Recalls, Warning Letters & Enforcement Actions

FDA tools for compliance; trends in enforcement and brand impact

Before FDA Comes

- Guidances
- Letters
- Rules

CHAPTER 03 - FOODBORNE BIOLOGICAL HAZARDS

SUBJECT:	IMPLEMENTATION DATE
	Upon Receipt
DOMESTIC AND IMPORTED CHEESE AND CHEESE PRODUCTS	COMPLETION DATE
	CONTINUING

DATA REPORTING

PRODUCT CODES	PRODUCT/ASSIGNMENT CODES
INDUSTRY CODE: 12 USE APPROPRIATE PRODUCT CODES	1. REPORT INSPECTIONS UNDER THE FOLLOWING PACS: 03037 Inspections, Investigations, and Sample Collections 03037B Filth Analysis 03037D Microbiological and Phosphatase Analyses

FIELD REPORTING REQUIREMENTS

NOTE: MICROBIOLOGICAL AND FILTH WORK FOR ALL CHEESE AND CHEESE PRODUCTS ARE COVERED UNDER THIS COMPLIANCE PROGRAM. MISUSE OF CHEMICALS BY THE FIRM AND COVERAGE OF ALL FOOD AND COLOR ADDITIVES IN CHEESE AND CHEESE PRODUCTS ARE COVERED UNDER THE DOMESTIC FOOD SAFETY (7303.803) AND IMPORTED FOODS - FOOD AND COLOR ADDITIVES (7309.006) COMPLIANCE PROGRAMS.

NUTRITION LABELING (NLEA), NUTRIENT CONTENT OPERATIONS, STANDARDS AND IDENTIFICATION FOR CHEESE AND CHEESE PRODUCTS ARE COVERED UNDER THE DOMESTIC AND IMPORT FOOD LABELING ENFORCEMENT (7321.005) COMPLIANCE PROGRAM.

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- About FDA guidance documents
- Browse guidance document collections by topic
- Commenting on guidance documents
- Report on good guidance practices
- FDA acronyms and abbreviations

Guidance for Industry and FDA: Dear Manufacturer Letter Regarding Food Labeling

Contains Nonbinding Recommendations

Guidance for Industry and FDA [1]
Dear Manufacturer Letter Regarding Food Labeling

This guidance document represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this document.

Dear Manufacturer:

The Food and Drug Administration (FDA) is reminding manufacturers and distributors of conventional food products about the different types of labeling claims available for use on conventional food products and how these claims are regulated by the Agency. Currently, claims that appear on conventional food labels and labeling generally fall into the

FDA also recognizes that information available through the Internet, including those websites that provide truthful and non-misleading information about conventional food products can serve a valuable and useful function. FDA addressed the issue of food product labeling and the Internet in a November 1, 2001 letter to the Washington Legal Foundation, which is available at http://www.cfsan.fda.gov/~dms/labwww.html. In certain circumstances, information that is disseminated over the Internet by, or on behalf of, a regulated company meets the definition of labeling in section 201(m) of the Act and is subject to the requirements of the Act. For example, if a company were to promote a regulated product on its website and allow consumers to purchase the product directly from the website, the website is likely to be "labeling." As another example, if the label for a product contained a statement that referred the consumer to a specific website for additional information about a claim for the product, the website is likely to be "labeling." The websites, in these cases, are considered written, printed, or graphic matter that supplements or explains the product and is designed for use in the distribution and sale of the product.

food allergen), section 403(w)(1)(B) of the Act, 21 U.S.C. § 343(w)(1)(B).

Further guidance and information on food allergens can be accessed on FDA's website at http://www.fda.gov/Food/LabelingNutrition/FoodAllergensLabeling/default.htm [2]

4.) Your Shrimp Egg Roll product is misbranded within the meaning of Section 403(i)(2) of the Act [21 U.S.C. § 343(i)(2)] because it is fabricated from two or more ingredients, and the label fails to declare the common or usual name of each ingredient as required by 21 CFR 101.4(b). For example:

- You fail to declare the **(b)(4)** ingredient as well as its sub-ingredients used to manufacture your product.
- The statement "fried in vegetable oil" is not provided for in 21 CFR 101.4." Fat and/or oil ingredients must be declared in accordance with 21 CFR 101.4(b)(14).

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating.

Failure to implement lasting corrective action of these violations may result in regulatory action being initiated by FDA without further notice. For example, we may take further action to seize your products and/or enjoin your firm from operating.

In addition, we note the following labeling issues:

1. Your Swiss Mix, Mexicali Corn, and Toasted Com products fail to bear the common or usual name of each ingredient as required by 21 CFR 101.4(b). Specifically:

a. Your Swiss Mix product label declares the ingredient "part hydrog palm kernel oil", an abbreviation of a specific common or usual name, and your Mexicali Corn and Toasted Corn product labels declare the ingredient "vegetable oil". According to 21 CFR 101.4(b)(14), each individual fat and/or oil ingredient of a food intended for human consumption shall be declared by its specific common or usual name (e.g., "beef fat," "cottonseed oil", "partially hydrogenated palm kernel oil").

b. Your Sierra Mix ingredient label declares the ingredients "gran" and "sa", which appear to be abbreviations of a specific common or usual name. According to 21 CFR 101.4(b), the label must bear the specific name of each ingredient (e.g., "salt").

c. Your Sierra Mix product is made with ingredients, some of which are themselves comprised of multiple ingredients,. including chili crescents. However, the chili crescent sub-ingredients are not listed on the product label in accordance with 21 CFR 101.4(b)(2). Additionally, Sierra Mix product label incorrectly lists the sub-ingredients for the ingredient "sesame sticks". The sub-ingredients for the "sesame sticks" ingredient are listed between dashes after the name of the main ingredient, "sesame sticks - flour, sesame seeds, bulgar [sic] wheat, salt, garlic/onion powder, soy, gran [sic], garlic, beet color, turmeric, soybean oil-".

After FDA Comes

- 483 and exit interview
- Warning Letters
- Recalls
- Justice Department

Compliance & Enforcement

To protect public health, FDA monitors domestic firms and the foods that they produce. FDA also has multiple initiatives for monitoring imported products and foreign firms exporting to the United States. FDA protects consumers from unsafe foods through:

- Research and methods development
- Inspection
- Sampling
- Recall
- Seizure
- Injunction
- Criminal prosecution

This section provides access to FDA's warning and untitled letters, information about inspection and compliance programs, and the Reportable Food Registry.

CFSAN Adverse Event Reporting System (CAERS) (/Food/ComplianceEnforcement/ucm494015.htm)

A database that contains information on adverse event and product complaint reports submitted to FDA for foods, dietary supplements, and cosmetics.

Warning Letters (/Food/ComplianceEnforcement/WarningLetters/default.htm)

When FDA finds that a manufacturer has significantly violated FDA regulations, FDA notifies the manufacturer. This notification is often in the form of a Warning Letter.

Untitled Letters (/Food/ComplianceEnforcement/UntitledLetters/default.htm)

Untitled letters address violations from manufacturing controls or labeling that do not meet the threshold of regulatory significance for a Warning Letter. Untitled letters can also be issued to websites.

Reportable Food Registry (/Food/ComplianceEnforcement/RFR/default.htm)

The Reportable Food Registry is an electronic portal for industry to report when there is reasonable probability that an article of food will cause serious adverse health consequences. The Reportable Food Registry helps FDA better protect public health by tracking patterns and targeting inspections.

Inspections (/Food/ComplianceEnforcement/Inspections/default.htm)

Learn about how FDA helps keep food safe through inspections, including the Foreign Food Inspection Program and inspections of aircraft water systems.

Sampling (/Food/ComplianceEnforcement/Sampling/default.htm)

Field Management Directive 120

Subject:
FDA-483, Inspectional Observations
Area:
Operations Management
Date Revised:
December, 29 2009

FIELD MANAGEMENT DIRECTIVE No. 120

PURPOSE

This Field Management Directive (FMD) describes policies for the quality review, distribution of Inspectional Observations (FDA 483), and general guidance for handling unsolicited responses resulting from the issuance of FDA 483s.

BACKGROUND

Inspectional Observations (FDA 483) are of critical importance to both the Agency and regulated industry. Individual FDA 483s may become public, from a Freedom of Information (FOI) inquiry, soon after an inspection ends. The Food and Drug Administration (FDA) frequently receives unsolicited responses to FDA 483s issued at the conclusion of inspections. These responses may be directed to various persons in the Agency: e.g., the investigator who performed the inspection, the District Director, a Center Director, or the Commissioner. Responses can range from proposed or completed corrections of the FDA 483 items, or a general acknowledgement the firm is evaluating the items listed, to a rebuttal of the items on the FDA 483 with no intent of correction.

GUIDANCE

All FDA 483s should adhere to the following general principles:

1. Observations which are listed should be significant and correlate to regulated products or processes being inspected.
2. Observations of questionable significance should not be listed on the FDA 483, but will be discussed with the firm's management so that they understand how uncorrected problems could become a violation. This discussion will be detailed in the EIR.

All FDA 483s should have the following characteristics to be useful and credible documents:

1. Each observation should be clear and specific.
2. Each should be significant. Length is not necessarily synonymous with significance.
3. Observations should not be repetitious.
4. The observations should be ranked in order of significance.

1. Distribution

The original FDA 483 is to be presented to the most responsible management official available at the firm upon completion of the on-site inspection. Where possible, this is the individual to whom the "Notice of Inspection" was issued. If the person is not available or is outranked by someone else, present the FDA 483 to the individual who meets the definition of owner, operator, or agent in charge. A copy of the FDA 483 will be sent to the top management official of the firm inspected unless the individual who received the original FDA 483 is the same person.

It is important to note that an exact copy of the FDA 483 is to be submitted with the EIR and kept in the official establishment file.

District management will avoid prolonged delays in sending the FDA 483 to top management while waiting for a Warning Letter or other correspondence to be approved and issued.

2. Response to FDA 483 Received

Unsolicited contact or correspondence concerning a FDA 483 is to be considered an effort by management of a firm to notify FDA of planned or completed corrections, or at least, that they are aware of the FDA 483 and are considering its ramifications.

Districts will issue a timely reply to all contact and correspondence from firms regarding FDA 483s. The type and depth of the reply will be based on the content of the contact or correspondence received.

The firm may request clarification, criticize FDA 483 items, disagree with the FDA 483, or raise other questions or issues. In these cases, the District will evaluate the firm's information and send the District's conclusion to the firm. A copy shall also be sent to the official establishment file.

Do not prepare a response which can be construed by the firm as an endorsement of its actions unless such a response is appropriate (which should usually be reserved until after verification). Be cognizant of the effect a reply may have on anticipated or ongoing regulatory actions against the firm.

Where no additional issues are to be discussed, simply acknowledging receipt of the firm's response and indicating that it will become a part of the official file will suffice.

The Home District will prepare the response, regardless of the office that received the correspondence from the firm.

WARNING LETTER
CIN-17-512640-05

VIA UPS

[redacted]

Louisville, KY 40203

Dear [redacted]

This is to advise you that the Food and Drug Administration (FDA) has reviewed your websites at the Internet address [redacted] in March 2017 and has determined that you take orders there for the product [redacted]. We have also reviewed your website at the Internet address [redacted], which you link to from your website [redacted] n where this product can be purchased directly. The claims on your websites establish that your product is a drug under section 201(g)(1)(B) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 321(g)(1)(B)] because it is intended for use in the cure, mitigation, treatment, or prevention of disease. As explained further below, introducing or delivering this product for

introduction into interstate commerce for such uses violates the Act. You can find the Act and FDA regulations through links on FDA's home page at **http:// (http://www.fda.gov/)www.fda.gov. (file:///C:/Users/Pamela.Ferrarelli/Documents/www.fda.gov)**

Examples of some of the website claims that provide evidence that your product is intended for use as a drug include:

- "Inhibit Malignant Progression of Lung Adenomas Induced by Tobacco,"
- "Sulforaphane and skin Tumors,"
- "Isothiocyanates as Cancer Chemopreventive Agents,"
- "Sulforaphane Protects Against UV light-induced skin carcinogenesis."

Jimmy's Cookies LLC Issues Allergy Alert on Undeclared Milk in The Bakery Peanut Butter Chocolate Chunk Cookies LOT# 047

The recall was initiated after it was discovered that the product containing milk was distributed in packaging that did not reveal the presence of milk. Subsequent investigation indicates the problem was caused by a temporary breakdown in the company's labeling processes.

Unilever Issues Allergy Alert on Undeclared Peanut in Limited Quantity of Ben & Jerry's Chocolate Fudge Brownie Pint Slices

Unilever is voluntarily recalling a limited number of boxes of Ben & Jerry's Chocolate Fudge Brownie Pint Slices, which may inadvertently contain Vanilla Peanut Butter Cup Pint Slices. Although the slices were individually wrapped and identified as Vanilla Peanut Butter Cup Pint Slices, the ingredient peanut butter (containing the known allergen peanut), is undeclared on the outer product packaging. Persons who have an allergy or severe sensitivity to peanuts run the risk of a serious or life-threatening allergic reaction if they consume the product.

This limited voluntary recall is being conducted in cooperation with the U.S. Food and Drug Administration (FDA).

CHAPTER 2- REGULATORY

CONTENTS

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 05 - 12

President

Minneapolis, Minnesota 55408

Dear

On December 20 and 22, 2004, an investigator from the Food and Drug Administration, conducted an inspection of your facility at Minneapolis, Minnesota. During this inspection, the investigator collected label samples from several of your firm's products. After reviewing the labeling for your products Healthy Hemp Sprouted Bread, Health Seed Spelt Wheat-Free Yeast-Free Bread, and Cinnamon Raisin Spelt Yeast Free-Organic Bread (each in 24 ounce packages) FDA concludes that these products violate provisions of the Federal Food, Drug, and Cosmetic Act (the Act). Regulations implementing requirements of the Act are found in Title 21, Code of Federal Regulations (21 CFR). Links to the Act and its regulations may be found at our web site, *www.fda.gov.*

Healthy Hemp Sprouted Bread

The product labeling includes the statement, "hempseed is one of the most nutritious plant foods available with ... a near-perfect composition of the essential fatty acids, Omega 3 & 6. These 'good fats' are necessary for optimum health by lowering cholesterol...." This claim indicates that the product is intended for use in treatment, prevention, or mitigation of hypercholesteremia and other cardiovascular diseases. Such claims are evidence that the product is intended for use as a drug within the meaning of section 201(g)(1)(B) of the Act [21 U.S.C. 321(g)(1)(B)].

We request that you notify this office in writing within 15 working days of receipt of this letter stating the actions you will take to correct the violations and to prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Failure to make prompt corrections may result in further enforcement action being initiated by the Food and Drug Administration. This could include seizure of illegal products and injunction against the manufacturer of illegal products.

Center for Food Safety and Applied Nutrition

GOOD NEWS, BAD NEWS

Bakery Products

Seizure and Consent Decree of Condemnation and Injunction

Spelt (a Derivative of Wheat) Bread Labeled as "Wheat Free"

On January 25, 2006, United States District Judge Michael Davis entered a Consent Decree of Condemnation and Injunction in this seizure of misbranded food. The articles were misbranded because their labeling declared them to be "wheat free" or a "wheat alternative" when, in fact, they consisted in part of either spelt or Kamut®, which can cause adverse reactions in wheat-sensitive individuals.

The decree requires the Claimant, y, to: (1) pay $200,000 in the form of a cashier's check, to serve as a bond; (2) develop an appropriate reconditioning plan; (3) recondition the articles of food under FDA supervision; and (4) pay FDA's costs, including FDA's future costs of supervising compliance with the decree. The decree permanently enjoins Claimant from introducing misbranded food into interstate commerce and from causing food to become misbranded. The decree also contains a liquidated damages clause.

The Consent Decree of Condemnation and Injunction follows the seizure of bakery products, bread, toast, bagels, Kamut bread, and pizza crusts located at January 2006.

FDA investigators from the Minneapolis District Office accompanied the U.S. Marshals Service in a seizure of over 27,000 loaves of bread and Texas toast, with a retail value of $107,998. The products were located a

Previously, in April 2005, FDA issued a Warning Letter to advising the firm that the claim "Wheat Free" on the label of a product containing spelt, a species of wheat, is false and misleading and constitutes misbranding under 21 U.S.C. 343(a)(1). The letter also advised the firm that failure to make prompt corrections could result in further enforcement action, including seizure and/or injunction. After the firm proposed labeling revisions that did

not correct this problem, FDA issued a letter dated September 7, 2005, advising the firm that appropriate labeling corrections must be completed and implemented expeditiously.

A subsequent FDA inspection conducted November 16-23, 2005, revealed that the firm had not corrected the labeling, and FDA again advised the firm of the problem. The firm indicated that labeling revisions would be made, but that revised labels would not be implemented until the current stocks of labels were depleted. The existing label stocks were estimated to last another four to nine months for the various products. The firm's failure to comply with FDA regulations resulted in seizure of the products.

Consent Decree of Permanent Injunction -

On February 3, 2006, U.S. District Judge William C. Griesbach entered a Consent Decree of Permanent Injunction against [redacted] Inc., and its officers and directors. The Complaint alleged that the defendants violated the Act by introducing misbranded foods, including dietary supplements, and misbranded and unapproved drugs into interstate commerce and by causing foods to become misbranded. The labels on the defendants' bakery products did not accurately represent the actual content of the nutrients. The Complaint for Permanent Injunction detailed the firm's 20-year history of non-compliance with the Act and Federal regulations.

The Decree requires the defendants to hire experts to ensure that each product contains the quantity of each nutrient listed in the product's labeling and the omission of any claims that cause the products to be drugs within the meaning of the Act. In addition, within 20 days of the entry of the Decree, defendants must sample each of their finished food products and have them tested by a laboratory to ensure that the samples contain the quantity of each nutrient listed in the labeling. After this initial testing, defendants must sample each product and have the products tested at least three times per year. The Decree also provides letter shutdown authority and a provision for liquidated damages of $1,000 per day, per product, for each violation.

Top News

Jan 11, 2006 8:27 am US/Central

FDA Seizes 5,000 Cases Of Bread

Minneapolis (AP) — Federal authorities seized more than 30,000 loaves of bread from th[illegible]ery and a storehouse on Tuesday, accusing the company of mislabeling the products as wheat-free.

The products contain the grain spelt, which U.S. Attorney Thomas Heffelfinger said shares common proteins with wheat and is just as dangerous to those allergic to wheat.

The bakery said it considers spelt to be an alternative to wheat.

Wheat allergies are among the most common of food allergies and can be life-threatening, especially to children, according to the U.S. Food and Drug Administration.

"Mislabeling actually creates a serious health risk in a significant percentage of the population," Heffelfinger said.

Some of the products contain Kamut, a similar grain.

The FDA warned last April to relabel its loaves, but the company kept its original wheat-free labels anyway, according to papers filed in federal court.

, co-owner said the company has sold millions of loaves of spelt bread for 16 years with only one allergic reaction reported. But he said the company will change the labels once the new wording is approved.

"Spelt is an ancient grain. People with wheat allergies can tolerate spelt," said.

Under recently revised Food and Drug Administration labeling rules involving allergens, bread containing spelt and Kamut cannot carry labels describing them as "wheat-free" or "wheat-alternative."

Bea Krinke, a professor at the University of Minnesota's School of Public Health, was surprised to hear that had been labeling its spelt and Kamut bread that way.

"Spelt is a primitive form of wheat," said Krinke, a registered dietitian. "I would tell people who were allergic to wheat to avoid spelt as well."

The bread will remain frozen until the case is settled. Heffelfinger said none of the products already on food store shelves across the country will be recalled because the bread likely would exhaust its shelf life by the time a recall could be issued.

Trends

- ALLERGENS
- ALLERGENS
- ALLERGENS

Trends

- Claims

On the "New research indicates consumption of broccoli sprouts may reduce high blood pressure, risk of heart disease, stroke" PDF:

- "glucoraphanin, also known as sulforaphane glucosinolate (SGS(TM)), a naturally-occurring compound found in broccoli sprouts and broccoli, may reduce risk of high blood pressure, cardiovascular disease and stroke,"
- "can correct major dysfunctions such as hypertension and stroke,"
- "reduce their risk of cardiovascular disease."

Helping Yourself

- Relationships
  - Organizations
  - Networking
- Attitudes
  - Cooperative

Penny Hennessy

- Penny has been employed with Rich Products Corporation since 1988. She is currently Manager, QA & Regulatory Affairs.
- Her duties include all labeling approvals and development of graphics in coordination with Marketing as well as government liaison for the Consumer Brands Division. She is a member of AFDOSS; GMA's Regulatory, Inspection and Compliance Committee and the Georgia Food Industry group.
- Penny graduated from Barry College (now University) in Miami, Florida, with a B.A. in History.