

# FORM 483 TO WARNING LETTER – BEST PRACTICES

*ALMOND QUALITY & FOOD SAFETY SYMPOSIUM, 2012*  
*ALMOND BOARD OF CALIFORNIA*



Food  
Medical Device  
Dietary Supplements

# FORM 483

## What is Form 483?

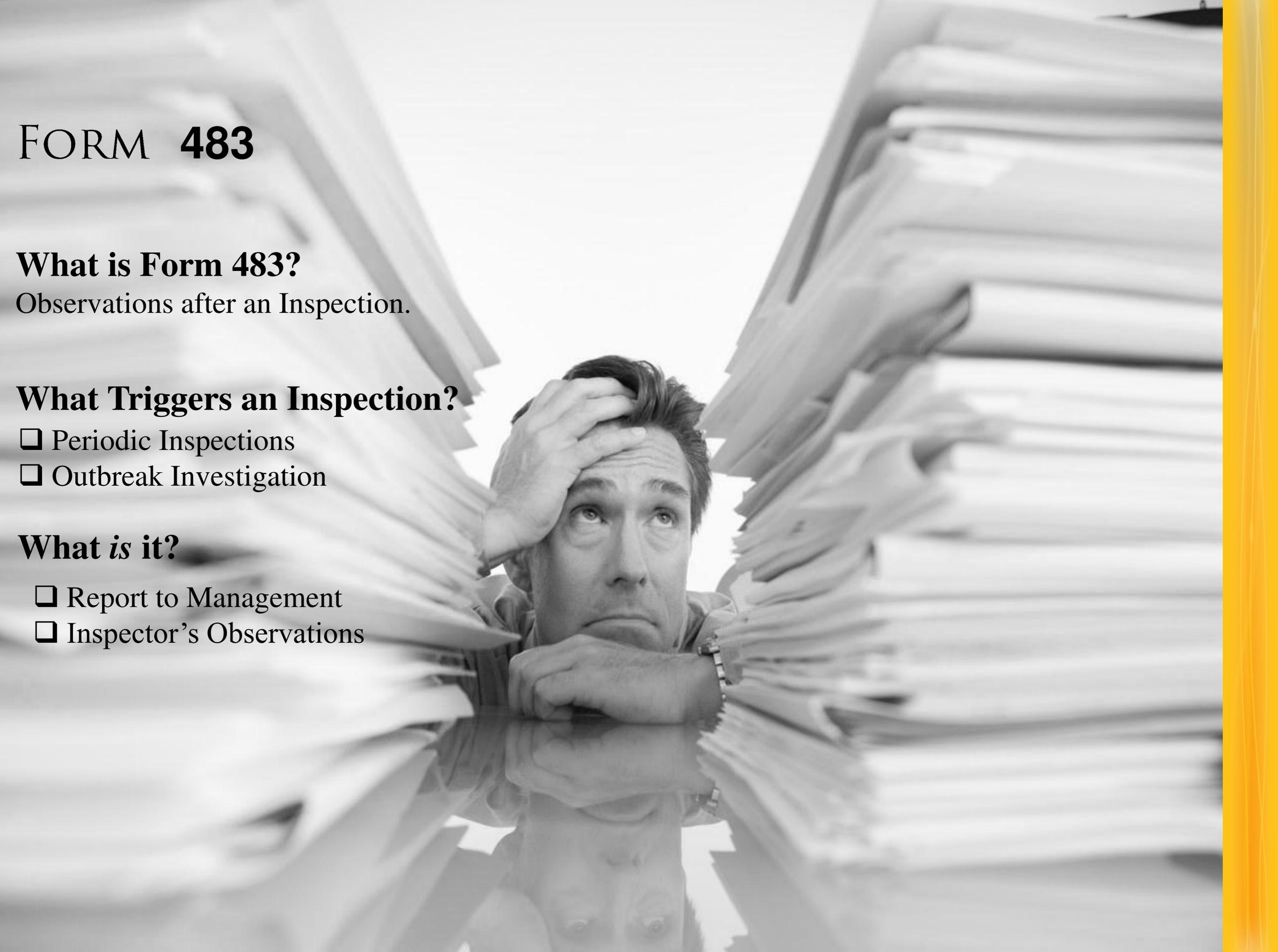
Observations after an Inspection.

## What Triggers an Inspection?

- Periodic Inspections
- Outbreak Investigation

## What is it?

- Report to Management
- Inspector's Observations

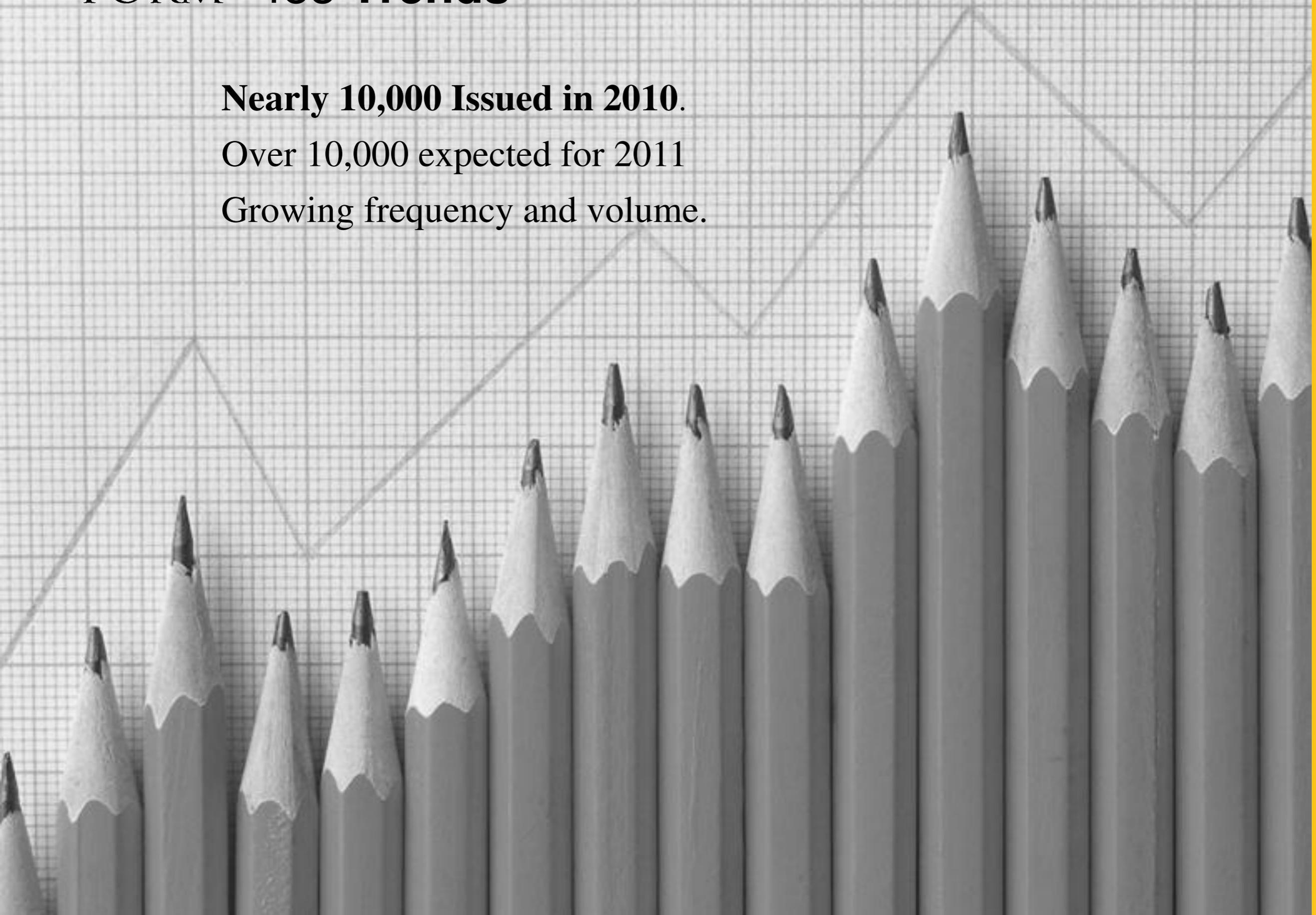


# FORM 483 Trends

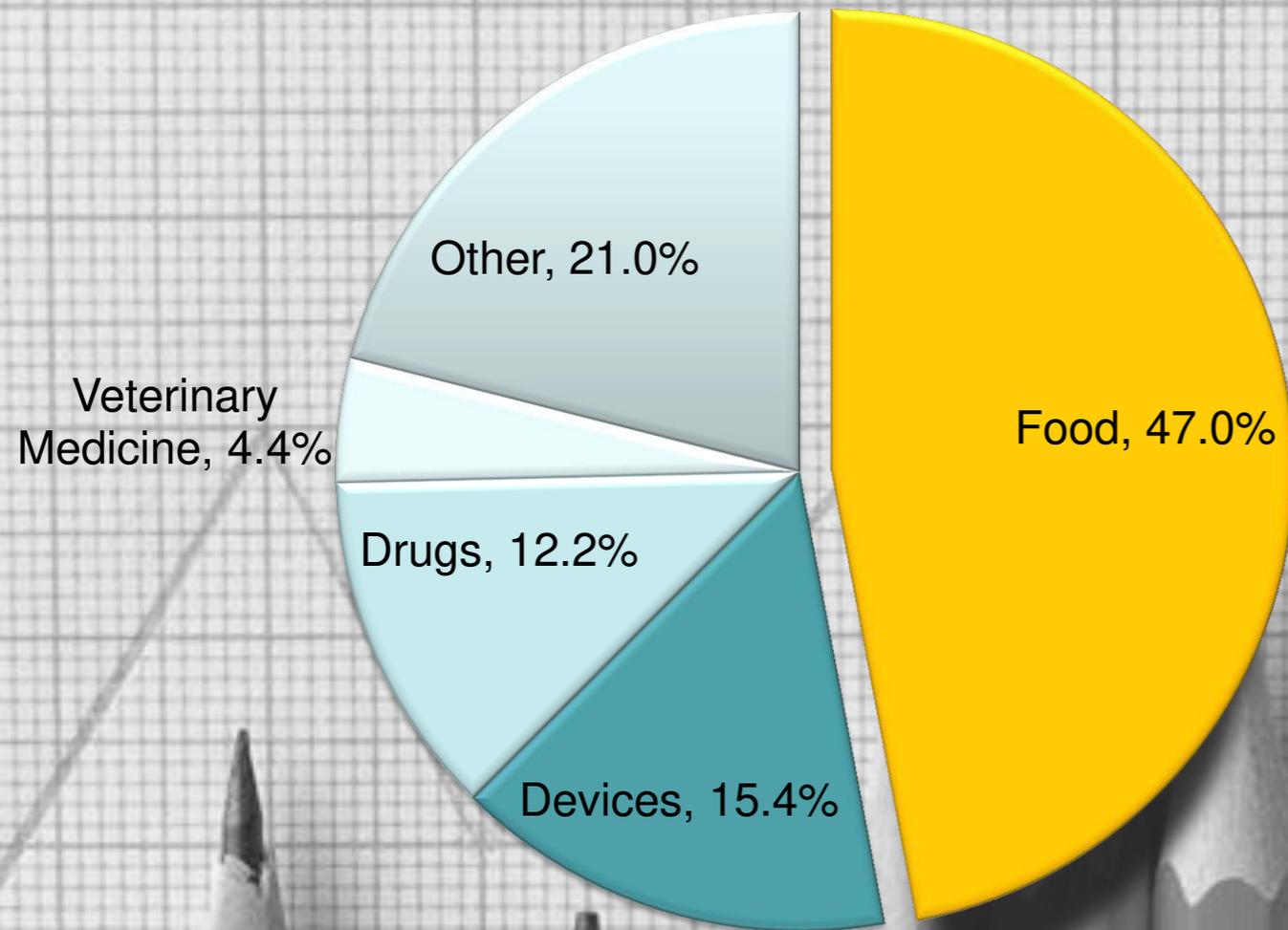
**Nearly 10,000 Issued in 2010.**

Over 10,000 expected for 2011

Growing frequency and volume.



# FORM 483 Trends





## WHAT DOES IT MEAN?

### **Implications?**

- Observations after an Inspection
- Establishment Inspection Report

### **Response Time**

- 15 Days



# WARNING LETTER

## What is a Warning Letter?

- Higher Level of Review
- Meant to Achieve Voluntary Compliance
- Establishes Prior Notice

## What Triggers it?

- Significant Violations
- Improper Response to Form 483
- Late Response to Form 483



# RESPONSES TO AVOID

## **Quick Trigger**

Creating the appearance you don't get it

# RESPONSES TO AVOID

## Anger Management

- “You call that an observation?!”
- Challenging Legal Authority

100 MUSIC DOWNLOADS

NUMBER OF HITS X 10

ACTIVITY LEVEL BY HOUR

# RESPONSES TO AVOID

**Did Not Do That Interrogation**



A black and white photograph of Barack Obama sitting at a desk in an office, looking down at papers and writing with a pen. The office has a window with curtains, framed pictures on a shelf, and a flag on the right. A yellow vertical bar is on the far right edge of the image.

# FSMA

- Increased Frequency
- Risk Based
  - High Risk Facility
  - High Risk Foods
- Re-inspection Fees

**Marc's legal and operational knowledge of the food safety arena bring him to the top of the field in supporting food producers..."**

Andy Moreno, Microbiological Surveillance Engineer and host of AME Food Testing Radio Show

QUESTIONS?

[msanchez@fdaatty.com](mailto:msanchez@fdaatty.com)

[www.foodct.com](http://www.foodct.com)

404.895.4882



Food  
Medical Device  
Dietary Supplements

**Marc's legal and operational knowledge of the food safety arena bring him to the top of the field in supporting food producers..."**

Andy Moreno, Microbiological Surveillance Engineer and host of AME Food Testing Radio Show

GET IN TOUCH

[msanchez@fdaatty.com](mailto:msanchez@fdaatty.com)

[www.foodct.com](http://www.foodct.com)

404.895.4882



Food  
Medical Device  
Dietary Supplements