Understanding the FDA's Gluten-Free Labeling Rule Part 2: Focusing on Compliance

With:

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July 24, 2014

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NFCA's Resources about the FDA Ruling

- September 2013, *"Understanding the FDA's Gluten-Free Labeling Rule Part 1: What You Need to Know"*
  - Tricia Thompson, MS, RD, The Gluten-Free Dietitian, Nutrition Consultant and Founder of Gluten-Free Watchdog, LLC
  - Matthew Cox, Marketing Director for Bob's Red Mill Natural Foods
- Free downloadable fact sheet about the final ruling, including FAQs and basic info to know
- www.CeliacCentral.org/FDA

Learning Objectives

① Provide background on the definition of FDA's gluten-free labeling rule

② Discuss compliance of the final rule and FDA enforcement of gluten-free food labeling

③ Start an open dialogue between NFCA, consumers and industry by understanding and compiling your questions

- Using the "Questions" feature, please submit all questions and concerns about the ruling
- Identify yourself, e.g. gluten-free consumer, foodservice operator, food manufacturer, medical provider
- NFCA is compiling your feedback as a first step in understanding our community's needs

Welcome!

- Suzanne M. Wolcoff, MS, RD
- Senior Regulatory Review Officer
- Labeling Regulations and Implementation Team
- Office of Nutrition, Labeling and Dietary Supplements/Center for Food Safety and Nutrition
- U.S. Food and Drug Administration

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National Foundation for Celiac Awareness
July 24, 2014

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Senior Regulatory Review Officer
Labeling Regulations Implementation Team
Office of Nutrition, Labeling, and Dietary Supplements
Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration (FDA)

Purpose of Rulemaking to Define GF

- Responds to a *Food Allergen Labeling and Consumer Protection Act of 2004* (FALCPA) directive to define and permit use of the food labeling term gluten-free (GF).
- Intended to benefit consumers with celiac disease (CD) and food manufacturers by clarifying the specific requirements for GF labeling claims:
  - Will ensure that consumers with CD are provided with truthful, accurate, and not misleading labeling information to better assist them in identifying foods they can use following a GF diet.
  - Will promote fair competition among food manufacturers.

FDA's Final Rule

- **"Gluten-free" food cannot contain:**
  - ingredients that are a gluten-containing grain (e.g., spelt wheat) **OR**
  - ingredients derived from a gluten-containing grain that have not been processed to remove gluten (e.g., wheat flour) **OR**
  - ingredients derived from a gluten-containing grain that have been processed to remove gluten (e.g., wheat starch) if the use of that ingredient results in the presence of 20 parts per million (ppm) or more gluten in the food (i.e., 20 milligrams (mg) or more gluten per kilogram (kg) of food) **OR**
  - The food inherently does not contain gluten (e.g., orange juice); and
  - Any unavoidable presence of gluten in the food is below 20 ppm gluten (i.e., below 20 mg gluten per kg of food)

FDA's Final Rule

- **"Gluten-containing grain" means any of the following grains or their crossbred hybrids (e.g., triticale):**
  - Wheat (i.e., any *Triticum* species)
  - Rye (i.e., any *Secale* species)
  - Barley (i.e., any *Hordeum* species)
  - **"Gluten" means the proteins that naturally occur in a gluten-containing grain and that may cause adverse health effects in persons with CD (e.g., prolamins and glutelins).**

FDA's Final Rule

- A food that bears a "gluten free," "no gluten," "free of gluten," or "without gluten" labeling claim will be deemed misbranded if the food does not comply with the definition of "gluten-free."
- Other terms regarding the absence of gluten will be evaluated under our general false and misleading misbranding provisions.

FDA's Final Rule

- A food that bears the term "wheat" in the ingredient statement or in a "Contains wheat" statement in its labeling as required by FALCPA and also bears a gluten free claim will be deemed misbranded unless the word "wheat" is followed by an asterisk that refers to the statement, "***The wheat has been processed to allow this food to meet the Food and Drug Administration (FDA) requirements for gluten-free foods.***"

<20 ppm Gluten Threshold

- Use of analytical method-based approach to establish a gluten threshold of < 20 ppm as a criterion to define the term GF.
- To FDA's knowledge, 20 ppm is currently the lowest level at which an ELISA-based method to detect gluten has been validated where the results have been published in the peer-reviewed scientific literature.
- Identify in codified language the analytical methods (i.e., proposed "ELISA R5 Mendez Method" and the "Morinaga method") that FDA will use for enforcement purposes.

Major Reasons for Using An Analytical Methods-Based Approach

- Use of a < 20 ppm gluten threshold is consistent with:
  - **international standards that define GF adopted in Europe**
  - **statements by some researchers and epidemiologic evidence reported in the scientific literature indicating that variable trace amounts of gluten in foods can be safely tolerated by most persons with CD**
- Analytical methods validated to detect gluten in foods at lower than 20 ppm gluten are not available. -- Validated methods are essential to FDA's enforcement of a regulatory definition of GF.

Major Reasons for Using An Analytical Methods-Based Approach

- Uncertainty about the ability of manufacturers of multi-ingredient foods, especially grain-based products, to comply with a gluten threshold much lower than < 20 ppm.
- Questionable whether a gluten threshold level lower than < 20 ppm would:
  - **make it more difficult or costly for persons with CD to adhere life-long to a GF diet**
  - **increase the prevalence of persons with CD not adhering to a GF diet; thereby, placing them at higher risk of developing serious health complications and other diseases associated with CD**

Major Reasons for Using An Analytical Methods-Based Approach

- Questionable whether a gluten threshold level lower than < 20 ppm would:
  - **influence some U.S. food manufacturers to discontinue labeling their products GF because they cannot consistently meet this lower gluten level**
  - **discourage other U.S. food companies from becoming manufacturers of products labeled GF**
  - **result in a significant increase in the cost of food labeled GF**
  - **negatively impact international trade of foods labeled GF which could affect the availability of certain foods to persons with CD**

FDA's Final Rule

Compliance –

When compliance is based upon an analysis of the food, FDA will use a scientifically valid method that can reliably detect the presence of 20 ppm gluten in a variety of food matrices (e.g., raw, cooked or baked).

Preemption –

No state or political subdivision may establish or continue into effect any law, rule, regulation or other requirement that is different from the definition for the use of the terms, "gluten-free," "no gluten," "without gluten," or "free of gluten."

FDA Position on Defining GF

- FDA will remain open to the feasibility and desirability of revising the gluten threshold level that the agency adopts to define the term GF in a final rule considering:
  - **the availability of more sensitive analytical methods that can detect gluten**
  - **further research on CD in the future that indicates that use of a lower gluten threshold level is warranted to be adequately protective of the CD population**
- FDA's Primary Goal: Define the term GF in a way that protects the vast majority of persons with CD without unnecessarily restricting their food choices or making it more difficult or costly for them to adhere life-long to a GF diet.

For More Information

- Gluten-Free Labeling of Foods Final Rule

http://www.gpo.gov/fdsys/pkg/FR-2013-08-05/pdf/2013-18813.pdf

- Q&A: Gluten-Free Food Labeling Final Rule

http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Allergens/ucm362880.htm

- Guidance for Industry: Gluten-Free Labeling of Foods; Small Entity Compliance Guide
  http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm402549.htm

Hydrolyzed and Fermented Foods

- **FDA will engage in additional rulemaking to establish how it will determine compliance for hydrolyzed and fermented foods (e.g., yogurt, sauerkraut, hydrolyzed protein) because the current ELISA methods can not quantify gluten in these foods.**

- **In the interim, hydrolyzed and fermented foods that meet the definition may bear a gluten free claim (manufacturers can implement measures that are necessary to prevent the introduction of gluten into the food that will ensure that the finished product will comply with the definition).**

Beer

- **FDA will exercise enforcement discretion to beers that currently make a "gluten-free" claim and that are:**
  - Made from a non-gluten-containing grain OR
  - Made from a gluten-containing grain, where the beer has been subject to processing that the manufacturer has determined will remove gluten.
- **This enforcement discretion pertains only to beers subject to FDA's jurisdiction and that were making a "gluten-free" claim as of August 5, 2013.**
- **Note: FDA regulates non malt beers (beers made without malted barley or hops)**

Compliance of the Final Rule

- The effective compliance date of the rule is August 5, 2014. Products labeled by the manufacturer prior to this compliance date that bear the claim "gluten-free" will not be subject to regulatory action by FDA. However, any product labeled by the manufacturer on or after August 5, 2014, bearing a "gluten-free" labeling claim that does not comply with the definition will be subject to regulatory action by FDA.
- To determine compliance based on analysis of the food, FDA will use a scientifically valid method that reliably detects 20 ppm gluten in various food matrices. Analysis will not be required if label declarations support violative declarations of the claim.

Compliance of the Final Rule

- Foods labeled “gluten-free”, “no gluten”, “free of gluten”, or “without gluten”, will be deemed misbranded under section 403(a)(1)/201(n) of the Act:
- If the food does not comply with the definition of “gluten-free” (21 CFR 101.91(a));
- If the food bears the term “wheat” in the ingredient statement or in a “Contains wheat” statement in its labeling as required by FALCPA and also bears a “gluten-free” claim unless the word “wheat” is followed by an asterisk that refers to the statement “The wheat has been processed to allow this food to meet the FDA requirements for gluten-free foods.” 21 CFR 101.91(b)
- Other terms regarding the absence of gluten will be evaluated under FDA’s general misbranding provisions.

How to Report a Problem

- Use of the Consumer Complaint System and MedWatch
  - http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm049087.htm
- Report adverse events to MedWatch at1-800-FDA-1088, Mon-Fri between 8 am – 4:30 pm EST.
- MedWatch Online Voluntary Reporting Form
  - https://www.accessdata.fda.gov/scripts/medwatch/
- Consumers and manufacturers can report any complaint such as misuse of GF claim on food labels in the state where purchased to their local FDA Consumer Complaint Coordinator
  - http://www.fda.gov/Safety/ReportaProblem/ConsumerComplaintCoordinators/default.htm

Consumer Complaint Reporting

- FDA has Consumer Complaint Coordinators (CCC's) located throughout the U.S. and Puerto Rico.
- Report problem with FDA regulated food to CCC's. Be sure to have the package available when reporting the product.
- Depending on the situation, an FDA investigator may visit the person who made the complaint, collect samples, initiate an investigation.

MedWatch Reporting

- Use to report adverse events (unexpected side effects) when using an FDA regulated product.
- Every MedWatch report is recorded in an FDA database for review and comparison to similar reports.
- Online/mail with FDA form 3500
- Fax: 1-800-FDA-0178
- Phone: 1-800-FDA-1088

Product Recalls

- The classification of recalls is done on a case-by-case basis based on various factors.
- Complaints can be made to the district complaint coordinators which in turn can be brought to the Center for Food Safety and Applied Nutrition (CFSAN) for consideration of a product recall.
- Please see FDA's website for identifying recalled products http://www.fda.gov/forconsumers/consumerupdates/ucm248864.htm

FDA Enforcement of Food Labeling

- FDA routinely inspects food manufactures for both Good Manufacturing Practices (GMPs) as well as food labeling.
- If a food manufacturer violates the GMPs or food labeling regulations that are mandated by the Food, Drug, and Cosmetic Act (the Act), the food is adulterated/misbranded and a Warning Letter (WL) may be issued.
- The WL specifically outlines the GMP and labeling violations of the Act and gives 15 working days for the firm to respond to FDA.
- Failure to promptly correct violations can result in seizures and/or injunctions.

Example of FDA Issued WL

- Nicola Pizza, Inc. 6/10/10
- View the WL at http://www.fda.gov/iceci/enforcementactions/warningletters/2010/ucm217573.htm
- Product misbranded for various violations including failure to declare major food allergen, wheat.
- Browse WLs by subject http://www.accessdata.fda.gov/scripts/warningletters/wlFilterBySubject.cfm

GF Labeling in Restaurants

- The GF final rule applies to packaged foods. FDA expects restaurants that choose to use "gluten-free" in labeling of their foods to be consistent with the federal definition.
- Given the public health significance of "gluten-free" labeling, we encourage the restaurant industry to be mindful of the use of gluten-free labeling. We encourage consumers to inquire what GF means in each restaurant that uses the GF claim.
- FDA's Retail Food Protection Team works with stakeholders to revise the Food Code to include issues such as food allergens and GF. Please contact the CFSAN Information Center at http://cfsan.force.com/Inquirypage for any retail food related questions.

As we finish…

Questions from the audience?

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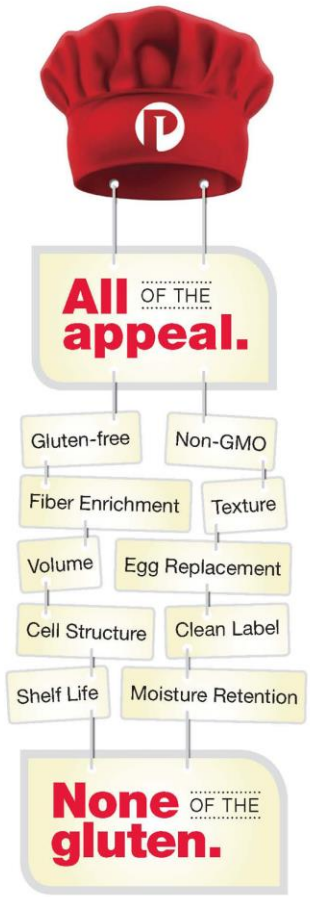

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  - Matthew Cox, Marketing Director for Bob's Red Mill Natural Foods
- Free downloadable fact sheet about the final ruling, including FAQs and basic info to know
- www.CeliacCentral.org/FDA

Save the Date!

www.CeliacCentral.org/webinars

Topic: "The Realities of Living with Celiac Disease in College"

Date: Tuesday, August 19, 2014

Time: 8:30 p.m. EDT/5:30 p.m. PDT

Speakers:

- Priyanka Chugh, blogger for Adventures of Anti-Wheat Girl
- Brandon Meck, vice president of Gluten-Free My Campus at the University of Pittsburgh
- Rachel Rieger, recently graduated from the College of Wooster and NFCA Patient Education Manager

Topic: Gluten-Free in K-12 Schools: What GREAT Schools Can Do for You

Date: Wednesday, September 17, 2014

Time: 8pm EDT/5pm EDT

Speakers:

- Beckee Moreland, NFCA Director of GREAT Kitchens Program
- Jessie Coffey, Lincoln Public Schools, Nebraska

Thank You!

Please submit all concerns and questions about the FDA gluten-free labeling rule to the NFCA team at webinars@CeliacCentral.org

- ***Important! Identify yourself, e.g. gluten-free consumer, foodservice operator, food manufacturer, medical provider***

To submit questions about the gluten-free labeling rule directly to the FDA:

Email: GlutenFreeFinalRuleQuestions@fda.hhs.gov

Food and Cosmetics Information Center Inquiry Form: http://cfsan.force.com/Inquirypage

Connect with NFCA:

