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Supermarket Industry Concerns and Questions - FDA Menu Labeling Regulation

1. **Public guidance** on these issues and questions are needed not only for stakeholder compliance but also for federal, state and municipal health officials to review, collaborate and adequately train inspectors to ensure consistent regulatory oversight.
 - **Partially Addressed; More Information and Flexibility Needed in Final Guidance issued in a timely manner:** DRAFT Guidance Released September 11, 2015 addressing some questions/concerns raised by the supermarket industry but many remain outstanding or flexibility was denied by FDA. Comments are due November 2, 2015. No timeline provided for addressing additional issues or for issuing Final Guidance or for training of oversight personnel.
2. **Additional time:** Allow for at least two years for compliance with FDA's final Menu Labeling Regulations, and at least one year for compliance with final FDA published guidance. Not only is this consistent with the timeframe allowed under the new regulations for vending machine compliance, it is also consistent with the compliance window granted by FDA in the context of the Nutrition Labeling and Education Act (NLEA).
 - **Partially Addressed; Need at least one-year after guidance is finalized:** FDA delayed the compliance date for the final regulations until December 1, 2016, but since the agency has not issued (or provided a timeline for) final guidance, the supermarket industry's request for at least one-year for compliance after final guidance has been provided remains outstanding.
3. **Items standardized at 20 or more locations rather than to those items served regularly at one location of a 20 store establishment:** Clarify that the menu labeling law is intended for "standard menu items," defined as a restaurant-type food that is routinely included on a menu or menu board or routinely offered as a self-service food or food on display at 20 or more locations. This ensures that the regulations apply only to those items that truly are standardized at 20 or more locations rather than applying to items sold on a regular basis at only one individual store.
 - **FDA Refused Flexibility Request; Need Legislation unless FDA changes final rule:** FDA denied providing flexibility for foods sold that use different ingredients and/or prepared differently at an individual store.
4. **Foods labeled with Nutrition Facts, "Facts up Front," and "Clear on Calories" should be deemed in compliance:** The preamble states that for packaged foods, Nutrition Facts labels can be used to provide the written nutrition information. Does the term "packaged foods" include foods that are not subject to the packaged food labeling requirements in 101.9? All foods labeled with a Nutrition Facts panel or a voluntary labeling program that is compliant with the NLEA and includes information required under the menu labeling rule should be deemed in compliance with menu labeling regulations so long as the consumer can view the information before purchasing the item.
 - **Partially Addressed; "Facts up Front" and similar labeling programs should be deemed compliant in final guidance:** Additional labeling or signage is not needed for items bearing a Nutrition Facts label if the label can be viewed before purchasing the item. However, FDA did not address whether labeling programs, such as "Facts Up Front" or "Clear on Calories," that are consistent with FDA nutrition labeling standards would also be deemed compliant and not have to provide additional labeling/signage.

5. **Corrective Action:** FDA should provide a 90-day corrective action window for establishments found to be in violation of the menu labeling regulations. FDA should take no enforcement action, including the issuance of any public letter, for violations that are corrected within such 90-day period.
 - **Not Addressed in FDA Draft Guidance; Need legislation or included in final guidance.** The supermarket industry seeks for FDA to allow at least 90-days for corrective action without enforcement action after FDA notifies a food retailer of potential non-compliance.
6. **Allowing a Menu or Menu Board at Salad/Food Bar:** Allow for a menu/menu board above or at the end of the salad bar, listing calorie information for all of the standard food items including a succinct statement with the additional nutrition information available upon request, to satisfy the menu labeling requirements regardless of the length in feet of the salad bar.
 - **Not Adequately Addressed; Flexibility Denied; Need legislation or included in final guidance.** The supermarket industry seeks for FDA to allow a menu or menu board that is adjacent to be used to provide nutritional information for “foods on display” (i.e. salad/food bar) in lieu of labeling each individual item or along a window guard since the placement of food items along a food/salad bar frequently changes, increasing the likelihood for errors in matching foods with labels.
7. **Succinct statements in one prominent location:** Allow the “succinct statement” (“2,000 calories a day is used for general nutrition advice, but calorie needs vary” and additional nutrition information available upon request) to be posted in one prominent location in the store in the vicinity where the majority of covered foods are generally offered for sale rather than in each case or display location for items without a menu or menu board.
 - **Not Adequately Addressed in FDA Draft Guidance; seek to address in final guidance or legislation if necessary.**
8. **Additional Nutrition Information for grab-and-go items:** For grab-and-go items that retailers generate a label for already (yogurt parfaits, prepared sandwiches etc.), can a line be added to that label that lists the calorie information without requiring additional signage? This is critical for “grab-and-go” items, such as sandwiches that may be made earlier in the day in a store deli and placed in a refrigerator case or a variable location in the store.
 - **Addressed in FDA Draft Guidance.** FDA is allowing “grab-and-go” items that are labeled with calorie information to be considered compliant with menu labeling regulations without additional signage if the customer can view the label prior to purchasing the item.
9. **Further Preparation of Cold Foods:** Can FDA clarify that the logic used for ordinary expectation of further preparation extends to other items in the deli case including cold prepared foods which require the consumer to take an additional step (heating up) before they are ready for consumption?
 - **Addressed in Draft Guidance:** FDA clarified what is considered further preparation by the consumer.
10. **Further Preparation Bakery:** Can you also clarify that this would include bread, rolls and bagels as they are generally eaten as part of a sandwich or spread with butter or cream cheese or baked in an oven?
 - **Not Addressed in FDA Draft Guidance**

Redundant Calorie Disclosure Requirements

11. **Calories on one display/panel:** Can FDA clarify that when a customer can simultaneously view a menu board including a standard menu item and/or a label or tag for the same item on display, only one calorie disclosure is required? For example, if a grab and go sandwich displays the calorie information on the label of the sandwich, along with the name and price, and a consumer can view that label prior to purchasing the item, the calorie disclosure would not be required on a sign or menu board highlighting the item or vice versa?
- **Addressed in FDA Draft Guidance:** FDA is allowing “grab-and-go” items that are labeled with calorie information to be considered compliant with menu labeling regulations without additional signage if the customer can view the label prior to purchasing the item.

Recordkeeping

12. **Certification:** The regulations state that establishments must provide upon request by FDA a statement “signed and dated by a responsible individual employed at the covered establishment certifying that the covered establishment has taken reasonable steps to ensure that the preparation of the item adheres to the factors on which the nutrient values were determined. Can a regional manager with general knowledge of how food is prepared at the covered establishment qualify as the responsible individual for the purposes of this statement? Does the statement need to be kept at the covered establishment or could it be held at a corporate headquarters?

Partially Addressed in FDA Draft Guidance: FDA clarifies certification requirements, including at a corporate level and at each individual establishment.

13. **Documentation:** The rules state that covered establishments must provide certain information to document their nutrient declaration within a reasonable period of time upon request from FDA, but do not state that such records must be maintained. Is it accurate that the documentation requirements in 101.11(c) are not recordkeeping requirements?

- **Not Addressed in FDA Draft Guidance; Seek clarification in final guidance**

14. **Electronic signatures:** Is the electronic form of a signature acceptable for documentation/auditing purposes?

- **Not Addressed in FDA Draft Guidance; Seek to address in Final Guidance**

Menu and Menu Boards

15. **Moving Digital Menu Boards:** Are digital menu boards displaying calorie information for a standard menu item required to be “static” or can the menu move from one menu to a different menu every 30 seconds or some other similar configuration in order accommodate all items?

Addressed in FDA Draft Guidance

Enforcement

- 16. Consistent Interpretation:** What kind of guidance and training is FDA going to provide to field personnel, as well as state and municipal health officials to ensure everyone has a consistent interpretation of the regulations and the goals of enforcement?

Not Adequately addressed in Draft Guidance; Potential Legislation Needed

6.23 What are the penalties for not providing accurate nutrient information?

Answer: If the calorie and other nutrition information is not accurate, the foods would be considered misbranded and subject to the same penalties that misbranded packaged foods are subject to under the FD&C Act.

6.24 What entities will enforce the menu labeling requirements?

Answer: In general, FDA is delegated with enforcing the provisions of the Federal Food, Drug, and Cosmetic Act (FD&C). However, under section 310(b) of the FD&C Act, a state could enforce certain provisions of the FD&C Act, including the menu labeling requirements of section 403(q)(5)(H), under certain circumstances. Alternatively, states or localities could establish menu labeling requirements that are identical to the federal requirements and enforce their identical requirements. FDA intends to work with state and local authorities, as appropriate to ensure that implementation and enforcement of the menu labeling requirements are uniformly applied.

- 17. Safe-Harbor for Using Accredited Nutritional Data Sources:** Provide food retailers a safe-harbor from federal, state and municipal enforcement actions, as well as from civil action, if an establishment relies on data contained in a nutritional data source and/or nutrient database accredited by (or references information from) a U.S. Government agency or other accredited body.

Partially Addressed: FDA provides examples of potential nutritional data sources and information an establishment may need to provide upon request, but does not accredit, certify or provide a safe-harbor for use of those resources.

- 18. Exclusion of single-ingredient or “minimally-processed” items:** Grocery, produce or bulk items that are otherwise not subject to the NLEA should not be subject to menu labeling regulations if the item remains a single-ingredient or is “minimally- processed.” “Minimally processed” would include processes that do not substantially alter the nutrient content of a food item, such as portioning or commingling of individual raw produce components (i.e., a salad) or bulk items.

Not Addressed in FDA Draft Guidance; Legislation needed to not apply menu labeling requirements to fresh fruits and vegetables used from a store’s produce area that are raw or minimally-processed (no additional ingredients or preparation that would change the nutritional profile) and used in a salad bar.

- 19. Transition Period:** Allow for a one-year menu labeling implementation transition period for businesses that add a 20th location.

- **Not Addressed in FDA Draft Guidance; Seek to be addressed in final guidance**

Calorie Disclosure for Self-Serve and Foods-on-Display

20. **Font-size:** Allow font size for menu labeling calorie counts to be proportional to (not the same size as) the name and/or price of the food item consistent with other food labeling regulations, so the calorie count does not get confused with the price of the food item or obscure the name of the food. This would potentially allow for scale-labels to be used rather than having to buy new labeling equipment and software. For reference, final vending machine labeling regulations allow for calorie font size to be no smaller than 50% of the largest size of the brand name on the item's package label.
- **Not Adequately Addressed in FDA Draft Guidance; Legislation Needed.** The supermarket industry seeks for FDA to allow a menu or menu board that is compliant with the Rule's font-sizing requirements to be used adjacent to a salad/food bar (i.e. "foods on display") in lieu of labeling and measuring font-sizes for each individual item or along a window guard.
21. **Fluid ounce abbreviation:** FDA states that for beverages, calorie declarations must be accompanied by the term "fluid ounces." Is using the abbreviation "fl. oz." acceptable under the rule?
- Not Addressed in Draft Guidance but abbreviation "Cal." allowed for "Calories"; seek to address in final guidance.
22. **Calorie declaration on cups:** For fountain drinks and dispensed beverages, is providing the calorie declaration for the beverages on a self-service cup acceptable under the final rule?
- **Partially addressed; FDA provides rigid requirements, more flexibility sought in final guidance**

Primary Writing

23. **Sign:** If a promotional sign for a sandwich includes both the name and price of the item, but the customer could not order it without visiting a kiosk (which declares the calories), the promotional sign would not be considered a "primary writing" and would not need to declare calories.
- **Partially Addressed; Seek Clarification in Final Guidance**