THE VOICE OF FOOD RETAIL

Feeding Families Enriching Lives

July 27, 2012

The Honorable Cass R. Sunstein
Administrator
Office of Information and Regulatory Affairs
Office of Management and Budget
Eisenhower Executive Office Building
1650 Pennsylvania Avenue, NW
Washington, DC 20503

Re: June 22 Memorandum for the Heads of Executive Departments and Agencies and FDA's Regulation on Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments

Dear Administrator Sunstein:

The Food Marketing Institute (FMI)[1] commends you for issuing your Memorandum for the Heads of Executive Departments and Agencies dated June 22, 2012, on regulatory reporting and paperwork burdens (Memorandum). The Memorandum states that: "Eliminating unjustified reporting and paperwork burdens . . . is a high priority of this Administration."

The Memorandum reminds agencies of their obligations pursuant to Executive Order 13610 which emphasizes that agencies should prioritize 'initiatives that will produce significant quantifiable monetary savings or significant quantifiable reductions in paperwork burdens." The Memorandum also directs agencies that impose high paperwork burdens—like the Department of Health and Human Services—to "attempt to identify at least one initiative, or combination of initiatives, that would eliminate two million hours or more in annual burden." In addition, the Memorandum cites the requirement of E.O. 13610 that agencies focus on cumulative burdens and give priority to reforms that would make significant progress in reducing them.

[1] The Food Marketing Institute conducts programs in public affairs, food safety, research, education and industry relations on behalf of its nearly 1,250 food retail and wholesale member companies in the United States and around the world. FMI's U.S. members operate more than 25,000 retail food stores and almost 22,000 pharmacies with a combined annual sales volume of nearly $650 billion. FMI's retail membership is composed of large multi-store chains, regional firms and independent operators. Its international membership includes 126 companies from more than 65 countries. FMI's nearly 330 associate members include the supplier partners of its retail and wholesale members.

On April 6, 2011, the U.S. Food and Drug Administration (FDA) published a proposed rule to implement § 4205 of the Affordable Care Act,[2] which requires restaurants and "similar retail food establishments" that are part of a chain with 20 or more locations doing business under the same name to provide calorie and other nutrition information for standard menu items (Proposed Rule). The Proposed Rule has been estimated by OIRA to impose a paperwork burden of more than 14.5 million hours, a burden we believe will be in actuality much larger. Supermarkets face millions of burden hours under the Proposed Rule.

While FDA acknowledged that § 4205 did not require them to regulate supermarkets, the agency proceeded to do so anyway—in virtually the broadest manner conceivable. As a consequence, grocers bear a far more costly burden than restaurants. FMI has estimated that this burden will exceed $1 billion in the first year of compliance alone, with ongoing burdens costing the industry hundreds of millions of dollars annually. Significant questions exist regarding the agency's authority to regulate supermarkets in this fashion.

In addition, FDA failed to consider cumulative regulatory burdens in light of its proposal to extend menu labeling requirements to supermarkets. Supermarket compliance staffs are already stretched thin in dealing with a raft of regulations (Attachment A) and contending with a new burden like menu labeling will push them to the brink. Existing compliance staffs simply cannot handle a new regulatory burden of this scale. In an industry where profit margins average about one penny on the dollar, resources expended on regulatory compliance are diverted from those expended on investment and job generating activities. Cumulative burdens must be contemplated pursuant to E.O. 13610 as emphasized in the Memorandum.

FDA included an option in the Proposed Rule—referenced as "Option 2"—that would eliminate millions of paperwork burden hours and provide more than $1 billion in relief to the supermarket industry and consumers while allowing the agency to achieve regulatory objectives. We believe that the Memorandum and EO. 13610 demand that FDA adopt Option 2 and respectfully request that you ensure that the agency does so.

We also would like to make you aware that earlier this week, a bipartisan group of House members introduced legislation the "Common Sense Nutrition Disclosure Act of 2012" (H.R. 6174) which defines the term "similar retail food establishment" to generally exclude supermarkets among other things. During the press conference for the introduction of the legislation, members indicated that this definition reflected the original intent of Congress.

2 Pub. L. No. 111-48.

We appreciate your consideration of this matter.

Sincerely,

Erik R. Lieberman
Regulatory Counsel

Attachment A

Regulatory Burdens Faced by Supermarkets and Restaurants		
Regulation	***Compliance Required by Supermarkets***	***Compliance Required by Restaurants***
Country of Origin Labeling (7 C.F.R. pt. 60; 21 U.S.C §§ 301-399)	Yes	No
Identity Statement (21 C.F.R. § 101.3; 21 U.S.C. § 343(i)(1))	Yes	No
Net Quantity of Contents (21 C.F.R. § 101.105; 21 U.S.C. § 343(e)(2))	Yes	No
Ingredient Labeling (21 C.F.R. §§ 101.4; 21 U.S.C. § 343(i)(1))	Yes	No
Use By Dating	Yes	No
Nutrition Labeling (FDA) (21 C.F.R. § 101.9; 21 U.S.C. § 343(q))	Yes	Pending
Nutrition Labeling of Raw Meat and Poultry (9 C.F.R. §§ 317.300-345 and 381.400-445; 21 U.S.C. § 343(q))	Yes	No
Allergen Labeling (Pub. L. No. 108-282)	Yes	No
Presence of Artificial Colors, Chemical Preservatives and Artificial Flavors (21 C.F.R. 101.22; 21 U.S.C. § 343(i)(1))	Yes	No
Signature Line (21 C.F.R. § 101.5; 21 U.S.C. § 343(e)(1))	Varies by state	No
Safe Handling Instructions (21 C.F.R. § 101.17)	Yes	No
Bioterrorism Act Recordkeeping (21 C.F.R. § 1.327; Pub.L. No.107-188)	Yes	No
Recall Notification (Pub. L. 111–353)	Yes	No