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Food, Drug & Device/FDA ADVISORY ■

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FDA Finalizes "Gluten-Free" Labeling Rule

Today, the U.S. Food and Drug Administration (FDA) issued its much anticipated and long-awaited Final Rule on the "Gluten-Free Labeling of Foods"—more than six years after the agency published its Proposed Rule in January 2007. The final rule was issued under the authority of the Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA) and defines the term "gluten-free" for voluntary use in the labeling of foods, setting forth conditions on the use of the term. The final rule seeks to answer many of the lingering questions from both food manufacturers and those consumers who suffer from celiac disease by establishing a standardized federal definition of the term "gluten-free" across the food industry. Although the final rule becomes effective on September 4, 2013, companies will have one year to comply with the regulation until **August 5, 2014**.

Defining "Gluten-Free"

Under newly added 21 C.F.R. §101.91(a)(3), the labeling claim "gluten-free" means that any food bearing the claim in its labeling:

- does not contain an ingredient that is a gluten-containing grain (e.g., wheat, rye, barley or any of their crossbred hybrids);
- does not contain an ingredient derived from a gluten-containing grain that has not been processed to remove gluten (e.g., wheat flour);
- does not contain an ingredient derived from a gluten-containing grain that has been processed to remove gluten if use of that ingredient results in the presence of more than 20 ppm of gluten in the food; and
- does not contain 20 ppm or more gluten.

The final rule allows voluntary "gluten-free" claims—including "no gluten," "free of gluten" or " without gluten" claims—on any food that meets the aforementioned requirements. Any food bearing a gluten-free claim that does not meet these requirements will be deemed misbranded.

Significant Changes from 2007 Proposal

The final rule also includes a significant change from the proposed rule regarding the gluten-free labeling of foods that do not inherently contain gluten. The final rule permits gluten-free claims, *without* any qualifying language, for any foods that are inherently gluten-free, as long as any unavoidable presence of gluten falls below the 20 ppm threshold. In the 2007 proposed rule, FDA had proposed to deem misbranded any food bearing a gluten-free claim if the food is inherently free of gluten and the claim does not refer to all foods of the same type (e.g., "milk, a gluten-free food" or "all milk is gluten-free"). FDA determined that the proposed rule's additional clarifying language would cause confusion among consumers and thus reversed its initial position that a gluten-free claim, without qualifying language, on a food that is inherently free of gluten would be misleading.

Additionally, FDA determined that other qualifying language in conjunction with a gluten-free claim was unnecessary, including any potential clarification that a food bearing a gluten-free claim may potentially contain small traces of gluten (but always less than 20 ppm). FDA had contemplated in its proposed rule whether the use of qualifying language was necessary to inform individuals with celiac disease that a food labeled as gluten-free may nonetheless contain less than 20 ppm of gluten (e.g., "does not contain 20 ppm or more gluten"), but ultimately determined that such language would be inconsistent with other FDA-regulated labeling claims (e.g., "fat-free" or "sugar-free") that explicitly define the term without requiring additional clarifying language to qualify the regulatory definition. This is significant because manufacturers no longer need to worry about gluten cross-contact, as long as the unavoidable presence of gluten due to cross-contact situations or migration from packing/processing materials does not cause the food to exceed the 20 ppm threshold. That said, in its Questions and Answers, FDA indicated that it would permit advisory statements such as "made with no gluten-containing ingredients" or "made in a factory that also processes wheat products," provided the statements are truthful and not misleading.

The final rule provided for only one scenario where manufacturers would be required to include specific clarifying language. 21 C.F.R. §101.3(b)(3) states that any food that lists "wheat" in the ingredient list or includes a "contains wheat" statement (as required under FALCPA) and also bears a gluten-free claim will be misbranded unless the word "wheat" or the "contains wheat" statement are immediately followed by an asterisk that directs the consumer to the following disclaimer: "*The wheat has been processed to allow this food to meet the Food and Drug Administration (FDA) requirements for gluten-free foods*."

Very few of the other proposals in the 2007 proposed rule were included in the final rule. For example, FDA declined to define the terms "low-gluten," "very-low gluten" or other tiered labeling claims because the agency determined that there was no scientific basis for these claims. Additionally, the final rule specified no technical requirements for gluten-free labeling statements, including size, conspicuousness or placement of the statement. FDA also explicitly declined to establish the use of any universal symbol, logo or standardized print format to identify a gluten-free food. Nevertheless, companies who voluntarily label food products with a gluten-free claim must still comply with basic labeling regulations regarding prominence and conspicuousness, and gluten-free claims cannot appear as "intervening material" between mandatory label information (e.g., Nutrition Facts box, Ingredient List and manufacturer information).

Testing Methodologies & Certifications

One of the most significant omissions from the final rule is that manufacturers are not required to use any particular test methodology to detect gluten at levels of 20 ppm to ensure that foods bearing a gluten-free claim meet the regulatory definition. In its earlier proposed rule, FDA had considered whether to require manufacturers to have a scientifically valid method that could reliably detect gluten at 20 ppm prior to labeling foods with gluten-free claims. In fact, FDA had at one time selected the ELISA R5-Mendez Method as a precise and reliable analytical methodology to assess compliance with the gluten threshold level of 20 ppm. Ultimately, however, FDA concluded that specifying an analytical method in the final rule that manufacturers must use might limit flexibility and deter the development of new and better analytical methodologies. FDA stated in the comments section that any scientifically valid method that it will consider for use by manufacturers would be identified not in the final rule, but through other means, such as an FDA guidance document. However, FDA did indicate that it will use two enzyme-linked immunosorbent assays (ELISA)-based methods to determine compliance on its end—1) R-Biopharm: Food and Feed Analysis; and 2) Morinaga Institute of Biological Science: Wheat Protein ELISA Kit (Gliadin).

In the absence of any defined testing methodologies, manufacturers might wonder how to comply with the final rule. As it stands, manufacturers are free to develop their own methods that best suit their products and their needs to determine gluten content and whether gluten levels fall below the 20 ppm threshold. Companies may choose to have third parties certify or otherwise verify the gluten content of their products to ensure that any products bearing a gluten-free claim fall within the definition of gluten-free. However, just as FDA declined to mandate that manufacturers use a particular test methodology to certify their products, the agency also declined to require certifications, and thus, any companies who seek a certification would do so voluntarily.

Enforcement

Although the final rule will be effective in one month, manufacturers will have one year to comply with the rule, until **August 5, 2014**. This means that foods already on the marketplace, and even those foods that are shipped into commerce for approximately the next year, will not be scrutinized or otherwise deemed to be misbranded until the August 5, 2014, compliance date. Nevertheless, manufacturers should take note of this important rule, and begin the process of labeling revisions, or in some cases reformulation, in order to ensure compliance by the August 5, 2014, deadline. FDA enforces its regulations primarily through inspections, examination of imports, collection and testing of products and by imposing enforcement measures necessary to protect consumers. Alston & Bird's FDA Group has significant experience in this area and can assist you or your company with its compliance efforts.

***This advisory was written by* Donald Segal *and* Brendan Carroll.**

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