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# E-ALERT | Food & Drug

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## FOOD LABELING MODERNIZATION ACT OF 2013

Last Thursday, September 19, 2013, Representatives Frank Pallone, Jr. (NJ-06) and Rosa DeLauro (CT-03) along with Senator Richard Blumenthal (D-CT) introduced new legislation, HR 3147, the "Food Labeling Modernization Act of 2013," that would require FDA to impose requirements and criteria for a broad range of label statements and claims that have become of significant interest to consumers, advocacy groups, and plaintiff lawyers.

The proposed amendments would require: uniform front of package labeling; adherence to new requirements for "natural," "healthy," and "whole grain" claims; disclosure of added colors, sweeteners, calories, trans fats, and total caffeine amount; revisions to ingredient declarations; changes to labels of single-serve packaging; and revisions to substantiation requirements for structure/function claims. Non-compliance with the majority of the proposed amendments would result in a product being deemed misbranded and subject to FDA enforcement actions.

While this bill is unlikely to be enacted, at least in its current form, it addresses issues that are under active consideration by FDA, consumer advocacy groups, and plaintiffs' lawyers. Accordingly, the bill may play a role in influencing proposed FDA regulations that are anticipated in the coming year, and could shape or further reinforce litigation trends.

### HIGHLIGHTS OF THE PROPOSED FOOD LABELING MODERNIZATION ACT

The proposed requirements apply only to conventional foods. The legislation expressly carves-out dietary supplements, and the proposed amendments to the nutrition information labeling requirements expressly do not apply to medical foods, restaurant food, and other food product categories that are not otherwise subject to FDA's nutrition labeling requirements.

#### Front-of-Package (FOP) Labeling

The legislation would amend section 403 of the Food, Drug, and Cosmetic Act (FDCA) by adding a new paragraph (z), which would state that a food is misbranded if its principal display panel (PDP) does not include standardized FOP labeling, to be specified in FDA regulations. In promulgating such regulations, FDA would be required to take into account the Institute of Medicine's (IOM's) recommendations set forth in the 2011 report, "Front-of-Package Nutrition Rating Systems and Symbols: Promoting Healthier Choices,"[1] and to require that FOP labeling:

- use a single, simple, standard symbol system displaying calorie information and information related to nutrients strongly associated with public health concerns (identified in the IOM report as saturated and trans fat, sodium, and added sugars);
- appear on all products that are required to bear nutrition labeling;

[1] Please click here for Covington's client alert on this IOM report.

- appear in a consistent location on the PDP across products with sufficient and contrasting prominence;
- be consistent with the Nutrition Facts Panel and the recommendations of the Dietary Guidelines of Americans; and
- be easily identified by consumers as an indicator of a product's contribution to a healthful diet, including consumers who are among nutritionally at-risk sub-populations.

In addition, the legislation recommends that FDA periodically evaluate the FOP information to determine whether consumers are selecting more healthful food products and whether food manufacturers are offering more healthful food products as a result of the disclosure requirements. The bill also recommends that FDA implement consumer education and promotion campaigns.

## "Natural" Claims Requirements

Under the proposed legislation, food products would be deemed misbranded for carrying a "natural" claim if the food contained any artificial flavor or artificial color, which is further defined to include: synthesized ingredients that are the same as naturally occurring ingredients; chemically altered ingredients like corn syrup, high-fructose corns syrup, high-maltose corn syrup, maltodextrin, chemically modified starch, and cocoa processed with alkali; and any other artificially-created ingredient FDA specifies by regulation.

Processing that would be expressly permitted for "natural" products includes smoking, roasting, freezing, drying, fermenting, and physical processes that do not alter the raw product such as grinding grains, separating eggs into albumen and yolk, or pressing fruits to produce juice.

## "Whole Grain" Claims Requirements

The legislation proposes that food products would be misbranded if they bear claims such as "made with whole grain," "multigrain," or similar descriptions relating to the product's whole grain content and do not conspicuously disclose immediately next to the claim the amount of whole grains in the product as a percentage of the total grains in the product (e.g., "50% of the grains are whole grains"). Similarly, products using the terms "wheat" or "whole wheat" would be deemed misbranded unless they conspicuously disclose immediately next to the claim either the percentage of whole wheat by weight contained in the product or the phrase "contains no whole wheat."

## "Healthy" Claims Requirements

The bill requires FDA to revise the existing regulation for "healthy" claims (at 21 C.F.R. § 101.65(d)(2)) to include limits on the levels of added sugars. In addition, grain products would be prohibited from carrying "healthy" claims unless at least half of the grains in the product, by weight, are whole grains.

## Disclosures of Added Colors, Sweeteners, Calories, Trans Fats, and Total Caffeine Amount

The bill also proposes that food products would be deemed misbranded if the products contained any added artificial or natural coloring, any added artificial or natural non-caloric sweetener, or any added artificial or natural flavoring, unless such facts were prominently disclosed on the PDP (except that the artificial color disclosure would not apply to butter, cheese, or ice-cream).

The legislation also proposes amendments to the Nutrition Facts panel, which would require disclosure of calories per serving as a percent of recommended daily calories, which may also

include percent recommended daily calories for sub-populations (e.g., children). This calorie declaration would be required to appear in typeface and design that is more prominent and conspicuous than other information in the Nutrition Facts panel. The bill would also require disclosure in the Nutrition Facts panel of sugars and added sugars per serving by a percent of recommended daily intake.

The bill would also add criteria and disclosure requirements for claims relating to trans fats. It would permit claims about the level of trans fats if the food contains less than 1 g of saturated fat per serving or discloses the amount of saturated fat immediately next to the trans fats claim. The bill would also extend the current requirements relating to the interplay of cholesterol and saturated fat claims and disclosures to trans fats.

Finally, products with 10 mg or more of total caffeine per serving from all sources would need to declare the amount of total caffeine (in mg) per serving and the size of the serving (e.g., "10 mg caffeine per 8 oz. serving"). This information would need to appear on the information panel with prominence near the ingredient declaration.

### Ingredient Declaration Revisions

For purposes of determining the order of predominance of ingredients, the bill would require declaring sugars as collective categories, with the categories designated as "sugars," "non-caloric sweeteners," and "sugar alcohols." The individual ingredients within each category would be listed parenthetically in their order of predominance.

In addition, the legislation would revise the ingredient declaration formatting requirements to require upper- and lower-case characters, serif and non-condensed font types, high-contrast between text and background, and bullet points between adjacent ingredients. Packages with insufficient space would be exempt from such requirements.

### Single-Serve Packaging Changes

The bill would require packages of food that could reasonably be consumed in a single-eating occasion be labeled as single servings and be treated as single servings for purposes of nutrition labeling.

### Substantiation Requirements for Conventional Food Structure/Function Claims

The legislation would require FDA to issue guidance clarifying requirements for structure/function claims for conventional food and would specifically authorize FDA to demand substantiating evidence for such claims within 90 days of FDA's request.

## IMPLICATIONS OF THE PROPOSED FOOD LABELING MODERNIZATION ACT OF 2013

While the proposed legislation is unlikely to gain traction in Congress, its existence indicates that the topics identified in the bill have gained the attention of at least some key Congressional officials. Moreover, both the Unified Agenda and Regulatory Plan for FDA and FDA's Center for Food Safety and Nutrition (CFSAN) 2013-2014 program priorities have identified the revision of nutrition labeling as a priority. CFSAN's program priorities call for proposed and final rules to update the Nutrition Facts label and serving size information to improve consumer understanding and use of nutrition information on food labels. The provisions in the bill could play a role in shaping the agency's thinking on these issues.

In addition, the proposed "natural" claims requirements underscore the narrow view that plaintiff lawyers and others have taken for the "natural" foods product category, which, in turn, highlights the risk of making such claims in the current wake of aggressive consumer fraud litigation against "natural" claims.

Many of the provisions in the bill harmonize with priorities previously articulated by consumer advocacy groups, and the legislation was well-received by groups such as the Consumers Union and the Center for Science in the Public Interest (CSPI).

Covington is tracking the proposed legislation and will provide updates if and as the legislation proceeds.

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If you have any questions concerning the material discussed in this client alert, please contact the following members of our Food & Drug Practice Group:


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|---|---|---|
| Miriam Guggenheim | +1.202.662.5235 | mguggenheim@cov.com |
| Jeannie Perron | +1.202.662.5687 | jperron@cov.com |
| MaryJoy Ballantyne | +1.202.662.5933 | mballantyne@cov.com |