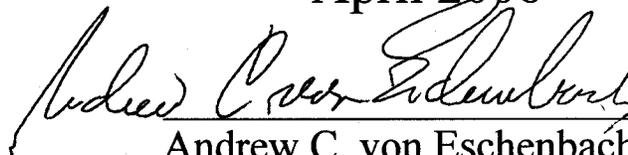


Report to Congress on
Compliance with Food Label Regulations under the
Food and Drug Administration's Purview

Senate Report 109-92

April 2006

 Date APR 19 2006

Andrew C. von Eschenbach, M.D.
Acting Commissioner of Food and Drugs

Report Language – Senate Report 109 - 92

“Given the important nature of the information provided on the food label and in light of the New Dietary Guidelines for Americans 2005, the Committee is interested in ensuring that food labels can be easily understood and reflect information that is factual. The Committee is concerned that consumers may be faced with misleading information on caloric and nutrient content and health-related claims, and believes it is vital that consumers are able to trust the accuracy of food labels. Therefore, the Committee directs the FDA to continue to apply resources to efforts that ensure the accuracy of the Nutrition Facts panel and address potentially misleading health and nutrition statements on the food label and to report to the Committee by February 1, 2006, on the types of labeling violations discovered and actions taken in response to such violations.”

Introduction

This report addresses the Food and Drug Administration’s (FDA) accomplishments under the Food Labeling Compliance Program as well as the enforcement activities that were conducted between October 1, 2004, and December 6, 2005, relating to the labeling of conventional food products.

Background – FDA’s Legal Basis for Regulating Food Labels

The Federal Food, Drug, and Cosmetic Act (the Act), as amended by the Nutrition Labeling and Education Act of 1990 (NLEA) (Public Law 101-535), together with FDA’s implementing regulations, established mandatory nutrition labeling for packaged foods to enable consumers to make informed and healthier food product choices in the context of their daily diet. The cornerstone of the NLEA is the requirement that packaged foods bear a Nutrition Facts Panel (NFP), which provides product-specific information on serving size, calories, and nutrient content. FDA’s final regulations establishing nutrition labeling were published in 1993 (58 FR 2079, January 6, 1993) (the nutrition labeling final rule). FDA is responsible for enforcing the Act’s misbranding provisions for foods. Under these provisions, a food is misbranded if (among other things) its labeling is false or misleading in any particular. All claims and information presented on the label of a food or on its other labeling are subject to this requirement. One example of misbranding under the false or misleading labeling provision of the Act involves a product that is found to have nutrient values that are not consistent with the nutrient values declared in the nutrition label.

In addition to the general prohibition on false or misleading labeling, the Act and FDA’s regulations contain additional labeling requirements for packaged foods, including requirements pertaining to product name, ingredients, and quantity of contents. These requirements are designed to prevent fraud and ensure that consumers receive accurate information to make informed choices about foods in the marketplace. The Act and regulations also require premarket review and/or specification of nutritional criteria for certain types of claims in food labeling, such as nutrient content claims and health claims, to help ensure that such claims will be useful to consumers in selecting foods that contribute to good health.

FDA's Food Labeling Compliance Program

As part of FDA's NLEA Compliance Program (the Compliance Program), FDA investigators routinely review selected food labels during regularly scheduled food manufacturer inspections performed under the agency's food safety compliance programs. The Compliance Program includes guidance for collecting and analyzing food samples for nutrition analysis, and also directs FDA investigators to review labels and collect samples for nutrition analysis during field examinations of imported food products.

The Compliance Program is designed to identify significant food labeling deviations. Examples of such labeling deviations include the inaccurate declaration of nutrients, the use of a nutrient content claim or health claim on foods that do not qualify for the claim, the use of nutrient content claims or health claims that have not been sanctioned by FDA, and the misrepresentation of a food as a standardized food when the food does not comply with the requirements set forth in the standard of identity for the food.

FDA's Compliance Program must respond to a wide-spectrum of labeling violations ranging from minor to significant. When the agency identifies significant deviations from the labeling requirements, FDA issues Warning Letters to inform manufacturers of the violations and to give manufacturers an opportunity to provide FDA with a plan to voluntarily correct their food labels. If FDA finds a minor labeling violation, the agency may issue an "untitled letter" to the violator that advises the firm on how to achieve voluntary compliance with food labeling regulations. If the firms do not voluntarily correct significant food labeling violations, FDA may initiate a process to gather evidence, through inspections, sample collections, or other activities, to take further enforcement action. These actions may include seizing misbranded products and/or seeking a court order enjoining a firm from marketing misbranded products.

FDA Actions

Between October 1, 2004, and December 6, 2005, FDA conducted approximately 28,000 field examinations of domestic and imported food labels. FDA also collected 543 samples for nutrient analysis and/or label review. As a result of FDA's label reviews and nutrient analysis, FDA issued 56 Warning Letters addressing misbranding violations involving a variety of food products. The labeling violations addressed in these Warning Letters include the following:

- False or misleading nutrition information;
- Use of a nutrient content claim or a health claim for which the product does not qualify;
- Use of a nutrient content or health claim that is not provided for by regulations or under FDA's enforcement discretion;
- Use of drug claims;
- Failure to list all ingredients, including allergenic ingredients; and,

- Failure to properly identify a product that is subject to an established standard of identity or that does not meet the requirements that have been established in the standard of identity.

With assistance from the Department of Justice, FDA filed one injunction action against a firm that has a history of labeling its bakery products with false nutrition information.

FDA also classified 291 voluntary recalls of numerous food products that were attributed to labeling violations discovered during an FDA label review. The agency initiated one of these recalls because a bakery product formulated with sugar was falsely labeled as "sugar free." The remaining recalls were conducted because the products contained ingredients that were not listed in the ingredient statement. Many of these recalls involved the failure to list allergenic ingredients, which can result in serious to moderate adverse health consequences to allergic consumers. When a firm initiates a voluntary recall to remove a misbranded product from the market, FDA monitors the recall to ensure that the recall is effective. FDA's recall guidelines include measures for a recalling firm to communicate to FDA how it has corrected the labeling error and the measures it has instituted to assure that all of its labels conform to FDA's laws and regulations. Initiating and effectively completing a voluntary recall often precludes the need for additional regulatory action on the part of the agency to bring a misbranded product into compliance.

Finally, FDA is updating the Compliance Program to provide increased emphasis on ingredient labeling in conjunction with our efforts to implement the Food Allergen Labeling and Consumer Protection Act, which became effective on January 1, 2006.

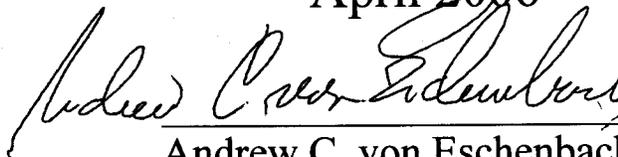
Conclusion

Ensuring accurate nutrition information and truthful, non-misleading nutrient content and health claims will continue to be areas of emphasis in the FDA's NLEA Compliance Program. FDA will continue to apply its resources, in conjunction with food safety initiatives, to efforts that ensure that consumers have accurate nutrition information and truthful food labeling information so that they can make informed choices when selecting and purchasing foods. Through accurate nutrition label information, consumers can select food products that assist them in implementing the recommendations of the Dietary Guidelines for Americans 2005.

Report to Congress on
Compliance with Food Label Regulations under the
Food and Drug Administration's Purview

House Report 109-102

April 2006

 Date APR 19 2006

Andrew C. von Eschenbach, M.D.
Acting Commissioner of Food and Drugs

Report Language – House Report 109 - 102

“The Committee is interested in ensuring that the public can be certain that the Nutrition Facts panel on food products reflects accurate, lawful, and factual nutritional information, particularly as it relates to the New Dietary Guidelines for Americans 2005. Given the important nature of the information provided on the food label, the Committee is concerned that consumers may be faced with illegal low calorie claims, healthy claims, and heart health claims. Additionally, there may be product names that violate the standards of identity for particular products. Consumers need to know that they can trust the accuracy of food labels. The Committee, therefore, directs the agency to systematically examine Nutrition Facts labels, and report to the Committee by February 1, 2006, with a summary of the types of labeling violations discovered, and the actions taken to address such violations.”

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