Rebuttal to FDA Report to Congress on Agency Enforcement Actions Regarding Health-Related Claims on Food Labels

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I. Introduction

The Food and Drug Administration’s (FDA) Report to Congress on Compliance with Food Label Regulations under the Food and Drug Administration’s Purview confirms that the Agency is ignoring the enforcement of key regulatory provisions intended to prevent misleading food labeling.

In light of the new Dietary Guidelines for Americans 2005, the Senate Appropriations Committee wanted to ensure that “food labels can be easily understood and reflect information that is accurate” and not misleading. The House Committee was concerned that consumers would lose confidence in the trustworthiness of the food label because of inaccuracies in the amount of nutrients declared in the Nutrition Facts Panel, the misuse of terms such as “low calorie” and “healthy,” misleading nutrient content, heart health and other health-related claims and the use of product names that violate standards of identity. The Committees asked the FDA to report on the types of food labeling violations that the Agency had uncovered in these areas and the actions taken to address them.

In its report, the FDA states that from October 1, 2004 to December 6, 2005, it conducted 28,000 field examinations of domestic and imported food labels, collected 543 samples for nutrient analysis and/or label review, issued 56 warning letters, and initiated 291 voluntary recalls.

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1 This report was prepared by Bruce Silverglade, director of legal affairs and Ilene Ringel Heller, senior staff attorney.


attributed to labeling violations.\(^4\) An analysis of these figures, however, reveals that most are non-responsive to the Committees’ requests and that the specific issues of concern to the Committees have been a casualty of not just budget cuts, but a lack of commitment on the part of the Agency.

II. The number of field examinations conducted by the FDA is irrelevant to the Committees’ requests for information on the accuracy of nutrition statements on food labels and the prevalence of potentially misleading health-related claims.

- A “field examination” is an on-the-spot glance at a product by an inspector to determine that mandatory information – the ingredient list, the net weight, the product name, the name and address of the manufacturer, and the Nutrition Facts Panel – all of which (except for nutrition labeling) have been required since 1938 – is printed on the label. In general, these examinations do not attempt to ascertain whether such information is accurate, nor do they attempt to determine whether health-related label statements are misleading. The FDA report counts each label eyeballed by an inspector as a separate “field examination.” The fact that FDA inspectors eye-balled 28,000 labels to see if mandatory information was listed does little to stop misleading health-related claims that pervade the marketplace and that make it difficult for consumers to comply with the Dietary Guidelines for Americans.

- Moreover, field examinations of labels are conducted as part of a general inspection of a producer’s facilities. Because inspections are targeted at specific facilities based on safety risks, such establishments are not necessarily the same companies that may market products with misleading health-related claims.

- In addition, inspectors are instructed to give labeling review very low priority during such inspections. Although a company may produce dozens or even hundreds of products, inspectors are instructed to conduct no more than 3 label examinations per inspection.\(^5\) The FDA instructional course manual for inspectors tells them not to “undertake a critical label review during an inspection unless directed by the assignment, program or your

\(^4\) FDA, Report to Congress on Compliance with Food Label Regulations under the Food and Drug Administration’s Purview House Report 109-102 (April 2006); FDA, Report to Congress on Compliance with Food Label Regulations under the Food and Drug Administration’s Purview Senate Report 109-92 (April 2006) [hereinafter “report”]. The House and Senate versions are identical except for the Committee Report language quoted at the beginning of each report.

\(^5\) FDA, Center for Food Safety and Applied Nutrition, Food Compliance Program, Domestic NLEA, Nutrient Sample Analysis, and General Food Labeling Program 7321.005 at 7 (Nov. 30, 2000).
Inspectors are further instructed to only “bring obvious label discrepancies, such as the failure to declare ingredients on the label, to the management’s attention” and not to list labeling violations on inspection reports.

III. The 543 domestic and import samples taken for “nutritional analysis and/or label review” is overstated and taken out of context because most samples involved potential safety issues and do not relate to the Committees’ inquiries about the prevalence of inaccurate or misleading health-related statements.

- The Agency’s report to Congress states that the Agency “also collected 543 samples for nutrient analysis and/or label review.” Based on our review of the warning letters and recalls that resulted from the analysis of the 543 samples taken by the Agency, most appear to involve safety concerns, e.g., failure to include allergenic ingredients in the ingredient list, which was not within the scope of the Committees’ requests for information on enforcement actions related to inaccurate nutrition information or misleading health-related claims on food labels.

IV. Some of the 56 warning letters mentioned by the Agency in its report may be irrelevant to the Committees’ inquiries, and in any event, represent only a small fraction of actual violations in the marketplace.

- Some of the 56 warning letters issued by FDA may concern matters unrelated to the Committees’ inquiries such as the failure to list allergenic ingredients and net weights on

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6FDA On-Line Instruction Food Labeling Module, FDA 45 at 2.

7FDA On-Line Instruction Food Labeling Module supra at 12.

8 FDA stated in its report that all but one of the 291 recalls resulting from inspections involved ingredients that were not listed in the ingredient statement. FDA further stated that “Many of these recalls involve the failure to list allergenic ingredients, which can result in serious to moderate adverse health consequences to allergic consumers.” Report at 4. Such actions, while important, are irrelevant to the Committees’ inquiries.

9 The FDA did not provide Congress with the actual warning letters, or even a list of the documents. When we contacted the Agency, FDA officials referred us to the FDA website. However, the information on the FDA web site does not comport with the information the Agency supplied to Congress; the website contains approximately 100, not 56, warning letters relating to foods and dietary supplements (the latter of which were outside of the scope of the Committees’ inquiries). It is not clear which of the 56 warning letters discussed in the Agency’s report provided to Congress are included within the warning letters we found on the FDA web site or how many of those letters are relevant to the Committees’ inquiries.
While those kinds of violations should not be tolerated, they are not related to the House and Senate report language which focused on concerns about “health-related” claims for foods that interfere with attempts by consumers to follow the Dietary Guidelines for Americans.

- In some cases, the FDA did take appropriate action. For example, three warning letters issued by the Agency related to improper use of terms such as low calorie and sugar free; six related to inaccurate amounts of nutrients listed on product labels; one related to misuse of a standardized name. In one coordinated sweep, the FDA issued 27 warning letters to distributors of cherry juice, dried cherries, and other fruit products containing cherries that made illegal disease prevention claims on company websites and/or food labels. This type of nationwide action, which focused on a particular category of misleading health-related claims, is the type of action that the Agency should be taking much more frequently. Unfortunately, that type of crackdown was an aberration. Misleading claims for everything from “energy” drinks to ordinary bread masquerading as “whole wheat” have proliferated and also deserve systematic enforcement efforts, but the Agency has taken no action.

In any event, the 56 warning letters mentioned in the Agency’s report represent only a small fraction of the actual number of products with inaccurate nutrition information or misleading health-related claims.

- In recent years CSPI alone has asked the Agency to take action against almost 200 misleadingly labeled products discovered during occasional visits to supermarkets just in the Washington, D.C. area. Furthermore, judging by the number of complaints we receive from aggrieved competitors and consumers, the Agency has failed to take action against numerous other instances of misleading health-related claims and inaccurate nutrition information.

- State officials have uncovered dozens more instances of violations. For example, the Florida Department of Agriculture and Consumer Services concluded that 67 diet products that it reviewed for nutritional accuracy were misbranded in some fashion. Eighty-four percent of the products claiming to be sugar free or low in carbohydrates were in fact neither and violated the law. Almost 30% of “low fat” products tested by the state contained more fat than claimed. Similarly, the State of Connecticut reached settlements with Keystone Foods, a snack food company, to halt claims that herbal substances in its Robert's American Gourmet products would increase energy and help fight colds and other

10 E.g., Letter to Alain J. Franques, Le Gourmet Lorrain, Inc. (July 25, 2005).
11 See FDA Press Release, FDA Warns Companies to Stop Marketing Fruit Products with Unproven Disease Claims (Oct. 24, 2005).
Soon thereafter, the State also reached a settlement with the South Beach Beverage Company (SoBe), now owned by PepsiCo, to halt unproven health claims for many of its beverages. Furthermore, unlike companies subject to FDA warning letters, these firms were required to pay substantial financial penalties to settle the matter.

Given the number of violations identified by CSPI, state officials, aggrieved competitors and consumers, the small number of warning letters issued by the Agency is an indication that the FDA has all but abdicated its responsibility to police inaccurate nutrition statements and misleading health-related claims on food labels.

V. Almost all of the 291 recalls mentioned in the FDA report are related to safety, not nutritional health issues, and hence are irrelevant to the Committees’ inquiries.

- Of the 291 recalls mentioned by the FDA in its report, only one involved a matter relevant to the Committees’ inquiries -- a product containing sugar was misleadingly labeled as “sugar free.” All of the other recall notices related to the failure to list ingredients in the ingredient list; many of those unlisted ingredients were allergens. While this work is important, the Agency’s use of the “291 recalls” figure is not responsive to the Committees’ requests for enforcement information relating to inaccurate Nutrition Facts statements and misleading health-related claims that make it difficult for the public to comply with the Dietary Guidelines for Americans.

VI. Conclusion

Consumers depend on honest, accurate, and reliable information on food labels to improve their diets. Despite FDA’s express mandates to prevent false and misleading food labeling and to ensure that health and nutrition information on labels is reliable and accurate, food labels continue to be virtual minefields of misleading information. The FDA has provided Congress with enforcement figures that are irrelevant to the Committees’ requests and/or are presented out of context. In reality, the FDA has not allocated sufficient resources to remedy the problems identified by the Committees, nor does the Agency appear committed to fulfilling its statutory mandates in this area.

Instead of beefing up its resources, the FDA is actually reducing the number of staff.


15 Supra, note 8.
assigned to food labeling initiatives to help consumers make healthier choices. Just a year ago, FDA was planning to develop proposed rules to give more prominence to calories on the Nutrition Facts Panel and revise the serving size requirements for foods that can be consumed in a single eating occasion. The Agency also planned to develop guidance on the disclosure/footnote statements for trans fatty acids and to develop a strategy to initiate rulemaking on whole grains. But CFSAN’s priorities for 2006 do not include any of these matters.

The Agency will surely claim that budget cuts prevent it from undertaking these initiatives. Yet, effective enforcement need not consume additional resources. In light of the FDA’s abdication of its traditional role, CSPI has sued, or threatened to sue, leading companies engaged in misleading labeling. In the last year, we obtained settlements from such companies as Tropicana, Quaker Oats, Frito-Lay, and Pinnacle Foods. If a small non-profit association can force settlements with major companies, then the FDA surely could find a couple of motivated lawyers among its more than 10,000 person staff to stop misleading labeling practices. Presently, at FDA’s headquarters, only four people are assigned to identify and stop deceptive labeling, but they told CSPI that they only have time to respond to questions, not take the initiative. If the Agency had the will to act, it could find the necessary resources to enforce the law.

VII. Recommendations

1. Conduct targeted supermarket sweeps - FDA should be directed to carry out targeted supermarket sweeps to stop the misuse of claims such as “made with real fruit,” “healthy,” “made with whole grain,” “trans fat free” (when foods have significant amounts of saturated fat) and other misleading health-related statements that interfere with consumers’ attempts to adhere to the Dietary Guidelines for Americans.

2. Systematically test the accuracy of the Nutrition Facts Panel - FDA did not conduct a systematic examination of the accuracy of the Nutrition Facts Panel as requested by the House Committee. The last time the Agency conducted a systematic examination to test for accuracy (which is different from telling inspectors to eyeball labels to determine whether they merely depict a Nutrition Facts Panel) was in 1996. In light of known inaccuracies identified by state

16 FDA, CFSAN 2005 Program Priorities (Dec. 1, 2004). A FDA guidance statement that was issued on whole grains only deals with the question of what constitutes “whole grain” but does not specify when companies can claim that a product is “made with whole grains” when it primarily consists of ordinary enriched wheat flour. FDA, Whole Grain Label Statements, Draft Guidance, (Feb. 17, 2006).

17 FDA, CFSAN 2006 Program Priorities (May 3, 2006).

officials and private litigants, another systematic survey by the FDA is long overdue.

3. **Give labeling enforcement higher priority in the field** - Food labeling issues need to be separated from inspections based solely on safety risks. FDA headquarters needs to develop a policy statement to the field that will encourage District Offices to periodically conduct strategic reviews of labeling to determine whether they bear false or misleading health-related claims. Subsequent inspection of plants producing misbranded products should be scheduled as appropriate.

4. **Modify the instruction course manual for inspectors** - Similarly the FDA’s existing course manual that instructs inspectors *not* to undertake critical label reviews unless ordered to do so and *not* to list labeling violations on inspection reports should be revised. Inspectors should be given sufficient training to conduct critical label reviews and should be encouraged to do so periodically at supermarkets as well as at manufacturing facilities.

5. **Promptly issue guidance documents for industry** - FDA should issue guidance documents in a timely fashion before marketplace trends get out of control. For example, the Agency took so long to act on nutrient content claims for whole grains that the industry developed its own rating system which is confusing to consumers. Similarly, the FDA took so long to recognize that there was a low carbohydrate craze in the marketplace, that manufacturers invented terms such as “net” carbs or “essential” carbs that are misleading.

6. **Ensure adequate funding** - Congress should ensure that the FDA’s budget for the Office of Nutritional Products, Labeling, and Dietary Supplements has adequate funds to enforce the law and address new regulatory developments pertaining to the honesty of food labels.

These actions will help FDA tame the “supermarket jungle” and ensure once again that food labels provide consumers with accurate and honest health information.