DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

October 19, 2009

The Honorable Rosa L. DeLauro
Chairwoman
House Appropriations Subcommittee
on Agriculture Rural Development,
Food and Drug Administration, and Related Agencies
House of Representatives
Washington, DC 20515

Dear Chairwoman DeLauro:

Thank you for your letter of September 21 regarding nutrition labeling, in which you express your concern that the Smart Choices front-of-pack (FOP) labeling may not adequately help consumers reach accurate conclusions with regard to healthy food choices.

In this letter, I will describe FDA's concerns in this area, which extend beyond any particular program, and underscore the public health importance of devising a sound approach to nutrition-related FOP labeling. I'll also outline some steps FDA is taking to achieve this goal.

The agency believes that point of purchase labeling, including FOP labeling or corresponding shelf labeling, concerning the nutritional attributes of food, can be an effective way of promoting informed food choices and helping consumers construct healthier diets in accord with the Dietary Guidelines for Americans. FOP or shelf labeling that provides consumers with readily accessible information about a product's nutritional profile, in a manner that is consistent with and linked to the required Nutrition Facts panel, responds to today's marketplace realities and can be part of the education and outreach consumers need to understand and act on nutrition information at the point of purchase. Because of the large role diet plays in obesity and as a risk factor for chronic disease, we believe empowering consumers in this way can make a big difference for public health.

At the same time, FDA's research has found that with FOP labeling, consumers are less likely to check the Nutrition Facts label on the information panel of foods (usually, the back or side of the package). It is thus essential that both the criteria and symbols used in front-of-package and shelf-labeling systems be nutritionally sound, well-designed to help consumers make informed and healthy food choices, and not false or misleading. The agency is currently analyzing FOP labels that appear to be misleading. The agency is also looking for symbols that either expressly or by implication are nutrient content claims. FDA is assessing the criteria established by food manufacturers for such symbols and comparing them to its regulatory criteria. I assure you that FDA will proceed with enforcement action where FOP labeling makes unauthorized nutrient content claims.

It is important to note that nutrition-related FOP and shelf labeling, while currently voluntary, are subject to the provisions of the Federal Food, Drug, and Cosmetic Act that prohibit false or misleading claims and restrict nutrient content claims to those defined in FDA regulations. Therefore, FOP and shelf labeling that is used in a manner that is false or misleading misbrands the products it accompanies. Similarly, a food that bears FOP or shelf labeling with a nutrient content claim that does not comply with the regulatory criteria for the claim is misbranded. We will consider enforcement actions against clear violations of these established labeling standards.

FDA plans to do more, however, than act against claims that violate current requirements for nutrient content claims or that are false or misleading. The agency is also developing a proposed regulation that would more explicitly define the nutritional criteria that would have to be met by manufacturers making broad FOP or shelf label claims concerning the nutritional quality of a food, whether the claim is made in text or in symbols. FDA's intent is to provide standardized, science-based criteria on which FOP nutrition labeling must be based.

FDA also believes that it should continue to improve its understanding of how consumers view and use such labels. Research suggests that the proliferation of divergent FOP approaches is likely to be confusing to consumers and ultimately counter-productive. Therefore, FDA intends to work with the food industry – retailers and manufacturers alike – as well as nutrition and design experts, consumer groups, and the Institute of Medicine, to develop an optimal, common approach to nutrition-related FOP and shelf labeling that all Americans can trust and use to build better diets and improve their health. The foundation of that approach should be a common set of mandatory nutritional criteria that consumers can rely on when they view FOP labels, even if no one symbol is ultimately selected as superior.

The recent experience with FOP labeling in the United Kingdom demonstrates the potential of voluntary initiatives to provide consumers helpful FOP labeling. In that instance, the government set certain criteria for the use of such labeling, and retailers took the initiative to implement FOP labeling in their stores. The agency wants to explore the potential of that approach, so as to make timely progress in the United States. This would include assessing through consumer studies research the likely effects of FOP symbols on information search behavior related to the Nutrition Facts label, which in turn can affect consumer understanding of the full nutrition profile of a product. If voluntary action by the food industry does not result in a common, "gold standard" approach to FOP and shelf labeling, the agency will consider using its regulatory tools toward that end.

Finally, FDA will work on FOP labeling in collaboration with our sister public health agencies and the Department of Agriculture (which has authority over the labeling of meat and poultry). We will base our initiative on consumer research to ensure that we move toward an approach that will, in fact, help consumers in selecting a healthy diet.

Thank you for your interest, support, and input on this important matter, and for your long-standing commitment to FDA's efforts to protect and promote the public health.

We will be sending a similar letter to the food industry.

Sincerely,

Margaret A. Hamburg

Margaret A. Hamburg, M.D.
Commissioner of Food and Drugs