



# Traceability and Recalls, FDA Expectations & Perspective

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2008 AFDO Annual Conference

FDA-Regulated Product Recalls

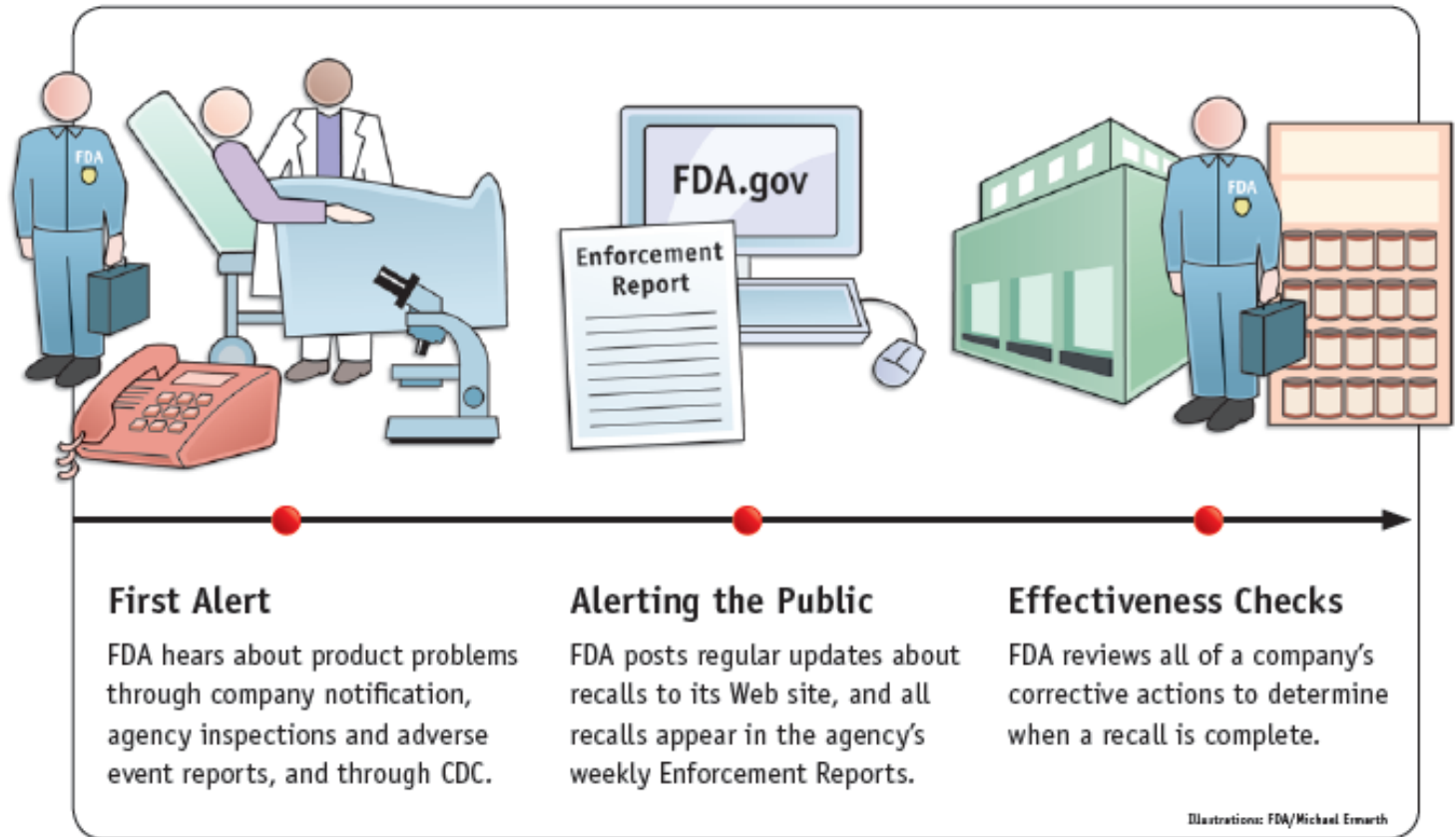
June 7, 2008

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Recall Coordinator, FDA, Los Angeles District

# FDA 101: Product Recalls

## From First Alert to Effectiveness Checks





# Definitions 21CFR7.3

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- Recall
- Product
- Correction
- Market Withdrawal
- Stock Recovery
- Classification



# Recall

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- A firm's removal or correction of a marketed product(s) that the Food and Drug Administration considers to be in violation of the laws it administers and against which the agency would initiate legal action, e.g., seizure.



# Product

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- An article subject to the jurisdiction of the Food and Drug Administration, including any food...intended for human or animal use...



# Correction

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- Repair, modification, adjustment, relabeling, destruction, or inspection (including patient monitoring) of a product without its physical removal to some other location.



# Market withdrawal

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- A firm's removal or correction of a distributed product which involves a minor violation that would not be subject to legal action by the FDA or which involves no violation (normal stock rotation, routine equipment adjustments, etc.)



# Stock recovery

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- A firm's removal or correction of a product that has not been marketed or that has not left the direct control of the firm, i.e. the product is located on premises owned by, or under the control of, the firm and no portion of the lot has been released for sale or use.





# Classification

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- Numerical designation, i.e., I, II, or III, assigned by the Food and Drug Administration to a particular product recall to indicate the relative degree of health hazard presented by the product being recalled.



# Health Hazard Evaluation

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- Diseases or injuries which have already occurred
- Existing conditions that can contribute to a clinical condition
- Population
- Seriousness of hazard
- Likelihood of occurrence of hazard
- Immediate and long term consequences



# Classification

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- **Class I** is a situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause **serious adverse health consequences or death.**



# Class I Examples

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- *Listeria monocytogenes, Salmonella, E. coli O157:H7 in RTE food*
- *Dietary supp. products containing aristolochic acid, a potent carcinogen and nephrotoxin*
- *Dietary supp. products containing a prescription drug that could have serious, life-threatening consequences in some people. (Liqiang Dietary Supp. containing glyburide)*



# Classification

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- **Class II** is a situation in which use of, or exposure to, a violative product may cause **temporary or medically reversible adverse health consequences** or where the **probability of serious adverse health consequences is remote.**



## Class II examples

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- *Hard/sharp foreign objects 7 – 25 mm*
- *Undeclared yellow 5 & 6*
- *Unapproved/uncertified colors*
- *Cosmetic products found to be contaminated with bacteria*



# Classification

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- **Class III** is a situation in which use of, or exposure to, a violative product is **not likely to cause adverse health consequences.**



# Class III examples

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- *Mold, yeast, lactobacillus*
- *Hard/sharp foreign objects less than 7 mm*
- *Off odor/off taste from contaminant at levels not likely to pose a hazard to health*
- *Misbranded products (The label states zero mg potassium per serving; the product actually contains 370mg potassium per serving)*





# Code of Federal Regulations

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- 21 CFR Part 7, Subpart C: Recalls (Including Product Corrections) – Guidelines on Policy, Procedures, and Industry Responsibility  
[http://www.access.gpo.gov/nara/cfr/waisidx\\_04/21cfr7\\_04.html](http://www.access.gpo.gov/nara/cfr/waisidx_04/21cfr7_04.html)
- Recall is a voluntary action by a firm
- Guidance on development of recall strategy (depth, public warning, effectiveness checks)
- Guidance on recall communications with consignees
- Who to contact at FDA and what information to provide



# Code of Federal Regulations

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- 21 CFR Part 107, Subpart E – Infant Formula Recalls (Food and Drug Administration-required recalls of adulterated or misbranded infant formula that presents a risk to human health)  
[http://www.access.gpo.gov/nara/cfr/waisidx\\_03/21cfr107\\_03.html](http://www.access.gpo.gov/nara/cfr/waisidx_03/21cfr107_03.html)
- Firm must report the recall to FDA and conduct the recall in the manner specified in this part



# Press releases

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- Issued by FDA or firm for almost all Class I recalls where the product is likely to be in the hands of the consumer
- May be issued by FDA or firm for some class II recalls
- Models for most class I recalls posted on FDA website
- Follow FDA models as closely as possible – “fill in the blanks”



## Press releases (cont.)

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- Do not change hazard statement – don't take out "life threatening"
- Issue press release to Associated Press
- Provide FDA with confirmation that press release was sent to AP
- FDA will issue if firm will not or if firm's is inadequate



# U.S. Food and Drug Administration



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## Products FDA Regulates

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Foodborne Illness, Nutrition, Dietary Supplements...
- [Drugs](#)  
Prescription, Over-the-



Multiple images of FDA employees and areas of regulation.

## FDA NEWS

- [Marketing of MS Drug Tysabri Suspended](#)
- [Illegal SciFit Procut Dietary Supplements Seized](#)
- [New Product Approved to Treat Smallpox Vaccination Complications](#)
- [New Improvements in FDA's Drug Safety Monitoring Announced](#)
- [Cellular, Tissue and Gene Therapies Advisory Committee to Meet March 3-4](#)

## [Recalls, Product Safety](#)

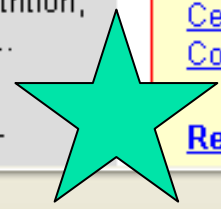
## Food Industry

- [Register a Facility](#)
- [Prior Notice of Imports](#)

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- [Losing Weight](#)
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- [Buying Medicines Online](#)
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- [More Hot Topics...](#)

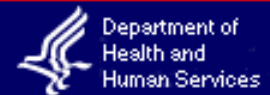
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## Recalls, Market Withdrawals and Safety Alerts

### Recalls, Withdrawals and Alerts in the Last 60 Days:

This list includes the most significant product actions of the last 60 days, based on the extent of distribution and the degree of health risk. The recalls on the list are mainly [Class I](#). A record of *all* recalls can be found in the [FDA Enforcement Report](#).

[FDA Provides Updated Patient and Healthcare Provider Information Concerning Crestor](#)  
(March 2, 2005)

[FDA Issues Public Health Advisory on Tysabri, a New Drug for MS](#) (February 25, 2005)  
[Public Health Advisory: Tysabri \(natalizumab\)](#) (February 28, 2005)

[Afrah Pastries Issues Allergy Alert on Multiple Undeclared Allergens in Bakery Products](#)  
(February 25, 2005)

[Medtronic Announces Voluntary Recall of Certain Monophasic LIFEPAK 500 Automated](#)

[MedWatch](#)  
Safety Information and Adverse Event Reporting

[Enforcement Report](#)  
Recalls, Product Seizures, Court Actions

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[Industry Guidance](#)

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[Product Safety News](#)

[Alan Pastres Issues Allergy Alert on Multiple Undeclared Allergens in Bakery Products \(February 25, 2005\)](#)

[Medtronic Announces Voluntary Recall of Certain Monophasic LIFEPAK 500 Automated External Defibrillators \(February 25, 2005\)](#)

[Murray Int'l Trading Co., Inc. Issues Allergy Alert on Undeclared Peanuts in Heng Tai Shi Crunch Snack \(February 25, 2005\)](#)

[Consumer Alert: Undeclared Peanuts in "An Ching Sweet Ball" \(February 24, 2005\)](#)

[Gemini Food Corp. Issues Allergy Alert on Undeclared Peanuts in Kamison Lucky Candy \(February 24, 2005\)](#)

[Parco Foods, L.L.C. Issues Voluntary Recall of "Fresh Batch" Candy Cookies Due to Undeclared Eggs \(February 24, 2005\)](#)

[Interstate Brands Corporation Issues Voluntary Recall of MERITA® Autumn Grain Bread in Northern Florida, Southeastern Georgia and the Hilton Head Area of South Carolina \(February 22, 2004\)](#)

[Fay's Foods Recalls Sandwiches and Salads Because of Possible Health Risks \(February 19, 2005\)](#)

[Drug Labeling Safety Information - Gabitril \(tiagabine\) \(February 18, 2005\)](#)

[Salton, Inc. Announces a Nationwide Recall of Approximately 2,700 Russell Hobbs® Mona Cordless Jug Kettles Due to Possible Lead Risk \(February 18, 2005\)](#)

[Great Kingsland, Inc. Issues Allergy Alert on Undeclared Sulfites in Fortuner's Brand Dried Honeysuckle and Bifeng Brand Dried Potato \(February 18, 2005\)](#)

[NY Fish Inc. Announces Recall of Uneviscerated Fish \(February 15, 2005\)](#)

[Gano Excel USA, Inc. Issues Recall and Allergy Alert on Undeclared Milk Protein in GANO CAFE 3-IN-1, GANO CAFE GINSENG TONGKAT ALI, and GANO C'REAL](#)

[Recalls, Withdrawals and Safety Alerts Archives](#)

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# Determining the scope of a recall

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- When did the problem start/end
- Can additional lots/products be affected other than the lot/product analyzed and found adulterated
- How many sizes/labels for the product
- Is the product coded with a lot number





# Responsibilities of Recalling Firm

## Preparing for a Recall

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- Review available recall guidance
- Develop a recall plan
- Maintain manufacturing and distribution records in a manner to facilitate a timely and effective recall
- Identify finished products with a lot number/code



# Responsibilities of Recalling Firm

## Communicating with FDA

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- Notify FDA and provide information in a timely manner (A current list of FDA recall coordinators can be found on FDA's website at: [http://www.fda.gov/ora/inspect\\_ref/iom/iomoradir\\_monitors.html#recall](http://www.fda.gov/ora/inspect_ref/iom/iomoradir_monitors.html#recall))
- Info needed by FDA includes: product (identity, size and type of containers, brand names, lot numbers, whether refrigerated/frozen/shelf stable), codes, amount manufactured and amount distributed, number of and types of consignees, area of distribution, reason for recall



# Responsibilities of Recalling Firm

## Communicating with FDA

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- Discuss recall strategy with FDA (including disposition of recalled product)
- Let FDA review text of phone notifications, written recall notifications, press releases (follow models provided in FDA guidance)
- Provide FDA with consignee list
- Provide actual labels or clear photos of labels



# Responsibilities of Recalling Firm

## Communicating with Consignees

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- The timely dissemination of communications about recalls of FDA-regulated products, important drug safety information, and other important product safety information is essential for the protection of the public health.



# Responsibilities of Recalling Firm

## Communicating with Consignees

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- The FDA's current thinking interprets the provisions of 21 CFR 7.49 and 200.5 to allow the use of e-mail and other electronic communication methods, such as fax or text messaging, to accomplish any recall notification or distribution of important safety information.



# Responsibilities of Recalling Firm

## Communicating with Consignees

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- Be brief and to the point
- Identify clearly the product, size, lot number(s), code(s) or serial number(s) and any other pertinent descriptive information to enable accurate and immediate identification of the product
- Explain concisely the reason for the recall and the hazard involved, if any



# Responsibilities of Recalling Firm

## Communicating with Consignees

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- Provide specific instructions on what should be done with respect to the recalled products
- Provide a ready means for the recipient of the communication to report to the recalling firm whether it has any of the product
- Provide sub-recall instructions (if necessary)



# Responsibilities of Recalling Firm

## Recall Monitoring/Closure

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- Maintain record of responses and re-contact non-responders
- Maintain record of units returned/reconditioned/destroyed
- Maintain returned product under quarantine
- Destroy/recondition product under FDA supervision
- Make corrections to minimize probability that problem will repeat





# Responsibilities of the FDA DISTRICTS

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- Submit a 24 hour alert of the recall to the affected FDA centers
- Collect information on the recall
- Offer guidance on recall (recall strategy & communications)
- Submit a recall recommendation to the affected FDA Center
- Monitor the recall



# Responsibilities of the FDA DISTRICTS

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- Witness product destruction or monitor the completion of an FDA approved reconditioning plan
- Initiate & monitor recall audit checks
- Notify the firm of recall classification and termination
- Terminate Class II and III recalls



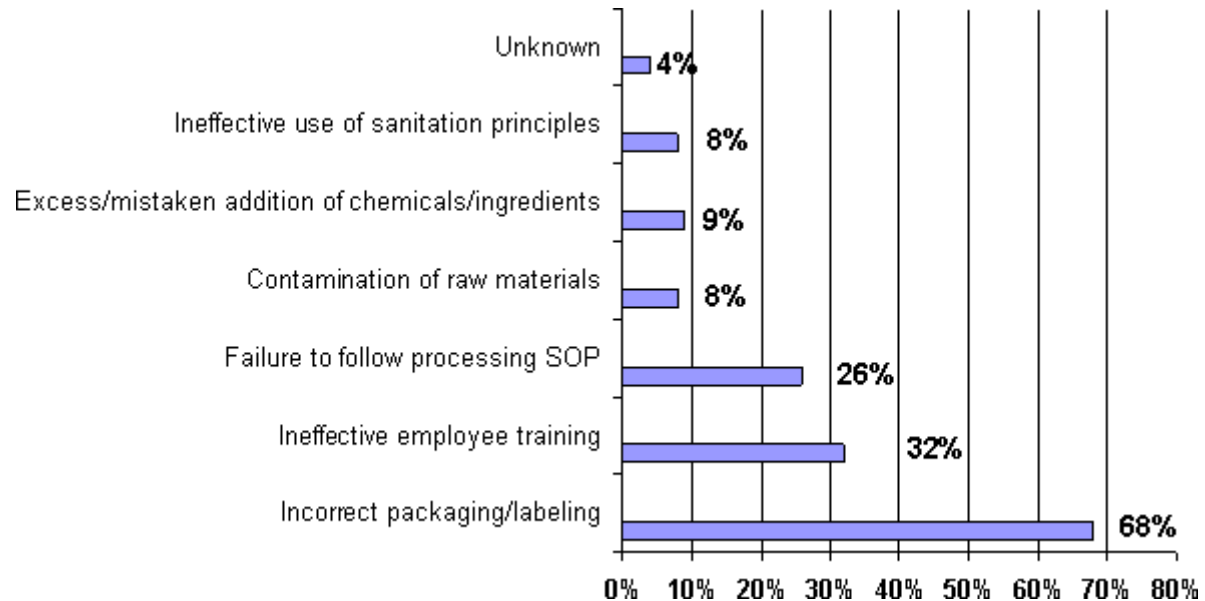
# Responsibilities of the FDA Centers

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- Receive & review recall recommendations
- Initiate Health Hazard Evaluations (HHE)
- Review and evaluate the firm's recall strategy
- Update FDA's recall database with recall classification, strategy and recommendations.
- Place recall information on the FDA Enforcement Report (weekly notice of recalls)
- Terminate Class I recalls

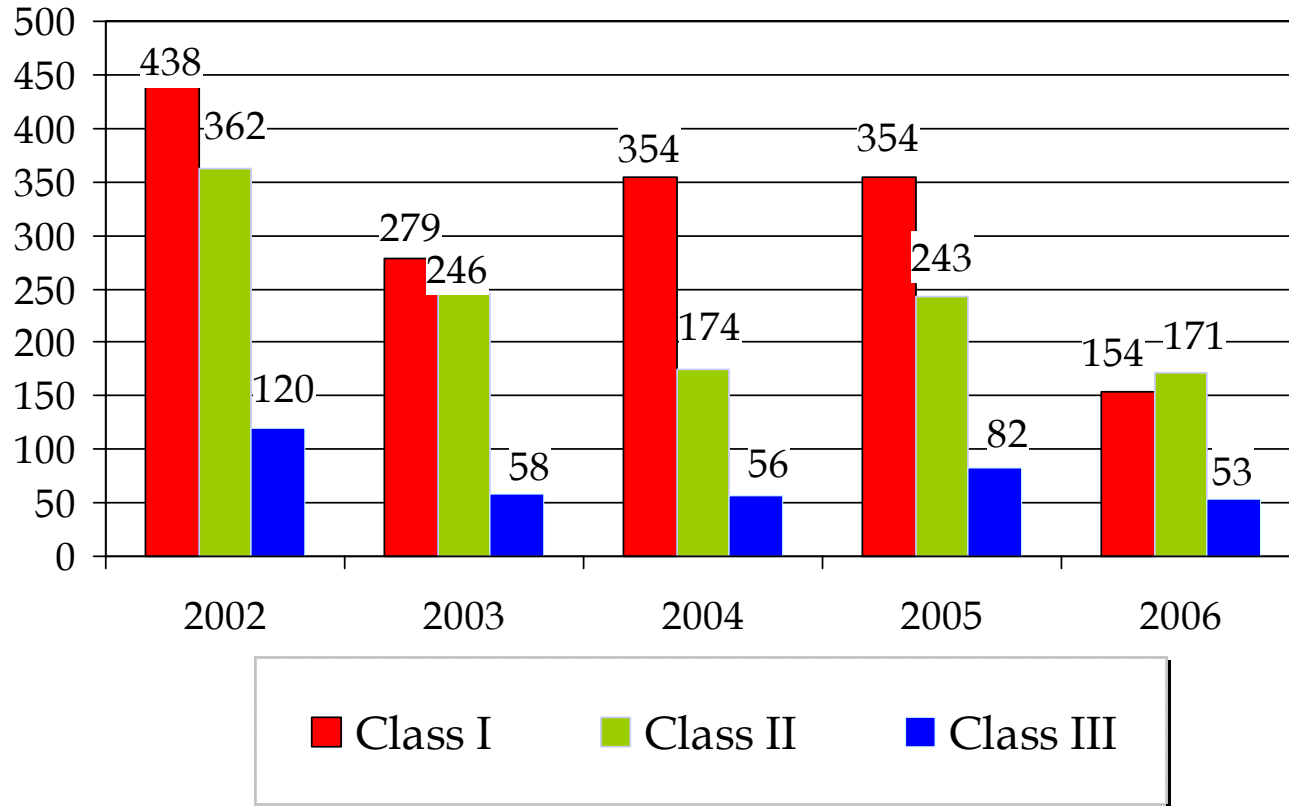
Root Causes for Class I and II Recalls FY 1999 – FY 2003  
(Extracted from **Food GMP Modernization Working Group:  
Report Summarizing Food Recalls, 1999-2003**)

<http://www.cfsan.fda.gov/~dms/cgmps2.html>



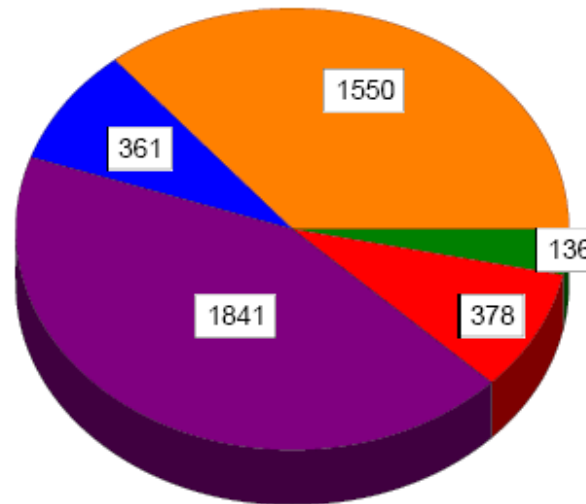
# FDA Five -Year Recall Activity

## Center for Food Safety and Applied Nutrition



# Recalls By FDA Center-FY2006

Recalls By FDA Center - FY 2006



- Center for Devices and Radiological Health
- Center for Drug Evaluation and Research
- Center for Biologics Evaluation and Research
- Center for Food Safety and Applied Nutrition
- Center for Veterinary Medicine



# RESOURCES

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- **WWW.FDA.GOV**
- **21 C.F.R. PART 7**
- **FDA REGULATORY PROCEDURES MANUAL, CHAPTER 7, "RECALL PROCEDURES" (MARCH 2006)**
- **FDA GUIDANCE FOR INDUSTRY, "PRODUCT RECALLS, INCLUDING REMOVAL AND CORRECTION" (NOVEMBER 2003)**
- **FDA INVESTIGATIONS OPERATIONS MANUAL, SUBCHAPTER 800, "RECALLS" (2008)**



# Recall Contacts

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- CDR Larry Howell

(949)608-4440

[Larry.howell@fda.hhs.gov](mailto:Larry.howell@fda.hhs.gov)

- Tamala Bogan

(949)608-3504

[Tamala.bogan@fda.hhs.gov](mailto:Tamala.bogan@fda.hhs.gov)

Food and Drug Administration

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Irvine, CA 92612

- A current list of FDA recall coordinators can be found on FDA's website at:

[http://www.fda.gov/ora/inspect\\_ref/iom/iomoradir\\_monitors.html#recall](http://www.fda.gov/ora/inspect_ref/iom/iomoradir_monitors.html#recall)