USDA and FDA Actions

ANPR

Advanced Notice of Public Rulemaking

A notice from the government wants to change regulations

Describes and asks questions about potential rule making

Published in Federal Register

Comments are accepted for a defined period of time

Final Rule

Notice that a regulation has been changed

- Includes date of the rule if effective
- Review of comments submitted in the proposed rule

Includes new CFR language

Preamble

- Supplemental information about the final rule

Interim Final Rule

A final rule that is published without a proposed rule

Allows for public comment on the final rule

May be changed at a later date

Typically done for food safety issues

- Rarely seen on labeling issues
- Omega 3 was published as interim final rule

Federal Notices

Items published in the federal register that are not law

Typically informing people in an official way of changes or request

Examples

- Grant requests
- Committee appointments (Dietary Guidelines)
- AMS bids
- Fees for service
- Uniform compliance date

Uniform Compliance Date

USDA and FDA set a date where all labeling changes are finalized

Help industry combine label changes

Regulations published between specified dates have 1 effectivity date

Example:

- Published between Jan 1, 2015 and Dec 31, 2016
- Jan 1, 2018 compliance date

Are not required to use uniform compliance date

Writing Federal Register Comments

Must include docket number

- Provided in the ANPR

Start with a thank you paragraph to government agency

List comments clearly and concisely

Use sub-headings to make comments clear

1 comment per paragraph

End with a thank you for being allowed to comment

Submitting Comments

Submitted online

- Hard copies in confidential company information is included
  - Very little confidential information is submitted in comments
  - Information can be summarized so not confidential

Submitted the day comments are due

- To prevent time for others to rebut your comments

Petitions

Making a request to the FDA for changes

Will confirm receipt

May or may not accept

Will respond with ANPR in Federal Register

FDA Guidance Documents

Documents that provide FDA position on a topic without being a law or regulation

Used to assist industry and inspectors in best practices

FDA will publish a documents in draft form

Notice is published in Federal Register to industry

Comments are received on the guidance

Final guidance is issued

List of some documents follows

FDA Guidance Documents cont…

Voluntary Labeling Indicating Whether Food Has or Has Not Been Derived From Genetically Engineered Atlantic Salmon

Voluntary Labeling Indicating Whether Food Has or Has Not Been Derived From Genetically Engineered Plants

Questions and Answers on FDA's Fortification Policy

Food Allergen Labeling Exemption Petitions and Notifications

A Labeling Guide for Restaurants and Retail Establishment Selling Food-Away-From-Home Part II

FDA's Policy on Declaring Small Amounts of Nutrients and Dietary Ingredients on Nutrition Labels

Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments; Small Entity Compliance Guide

Labeling of Certain Beers Subject to the Labeling Jurisdiction of the Food and Drug Administration

Gluten-Free Labeling of Food; Small Entity Compliance Guide

FDA Guidance Documents cont…

Proper Labeling of Honey and Honey Products

Question and Answers About the Food Additive Petition Process

Food Additive Expedited Review

Cochineal Extract and Carmine: Declaration by Name on the Label of All Foods and Cosmetic Products that Contain These Colors Additives Small Entity Compliance Guide

Ingredient Declaration as Evaporated Cane Juice

Letter Regarding Point of Purchase Food Labeling

Evidence-Based Review System for Scientific Evaluation of Health Claim

Food Labeling: Health Claims; Calcium and Osteoporosis, and Calcium, Vitamin D, and Osteoporosis Small Entity Compliance Guide

A Food Labeling Guide

FDA Guidance Documents cont…

Dear Manufacturer Letter Regarding Front-of-Package Symbols

A Labeling Guide for Restaurants and Retail Establishments Selling Away-From-Home Food Part I

Control of Listeria Monocytogenes in Refrigerated or Frozen Ready-To-Eat Foods

Standard of Identity for White Chocolate; Small Entity Compliance Guide

Food Labeling; Nutrition Content Claims; Definition for “High Potency” and Definition for “Antioxidant” for Use in Nutrient Content Claims for Dietary Supplements and Conventional Foods; Small Entity Compliance Guide

Dear Manufacturer Letter Regarding Food Labeling

FDA Guidance Documents cont…

Small Business Nutrition Labeling Exemption

Dear Manufacturer Letter Regarding Sugar Free Claims

Food Labeling: Trans Fatty Acids in Nutrition Labeling, Nutrient Content Claims, and Health Claims Small Entity Compliance Guide

Interim Procedures for Qualified Health Claims in the Labeling of Conventional Human Foods and Human Dietary Supplements

Implementation of Section 10809 of the Farm Security and Investment Act of 2002, Pub. L. No 107-171, 10809 (2002) Regarding the Petition Process to Request Approval of Labeling for Foods That Have Been Treated with Irradiation

Exemptions From the Warning Label Requirement for Juice – Recommendations for Effectively Achieving a 5-Log Pathogen Reduction

Serving Size Reference Amount for Baking Powder, Baking Soda, Pectin; Small Entity Compliance Guide

Food Labeling – Safe Handling Statement, Labeling of Shell Eggs; Refrigeration of Shell Egg Held for Retail Distribution; Small Entity Compliance Guide

FDA Guidance Documents cont…

Notification of a Health Claim or Nutrient Content Claim Based on an Authoritative Statement of a Scientific Body

FDA Nutrition Labeling Manual – A Guide for Developing and Using Data Bases

Labeling Declaration of Allergenic Substances in Food; Notice to Manufacturers

Guidelines for Determining Metric Equivalents of Household Measures

FDA Policy Guidelines

FDA products additional information

Designed to assist FDA inspectors and food companies

Does not have the same force as a regulation

List of items related to food

Compliance Policy Guides

540.700 Labeling of Processed and Blended Seafood Products Made Primarily with Fish Protein

510.800 Beverages Serving Size Labeling

555.250 Statement of Policy for Labeling and Preventing Cross-Contact of Common Food Allergens

562.600 Preservatives; Used in Non Standardize Foods; Label Declaration

587.100 Label Declaration of Certification-Exempt Color Additives

Thermal Process Control

Thermal process is treatment for canned and ascetically packaged foods

The time and temperature required to make the product commercially sterile

Process must be reviewed by a thermal process authority

- Person specially trained in thermal process

Issues a process letter

Thermal process must be submitted to FDA or USDA

- Include the thermal process letter

These questions often end up in labeling and regulatory

- Wanted you to be aware of process

FSIS Actions

Inspector in Charge (IIC) is the title for the local inspector

FSIS inspectors are in plants most days when production is running

For slaughter plants must inspect every animal

- Some risk based inspection on poultry plants
- Expect extending risk based inspection

FSIS has required inspection activities each day

FSIS reviews plant for general compliance

Actions are taken as needed

Different inspectors have different personalities

- Lead to inspection differences

FSIS Notices

Documents where FSIS announces projects it will be working on

Provides

- Purpose
- Background
- Outreach
- Other information as needed
- Question

Essential tool for understanding what FSIS priorities and projects are

All are listed with a number (1, 2, 3) followed by the year (16)

FSIS Directives

Instructions provided to FSIS inspectors on a variety of topics

Assist in plant inspectors in how to do their job

Describes that process that needs to be followed

Industry has access to information to assist them

ASK FSIS

A place for FSIS employees (in plant and district inspectors) to ask questions

Questions are referred to experts within FSIS

Questions and answers are posted on FSIS website

Provides assistance with changes in regulations and topics not clear in regulations

Have had mixed results when using this feature

- May be better ways to ask some questions

NR

Noncompliance Records

Completed by in-plant USDA inspectors

Completed when the local inspector finds non compliances in the plant

Can be on anything

- Food safety
- Food defense
- Labeling
- Micro testing

Typically done in the Public Health Information System (PHIS)

Writing NR Response

NR require a response
- Always do a written response

Typically done in PHIS
- Be sure to print or save a copy

Response requirements
- Acknowledge situation
- State position
- Cite regulations/directives/notices to support position
- Corrective actions
- Preventive actions

Appeals
- When disagree with NR
- Are allowed
- Only with significant information to support your position

Linking NR

Numerous NR on the same topic

If USDA in-plant personal feels that a specific issue has not been addressed

Must be taken seriously

Linking NR can lead to an FSA inspection

FSA

Food Safety Inspection

In-depth inspection of entire plant and process

Takes between 10 days and 2 month

USDA provides a written letter with results

Can issue the following

- NR as needed
- Notice of Intended Enforcement (NOIE)
- Rescind grant of inspection

NOIE

Notice of Intended Enforcement

Sometimes referred to as a 3 day letter

Requires action to make major changes to plant procedures in 3 days

Followed up by a plan to revamp plant issues in the next 6 month

Must make huge changes and fast

FDA

Conducts some inspections

- Have limited resources (money) for inspectors

Contracts with States for many inspections

Does inspections as possible

Frequency varies by state

Limited number of inspections

- State every 5 to 8 years
- Know of plant never been inspected

Warning Letters

Issued by FDA

Issued when issues are found

Variety of issues for warning letter

- Food
  - Food safety
  - Plant issues
  - Labeling
  - Thermal processing issues
  - Advertising or websites
- Dietary supplements
- Drugs
- Tobacco

Plants must respond in 15 working days

Warning Letter Response

Provide written response

Can meet with FDA to discuss

Address each individual point in the warning letter individually

Letter should outline changes and proposed timing

Some changes will take longer than 15 days

Expect to follow up with FDA until all changes are complete

Warning letter will not be closed out until all changes are done

- Some warning letters remain open for years

FDA Enforcement Report

Published weekly

Lists all FDA recalls regardless of type

Able to follow industry trends

Food Facility Registration

FDA requires all food plants to register

Done online

Includes all imported food plants

Way for FDA to contact food plants

Part of Food Safety Modernization Act (FSMA)

Reportable Food Registry

An article of food for which there is a reasonable probability that use of, or exposure to, such article of food will cause serious adverse health consequences or death in humans or animals

Industry must report all food issues

Typically items that will be recalled

- Reasonable probability of harm to consumers

Only required if food has left manufacturers control

- Still in plant not required

Completed online

FDA will contact if report is filed

Will trigger an FDA inspection at manufacturing site

FDA provides annual report

AMS Audits

Conducted on specific programs that companies have

All programs are voluntary

Examples

- CN PQC (Discussed later)
- GMO
- EU Dairy (Discussed later)
- EV Programs (Discussed later)
- Grading Programs

Fee for services

Labeling Recalls

Most labeling recalls are associated with allergens

Some color labeling recalls

Can recall for misbranding

- Economic adulteration
- Typically will not harm consumers

Warning letters are more common

Kind Bar
A case study

Kind Bar FDA Warning Letter

Healthy was in romance copy

Product does not meet FDA healthy definition

- More than 3 g of fat
- More than 1 g of sat fat

Included website copy issues

- Also healthy

Disclosure required for sodium

March 17, 2015

Kind Bar Healthy Petition

Updated FDA healthy definition

Current regulations

- Low fat
- Low sat fat
- Less than 480 mg sodium
- Less than 60 mg cholesterol
- 10% DV one vitamin, mineral or fiber

Currently does not include high fat items

- Nuts
- Salmon
- Avocados

Believe science has evolved in last 20 years

Healthy Choice Implications

Currently meeting FDA definition of healthy

- Individual foods
  - Low fat
  - Low sat fat
  - Less than 480 mg sodium
  - Less than 60 mg cholesterol
  - 10% DV one vitamin, mineral or fiber
- Meals
  - Less than 3 g fat/100 g
  - Less than 1 g sat fat/100 g
  - Less than 90 mg cholesterol
  - Less than 600 mg sodium
  - 10% DV one vitamin, mineral or fiber

Some meals contain

- Avocados
- Salmon

Kind Bar What Next?

FDA has stated they are interested in revising nutrition claim regulations in next few years

Has the science changed and how

- Are nuts, avocado and salmon necessary in the diet alone
- Can be used in combination now

Would expect changes with other changes

How will ConAgra Healthy Choice respond

- Does this help or hurt their brand

What will FDA do

Just Mayo Case Study

Just Mayo Case Study

Unilever sued over cholesterol free claim

- Maker of Hellmann's

Mayonnaise standard of identity includes egg yolk

- 21CFR169.140
- Egg yolk have cholesterol

FDA issued warning letter

Just Mayo Question?

Is mayo the same as mayonnaise

What could Just Mayo have done to comply

- Nutrient content claims allow for ingredients outside standard of identity
  - With contains not normally found in statement
- Other true product name
- Other options??

This is the gray area

- Correct labeling could have made it harder to get sued
- Prevented FDA warning letter

Sample Labeling

Meal Bars Case Study

Meal Bars

A number of bars that are labeled as meals

Some are labeled as a meal or snack

Snacks typically meet FDA individual foods definition

FDA Meal Definition

Contain at least 10 oz per serving

Contain not less than 3 - 40 g servings from the following food groups

- Bread, cereal, rice, and pasta
- Fruit and vegetable
- Milk, yogurt and cheese
- Meat, poultry, fish, dry beans, eggs and nuts

May not be a sauce, condiments, relishes, pickles, jams, jellies, syrup, breading, a dessert, or a beverage

- Allowed as part of the product or in the photo on package

21CFR101.13

Meal Replacement

No formal definition

Relating to RACC for milk and milk-based drinks

- meal replacement is one example given
- 21 CFR 101.12

Relating to label terms suggesting usefulness of meal replacements as low calorie or reduced calorie foods

- 21 CFR 105.66

Relating to folic acid fortification

- 21 CFR 122.345

Relating to Vitamin D fortification

- 21 CFR 172.380

Meal Bars What's Next?

Is it in compliance with FDA regulations to call this a meal?

- Is this a gray area?

What action should be taken?

Is a lawsuit likely?

What would you advise the following

- Your company?
- A client?
- FDA?