Articles & Commentaries

p-Watch — USA

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Exporting food, beverages, or dietary supplements to the USA? Pay close attention to product labeling requirements

The potential pitfalls for producers wishing to market their food and beverage products in the USA are many. Formula developers must ensure that each ingredient is generally recognized as safe. Manufacturers and processors must comply with current Good Manufacturing Practices. Relationships with importers and distributors must be fostered to ensure reliable trading. These challenges are well known, however, and successful exporters are therefore prepared to meet them. A more difficult challenge is confirming that products comply with US regulations before exportation. An array of federal agencies is responsible for ensuring the safety of the US food supply, including both domestically produced and imported food and beverages. Together, the Food and Drug Administration (FDA), which is part of the Department of Health and Human Services; Food Safety and Inspection Service, part of the US Department of Agriculture (USDA); National Marine Fisheries Service, part of the Department of Commerce; and Environmental Protection Agency regulate these products.

Most exporters will primarily contend with the FDA, whose many regulations set forth requirements from the minimum type point size for specific statements to the maximum tolerance for limited ingredients. The Food, Drug, and Cosmetic Act authorizes the FDA to take action in response to food that is "misbranded," or not appropriately labeled. Under this provision, the FDA has developed hundreds of pages of regulations defining what it means to be misbranded. While many of these regulations are codified in the Code of Federal Regulations, still more requirements are set forth in the Federal Register, the official daily publication for rules, proposed rules, and notices of federal agencies and organizations. Individual agencies also issue guidance documents, which provide insight on how they intend to interpret the often vague, confusing regulations.

Faced with such a huge body of requirements, it is understandable that mistakes are frequently made in labeling food products. The Economic Research Service (ERS), a research and analysis division of the USDA, stated that 33% of the violations reported from 1998 to 2004 were due to misbranding (ERS Report Summary, ERS, September 2008). While food and beverage products are

frequently, even commonly, mislabeled, this does not mean that the FDA takes the offense lightly. Misbranding violations can cause financial, public, and private loss; fines and other expenses are compounded by the public reprimand, as violations are announced in the FDA's public database, and the private consequences, as violators can be held personally responsible and may even face jail time.

Some labeling violations are purposeful; the labeling is designed to mislead consumers in an effort to make the product more attractive. Examples of this kind include food labels that state a product will cure cancer or declare the net weight as 500 g, when actually the package contains far less. Frequently, though, the violations are unintentional, caused when an exporter has not invested the time or resources necessary to ensure that the labeling is compliant. Unfortunately for well-intentioned exporters, the FDA will not excuse a labeling violation simply because the exporter did not know any better.

The FDA does not offer any review or preapproval of labeling for food and beverage products. As a result, it is the burden of exporters to confirm that their product labeling is compliant. Furthermore, regulations are frequently changed. If a product is not in compliance when a new rule goes into effect, it will be deemed misbranded. Again, it is the responsibility of the exporter to make sure that labeling remains current with the requirements.

Some of the most common mistakes occur in formatting, stating the net quantity of contents, declaring the presence of major allergens, and using languages other than English. The FDA has extensive regulations regarding the various type point sizes of almost every statement that must appear on labeling. Some of these requirements are based on the size and shape of the container, so copying a competitor's label, even if correct for the competitor, may result in a label that does not meet type size requirements. The FDA even goes so far as to set regulations regarding the weight, or thickness, of lines in the Nutrition Facts chart. While these issues may seem minor, the FDA regards consistency in labeling as a way to allow customers to understand nutritional information easily and therefore takes this matter very seriously.

Regulations pertaining to the declaration of the net quantity of contents are extensive and concern even minute details. Minimum size requirements must be met, the position of the statement on the label is regulated, and even the required space that must be kept blank around the net quantity is defined. The FDA has specific requirements for how the net quantity may be stated, and, unlike most other countries, a metric statement alone is not sufficient. As the net quantity statement is one of only two statements to appear on the front panel, also known as the principal display panel, of labeling, it is subject to close scrutiny.

Packaged foods and beverages that contain a major food allergen must declare its presence on the product labeling. Major food allergens include ingredients from milk, eggs, fish, crustacean shellfish, tree nuts, wheat, peanuts, and soybeans. These major food allergens account for 90% of all food allergies.

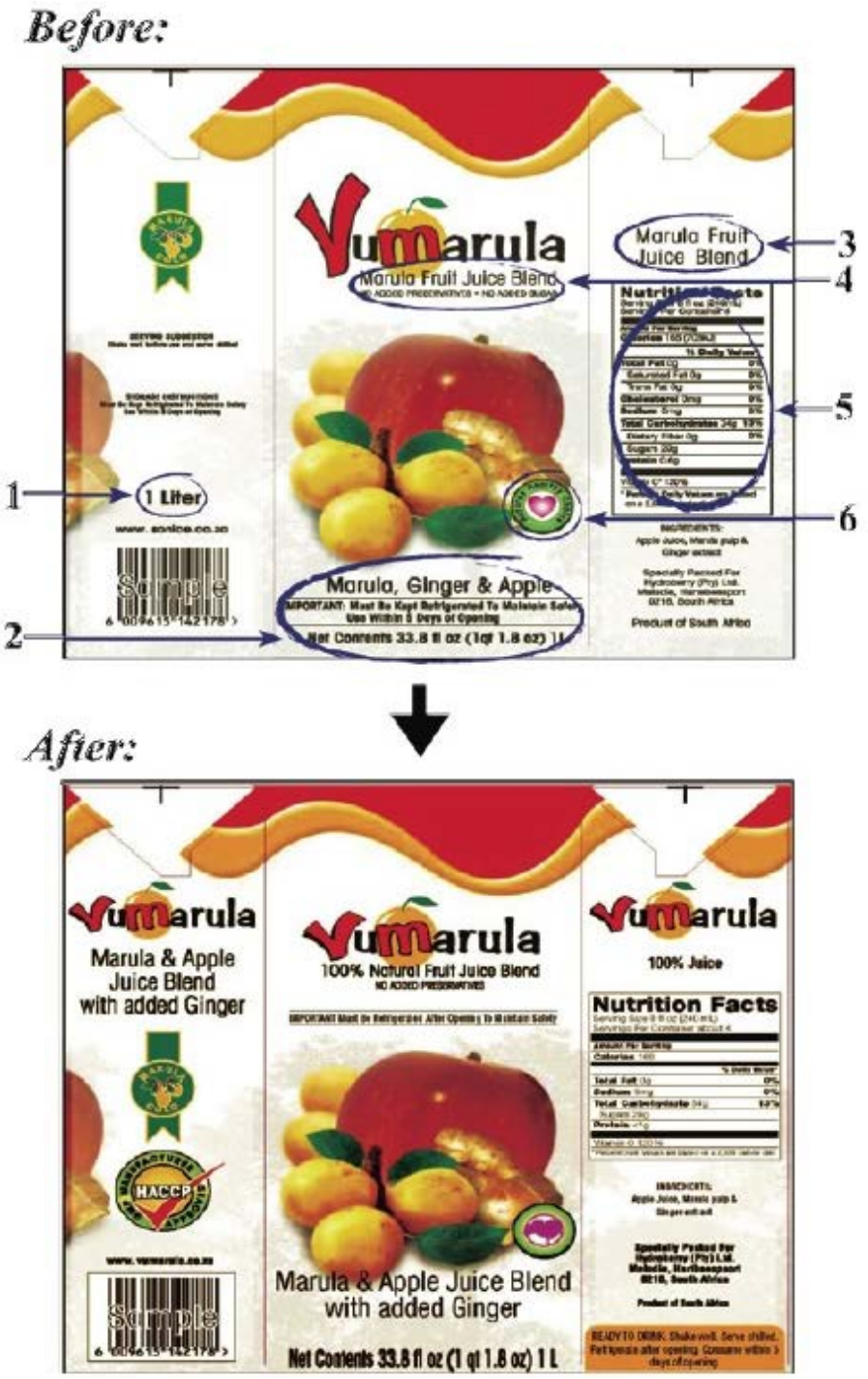

Figure. Noncompliant (upper panel) and compliant (lower panel) labeling under US FDA regulations

As such, the FDA has required that they be declared since 1 January 2006, as a result of the Food Allergen Labeling and Consumer Protection Act of 2004.

When any language other than English is used, a separate set of regulations comes into effect. Food and beverages on the US retail market must include an English version of all required statements. This often comes as a surprise to those who intend to market their products to specialized markets, such as grocery chains that serve primarily Spanish-speaking consumers. Further, the FDA requires that if any declaration is made in a language other than English, all other required declarations must be made in English. This may be a concern for those who market products in packages too small for all information to be repeated.

While the regulations for labeling are extensive and can be confusing, the requirements for a product to qualify for an exemption from a regulation are even more difficult to determine. The following are a few examples of such exemptions:

- Under certain circumstances, the size requirements for declarations may be relaxed or waived altogether.
- The Nutrition Facts chart may be presented in a special format, such as tabular format, or replaced with a toll-free phone number through which consumers can obtain nutrition information.
- Certain products, such as fresh fruit and vegetables, may be exempt from allergen labeling if they meet other requirements.
- When only a product's brand name is in a non-English language, the product may not be required to repeat the required information in the non-English language.

Special exemptions may apply in these and other circumstances, but determining whether a product qualifies for an exemption takes thorough research and a full understanding of applicable regulations.

Mistakes in labeling can spell disaster for an exporter. In authorizing the FDA to take action in response to misbranded food and beverage products, the Food, Drug, and Cosmetic Act authorizes the FDA to detain the product. While in detention, fees for demurrage, analysis, and fines quickly add up. When a product is detained, the FDA district office will issue a Notice of FDA Action specifying the nature of the violation to the owner or consignee, who is entitled to an informal hearing to provide testimony regarding the admissibility of the product. If the owner fails to submit convincing evidence that the product is in compliance or an acceptable plan to bring it into compliance, the FDA will issue another Notice of FDA Action refusing admission to the product. The product then must be exported or destroyed within 90 days. To the costs already incurred, new costs for return freight or loss of product due to destruction are now added.

Even if a violation can be corrected by relabeling, the cost of doing so can be staggering and the time needed often means late or cancelled orders. Forward-thinking exporters will invest the time, money, and energy to confirm that their product labeling complies with applicable requirements before shipping to the USA. Compliant, polished, professional labeling not only aids in successfully exporting products to the USA, but also meets US consumers' expectations for the appearance and content of food and beverage labels. By designing labeling in compliance with regulations, exporters can make their products more likely to receive approval not only from US inspectors and officials but also from US shoppers.

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