber, sugars, vitamin A, vitamin C, calcium and iron.

*Percent Daily Values are based on a 2,000 calorie diet.
The rules permit one to exceed the fat content declared by 20% because of normal product variation. A 9% declaration would cover all oils with a saturated fat content up to 2.15 grams.

A 10% declaration would cover all oils with a saturated fat content up to 2.4 grams. In choosing one’s label, one should know how much variation to expect in the product by conducting laboratory tests.

While the rule clearly states a company can calculate the percentage Daily Value on the basis of actual amounts of the nutrients or on the rounded declarations, the preamble to the rule directs manufacturers to maintain the greatest consistency in their label declarations, e.g. between grams declared and percentage of daily value declared. As the Daily Recommended Value of total fat (65 grams) and saturated fat (20 grams) are not declared on the Olive Oil Labels below it appears this consistency aspect is not relevant.

Serving Size Declaration/Servings Per Container

Serving Size for olive oil is 1 tablespoon (15 ml). One tablespoon is actually 14.786 ml. Either 15 ml or 14.786 ml can be used in calculating the number of servings in a container, and the servings are rounded to the nearest whole number.

In using the actual value of 14.786 ml to a tablespoon, the number of servings per container will be as follows: 1 liter – 68, 500 ml – 34, 250 ml – 17, in three liters – 203; and in a gallon – 256 servings. If one calculates serving sizes on the basis of 15 ml per tablespoon, there will be one or more fewer servings per container.

Nutrient Content Claims

21 CFR, Section 101.54 sets limitations on the use of terms that describe the nutrient value of a product, terms like: “high”, “rich in”, “excellent source of”, etc.

If there is no Recommended Daily Intake (RDI) or Daily Recommended Value (DRV) for a nutrient, then one is not allowed to use a descriptive term like “high in” to describe the nutrient on the label. For example, there is no RDI for monounsaturated fat. Therefore, one cannot describe olive oil as being “high in”, or a “good source of” monounsaturated fat.

Light or Lite

21 CFR, Section 101.56 deals with the nutrient content claims for “light” or “lite”.

“Light” or “lite” may be used on an olive oil label provided:

it describes some physical or organoleptic attribute of the food such as texture or color and it is stated in such a way (e.g. “light in color” or “light in texture”) that it clearly conveys the nature of the product; and

the attribute (e.g. color or texture) is in the same style, color and at least one-half the type size as the word “light” and in immediate proximity thereto.

The manufacturer must be able to demonstrate that the word “light” has been associated, through common use, with a particular food to reflect a physical or organoleptic attribute (e.g. light brown sugar, light corn syrup, or light molasses) to the point where it has become part of the statement of identity in order for the term “light” not to be considered a nutrient content claim subject to the requirements for such claims.

Sodium Content Claims

Olive Oil can make a “Sodium Free” claim. “Sodium Free” means that the food contains less than 5 milligrams of sodium per serving. A disclosure statement must accompany the claim: “See nutrition information for fat content.”

If the food is naturally sodium free, this must be so declared, e.g. “A sodium free food.”

Salt Free, No Salt Added

Olive Oil can make a “Salt Free” claim. Salt is not sodium. It is sodium chloride. A “salt free” claim can be made only when the food is also a sodium free food.

Nutrient Content Claims for Fat, Fatty Acid, and Cholesterol Content of Foods

21 CFR, Section 101.62 sets out the regulations on nutrient content claims for fat, fatty acid and the cholesterol content of foods. Olive oil cannot make any claims relative to fat content. It cannot claim to be “low in saturated fat” because the regulations state that for a food to make this claim it must have less than 1 gram of saturated fat per serving and the saturated fat only accounts for 15% or less of the calories in the food.

Olive oil cannot claim to be “high in monounsaturated fat”, because nutrient content claims can only be made if there is a recommended daily value for monounsaturated fat.

FDA seems to limit nutrient content claims on fatty acids to such terms as “saturated fat free”, “low in saturated fat”, and similar expressions. Although it permits truthful and non misleading graphic devices to amplify or explain nutrition information, it states that the supplementary information must be consistent with the requirements for nutrient content claims.

Cholesterol Content Claims

Olive oil can make “Cholesterol Free” and “No Cholesterol” claims provided that the food contains 2 grams or less of saturated fat and the label discloses the level of

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total fat in a serving in immediate proximity to the claim in type size no less than \( \frac{1}{2} \) the size of type in the claim. The disclosure statement is not necessary if the cholesterol free claim is only made on the information panel containing the Nutrition Facts.

An example of a cholesterol free claim on the principal display panel would be:

A Cholesterol Free Food
Contains 14 g of fat per serving
See nutrition information for fat content.

Implied Nutrient Content Claims

21 CFR, Section 101.65 differentiates between implied nutrient claims and claims that do not imply the presence of nutrients. This Section of the rules applies the same guidelines for implied nutrient claims as pertain to transparent nutrient content claims.

NAOOA is unaware of any “implied nutrient content claims” being made by any olive oil company.

Appropriate Claims

For non nutrient content claims, FDA only requires that they be accurate. “100% Pure” and “All Natural” are not nutrient content claims. As long as they are accurate they are permitted. However, members of The North American Olive Oil Association agreed not to use the word “Pure” or “100% Pure” as part of the statement of identity of the product, though it was agreed those words could be used in secondary label locations.

FDA has decided to maintain its current policy not to restrict the use of the term “natural” except for added color, synthetic substances, and flavors as provided in 21 CFR §101.22. Additionally, the agency will maintain its policy regarding the use of “natural” as meaning that nothing artificial or synthetic (including all color additives regardless of source) has been included in, or has been added to, a food that would not normally be expected to be in the food.

Thus, olive oil companies in the U.S. may use the term “Natural” on their olive oil labels. The IOOC says “Natural” may be used, but may not be associated with the grade designation.

The phrase “cold-pressed” may be used on a label solely for extra virgin olive oil and virgin olive oil grades when it can be proved that the oil has been obtained by cold pressing (the IOOC recommends a maximum temperature of 35 °C of the olive paste during mixing). Article 5 of the EC regulation on olive oil marketing standards (EC no. 1019/2002 of 13 June 2002) refers to the possibility of stating optional labeling indications that comply with the following requirements:

the indication “first cold pressing” may appear only for virgin or extra virgin olive oils obtained at a temperature below 27 °C from a first mechanical pressing of the olive paste by a traditional extraction system using hydraulic presses;

the indication “cold extraction” may appear only for virgin or extra virgin olive oils obtained at a temperature below 27 °C by percolation or centrifugation of the olive paste.

Article 7 of the same Regulation stipulates that the manufacturer, packer or seller appearing on the labeling has to supply documentation in support of the indications, based on one or more of the following elements:

factual elements or scientifically established facts;
results of analyses or automatic recordings taken on representative samples;
administrative or accounting information kept in accordance with Community and/or national rules.

Health Claims

FDA will promulgate regulations authorizing a health claim or qualified health claim only when it determines that there is or appears to be significant scientific agreement among experts qualified by scientific training and experience to evaluate such claims, and that the claim is supported by the totality of publicly available scientific evidence.

Health claims typically are not allowed on any product that contains more than 13 grams of fat per serving. Thus no health claim, would normally be allowed on an olive oil product. However, in 2004, FDA approved a health claim petition filed by the North American Olive Oil Association. The allowable wording is as follows:

“Limited and not conclusive scientific evidence suggests that eating about 2 tablespoons (23 grams) of olive oil daily may reduce the risk of coronary heart disease due to the monounsaturated fat in olive oil. To achieve this possible benefit, olive oil is to replace a similar amount of saturated fat and not increase the total number of calories you eat in a day.”

Olive-oil containing products would have to add the following sentence: “One serving of this product contains (x) grams of olive oil.”

The wording must be exactly as stated above. The claim must be in a type size no larger than two times the statement of identity and “shall not be unduly prominent in
type style compared to the statement of identity.” The disclaimer “See nutrition information for saturated fat content” must be placed immediately adjacent to the claim with no intervening material and in the same contrast as the claim itself.

Net Weight Declaration

The net weight or net contents declaration must be in the bottom 30% of the principal display panel. There are specific type size requirements. All information appearing on the principal display panel must be clear and conspicuous. In no case may the letters or numbers be less than one-sixteenth of an inch. Exemptions to this type size requirement are not relevant to olive oil containers or labels.

Under proposed regulations, olive oil labels may use the words “net” or “net contents” before the weight declaration or they may simply use the weight declaration. Fluid ounce declarations are used for sizes under one pint, but are optional for sizes one pint and over. The largest unit of measure must be stated in metric and English measure. Either can be first. For example, one can state: Net 1 pt 0.9 fl oz (500 mL), or it can be reversed and read: 500 mL (1 pt 0.9 fl oz). It appears that the following declarations would be acceptable:

Net 1 gallon (3.785 L) or 3.785 L (1 gallon)
Net 3 qt 5.4 fl oz (3 L) or 3 L (3 qt 5.4 fl oz)
Net 1 qt 1.8 fl oz (1 L) or 1 L (1 qt 1.8 fl oz)
Net 1 pt 0.9 fl oz (500 mL) or 500 mL (1 pt 0.9 fl oz)

Note that the word “Net” is not required but can be used.

Country of Origin Marking Requirements

Country of Origin Marking Requirements are set out in 19 CFR §134.11. Unless excepted by law, section 304, Tariff Act of 1930 as amended (19 U.S.C. 1304), requires that every article of foreign origin (or its container) imported into the United States shall be marked in a conspicuous place as legibly, indelibly, and permanently as the nature of the article (or container) will permit, with the English name of the country of origin. 19CFR § 134.35 exempts from the country of origin marking requirements those products that are substantially changed by manufacture in the United States. They are substantially changed in another country then that country is the country of origin. 19CFR§134.46 specifies that when a geographic representation appears on a label that would mislead the ultimate purchaser as to the actual country of origin then there must appear, in close proximity, the actual country(s) of origin preceded by “Made in”, “Produced in”, or “words of similar meaning.” It is more prudent not to use “words of similar meaning” because to do so raises a question of interpretation.

A country of origin declaration is required on all imports of olive oil, including those in bulk containers, and the proper declaration is “Made in” or “Product of”.

When an extra virgin olive oil imported from one country contains extra virgin oils from several countries, then each of those countries must be listed on the label in the country of origin declaration. It is also permissible to list the country from which the product was imported, but not without listing the country or countries where the extra virgin olive oils were produced. A country of origin declaration could appear as follows:

Imported from __________
Contains extra virgin olive oils from ____________, ____________, and ____________; or

Packed in __________
Product of ____________, ____________, ____________, and ____________

The origins of extra virgin olive oils that are blended in the United States to produce a new extra virgin olive oil must also be declared on the label.

The importer of bulk olive oil must also certify to U.S. Customs that if it repacks the oil, it will put the country of origin on the label, and if it sells the oil to a packer, it will inform the packer of its obligation to put the country of origin on the label.

The combining of a refined olive oil with extra virgin olive oil to produce “olive oil” does not constitute a substantial change. Therefore, as stated in the above section, each country would need to be listed on the label of such product.

The Customs regulations on country of origin do not control advertising messages. Advertising is subject to the jurisdiction of the Federal Trade Commission. It has not issued any rules restricting references to foreign countries in advertising. Statements, however, must be truthful.

Labeling in Two Languages

When labels contain words or statements in a language other than English, FDA regulations specify that all required information on the label must be in both languages. 21 CFR §101.15 (c) (2) reads in part: “If the label contains any representation in a foreign language, all words, statements, and other information required by or under authority of the Act [FD&C Act] to appear on the label shall appear thereon in the foreign language...”

On the Nutritional Label both languages can be used in the one “Nutritional Facts” box. It is a little crowded but the regulations permit it.

This Guide is an overview of labeling requirements. Before labels are printed, they should be reviewed by a competent expert.
Lot Codes
All olive oil products should be marked with a lot code. If the government determines that there is a violation of its regulations that requires product to be withdrawn from the marketplace, the only way to limit the extent of the recall is by isolating it to a particular lot or lots. If there are no lot codes, there is no way to limit the recall.

The “Agreement to Monitor Olive Oils and Olive Pomace Oils Sold on the U.S. Market” also requires the member companies of the Signatory Associations, that is, essentially all packers of olive oil, to use a lot code on each container of olive oil or olive pomace oil.

Product Descriptions
Product descriptions are regulated by Section 403 (a) (1) of the FDA&C Act which states that: “A food shall be deemed to be misbranded if its labeling is false or misleading in any particular...” Not only the product description must be accurate but all the information presented on any part of the label must be accurate and consistent with the product description.

Contradictory information on a label makes it misleading. If the principal display panel describes a product as Pure Olive Oil, and the information panel describes it as “Natural Product, Being Extra Virgin Olive Oil...” it is contradictory and misleading.

Use of the product descriptions “Extra Fine Olive Oil” and “Extra Fine Quality Olive Oil” are misleading. It is conceivable that these terms could be used on a label as advertising superlatives as long as they are not part of the product’s name, but when used as product descriptions they do not conform with the international standards for olive oil.

Use of the product description: “Olive Pomace Oil Containing Extra Virgin Olive Oil” is confusing and misleading. It conveys the false notion that the consumer is getting a product that is better than “Olive Pomace Oil”. By definition, Olive Pomace Oil contains virgin olive oil, be it extra virgin or not, and calling special attention to the presence of extra virgin olive oil is misleading.

Use of the product description “Pure Olive Oil with Extra Virgin Olive Oil” is likewise misleading. However, if one is stating that the “Pure Olive Oil” is enriched with “Extra Virgin Olive Oil”, as opposed to simply “Virgin Olive Oil” then the extra virgin olive oil may be considered the characterizing ingredient. In that case, the percentage of extra virgin olive oil must be declared on the label.

Pure Olive Oil, by definition, is a blend of refined olive oil and virgin olive oil. It cannot contain rectified oil, that is, refined olive pomace oil. If a company declares on the principal display panel that its product is Pure Olive Oil, and then on the information panel describes the ingredients as pure and rectified oil, the product is misbranded.

All the words in the product description “Olive Pomace Oil” should be of equal size. The word “Pomace” should not be smaller or less conspicuous.

Designating Extra Virgin Olive Oil as: “Highest Grade”; Virgin Olive Oil as: “Medium Grade”; and Pure Olive Oil as “Lowest Grade, chemically washed, Second Press” is confusing and misleading to the consumer. There is no basis in any standard for these classifications. It is also inaccurate to describe Pure Olive Oil as “chemically washed” because it conveys a false image about the safety of the product. To describe Pure Olive Oil as Second Press is inaccurate as well.

A claim that olive oil will not burn at high frying temperatures is misleading and dangerous. It subjects the packer to greater liability for law suits stemming from fire damage and physical harm that could occur from a consumer overheating olive oil.

Name and Place of Business
The name and place of business of the manufacturer, packer, or distributor of olive oil must be conspicuously shown on the label. It may be placed on the principal display panel or on the information panel. Street address, city, state and zip code are required. However, the street address may be omitted if it is shown in a current city directory or telephone directory. The address can be in the U.S. or abroad. The zip code is not needed for an address abroad.

Ingredient Statement
No ingredient statement is required on an olive oil because the product has no ingredient other than olive oil.

Organic Food Labeling
Imported olive oil may be labeled as organic if it complies with U.S. regulations. Labeling depends on whether an olive oil is 100% organic; 70% organic; or less than 70% organic.

The regulations establish standards for the production and handling of organically produced foods. They list approved substances and prohibited substances. They establish the requirements for accreditation.

Certifying agents operating in foreign countries may apply to the U.S. Department of Agriculture for accreditation. A foreign government can also request that the USDA recognize its authority to assess and accredit certifying agents as meeting the equivalent requirements of the U.S. National Organic Program.

Organic regulations are quite detailed. Companies should obtain legal counsel to ensure that all requirements are met. Civil penalties of $10,000 can be assessed for failure to comply with all the regulations on those who knowingly sell or label as organic a product that is not produced and handled in accordance with the regulations.

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**Principal Display Panel**

**Any Brand**

**Olive Oil**

A Cholesterol and Sodium Free Food

Contains 14 g of fat per serving

See nutritional information for fat content.

1 QT. 1.8 FL. OZ. (1 LITER)

**Bold Type** – size of the type to be reasonably related to the most prominent printed material on the label. It shall be parallel to the base of the label.

If this claim is made on the label, the disclosure statement that follows must be used:

Country of Origin, *the country from which the oil is imported or in which it is packed*, may appear on the principal display panel.

Net Contents must be easily readable in bold face print or in a type that is in distinct contrast to the background. It must appear in the bottom 30% of label and be parallel to the bottom of the label.

Type size requirements differ depending on the size of the label:

On labels of 5 square inches or less the type is to be at least one-sixteenth inch; over 5 square inches and under 25 square inches – not less than one-eight inch type; over 25 but under 100 square inches – not less than three-eighth inch type; over 100 square inches but under 400 square inches – not less than one-quarter inch type.

*If a foreign language is used on any label, all the required information must be in both English and the foreign language.*
This Guide is an overview of labeling requirements. Before labels are printed, they should be reviewed by a competent expert.