Institute of PACKAGING PROFESSIONALS

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Law Update Webinar:
Food Safety and FDA Enforcement

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TODAY'S AGENDA

NEW LAW ABOUT FOOD SAFETY:
THE FDA FOOD SAFETY MODERNIZATION ACT OF 2011

GENERAL RECOGNITION OF SAFETY:
RECENT DEVELOPMENTS

FDA ENFORCEMENT STATISTICS:
WHAT CAN THEY TELL US?

RECENT LABELING TRENDS AND ISSUES

YOUR QUESTIONS

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Packaging Law
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drug, dietary supplement, cosmetic and medical device manufacturers,
and packaging manufacturers, converters and designers
in all aspects of regulatory compliance and defense.

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NEW LAW ABOUT FOOD SAFETY: THE FDA FOOD SAFETY MODERNIZATION ACT OF 2011

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10 Quick Facts About the FSMA

1. Affects FDA and FDA-regulated foods, not USDA (That is, not meat and poultry)

2. Theme is prevention of food contamination problems

3. Food makers must put in place preventive controls “HACCP-type” control programs

4. FDA to set new rules for safe production of fruits and vegetables

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10 Quick Facts About the FSMA

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Gives FDA new enforcement powers:

5. To order food recalls *if* it suspects danger to health
6. To detain foods *if* it suspects adulterated or misbranded
7. To inspect documents *if* it suspects danger to health
8. To suspend registrations *if* it suspects danger to health
9. FDA ordered to inspect more, and set inspection priorities by degree of risk
10. Imported foods will have to be certified as complying with GMPs

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The Food Safety Modernization Act

Many of the sections require FDA to make regulations before they are effective, and they have gotten a start on making them

BUT

FDA's new powers to order recalls, see food company records, and suspend registrations are already effective

The Food Safety Modernization Act

The biggest, most widespread effect will be from the preventive controls requirement
(PROPOSED REGULATION PUBLISHED – Comments due SEPTEMBER 16, 2013)

Affects most food producers including

- Farms where foods are processed

Doesn't affect

- Exempted small operators
- Previously required
  - Juice manufacturers
  - Seafood processors

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The Food Safety Modernization Act

Under this requirement:

Food processors are required to evaluate their process

Put in place a plan that identifies risks

Put controls in place against those risks

Practice the controls every time, and

Keep records

AND MAYBE:
audit or require GMPs from their PACKAGING MAKERS

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The Food Safety Modernization Act

Is it REALLY a big deal?

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The Food Safety Modernization Act

Will food get any safer?

Would we be better off without any food regulation?

After all, we already had a thorough regulatory regime and pomegranate seeds still made people sick recently.

Without food regulation by FDA, there would still be other controls in place.

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GENERAL RECOGNITION OF SAFETY: RECENT DEVELOPMENTS

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“Generally Recognized As Safe”

also known as

General Recognition of Safety

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General Recognition of Safety

- "Food additives" are defined by law as substances that are added to or migrate to food that are NOT Generally Recognized As Safe ("GRAS")
- This applies to food ingredients, AND packaging components
- GRAS status is established through either
  scientific procedures, *or*
  common use in food before 1958.
- GRAS substances are both

  (1) demonstrably safe, *and*

  (2) recognized as such by the relevant scientific community.

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General Recognition of Safety

Because the law defines GRAS in terms of the opinion of relevant experts, and NOT in terms of any FDA approval, concurrence, license, or review, companies are free to make their own independent determinations that their use of a substance in food is GRAS

The question today is,
do GRAS substances require more regulatory intervention to assure safety?

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A tale of two recent studies

Government Accountability Office

and

PEW Health Group

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Government Accountability Office

- An oversight agency of US government
- Feb 2010 report recommending these steps to "strengthen FDA's oversight of GRAS determinations:

1. Require any company that conducts a GRAS determination to provide FDA with notice, and make it public;
2. Minimize the potential for conflicts of interest in companies' GRAS determinations;
3. Monitor the appropriateness of companies' GRAS determinations through random audits or some other means, including issuing guidance on how to document GRAS determinations;
4. Finalize the [1997] rule that governs the voluntary notification program;
5. Conduct reconsiderations of the safety of GRAS substances in a more systematic manner; and
6. Ensure safety of engineered nanomaterials.

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Pew Health Group
Food Additives Project

- A private “think tank”
- 2012 report raised these “concerns”:

1. FDA is unaware of a large number of chemical uses in food and, therefore, cannot ensure that safety decisions regarding these uses were properly made.
2. Food manufacturers are not required to notify FDA of relevant health and safety studies, thereby placing FDA in the difficult position of tracking safety information for more than 10,000 chemicals with limited resources and information.
3. The agency’s expedited approach to reviewing safety decisions since 1995 occurs with little public engagement.
4. FDA lacks the resources and information needed to identify and prevent potential health problems or to set priorities for systematic reevaluation of safety decisions made during the past half-century.

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Question: Is the safety risk great enough to warrant more regulatory involvement?

- What is the risk?
- FEMA review processes resulted in 11 substances being removed from the association's list of GRAS flavoring substances.
- 11 out of 2,600

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Food legal compliance IS the primary responsibility of the regulated businesses, not FDA

The law is structured that way

FDA consistently reminds companies of that fact in inspections, Warning Letters, etc….

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The question today is,
do GRAS substances require more regulatory intervention to assure safety?

Aren't there other assurances of safety?

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Other protections besides FDA review of GRAS substances

- Civil tort suits for injury
- Criminal liability for injury
- Adverse publicity

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The question today is,
do GRAS substances require
more regulatory intervention
to assure safety?

My answer: No, when balancing the benefits of regulatory intervention against the costs in light of the perceived problems, the record does not support more regulatory intervention.

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FDA ENFORCEMENT STATISTICS: WHAT CAN THEY TELL US?

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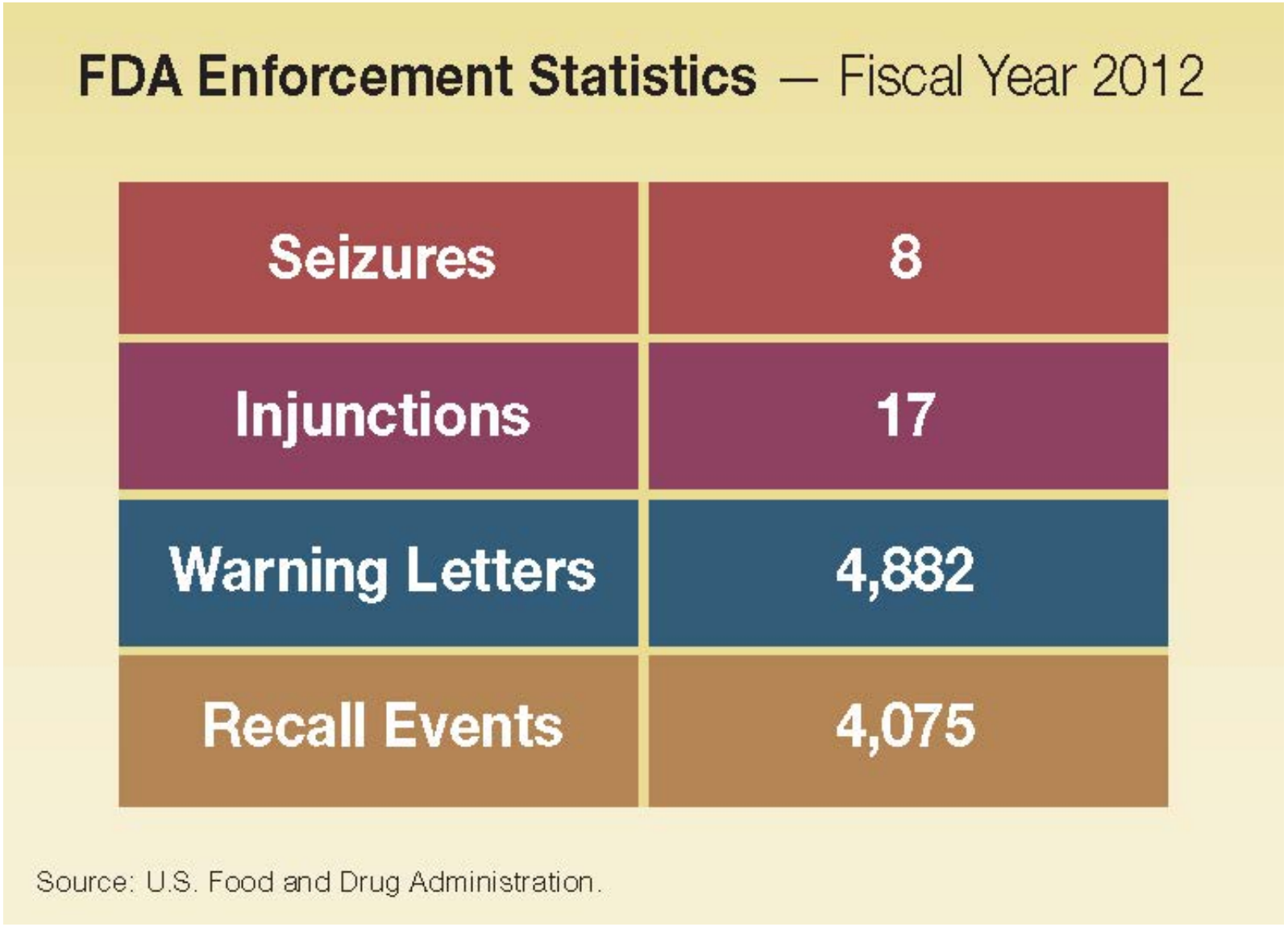

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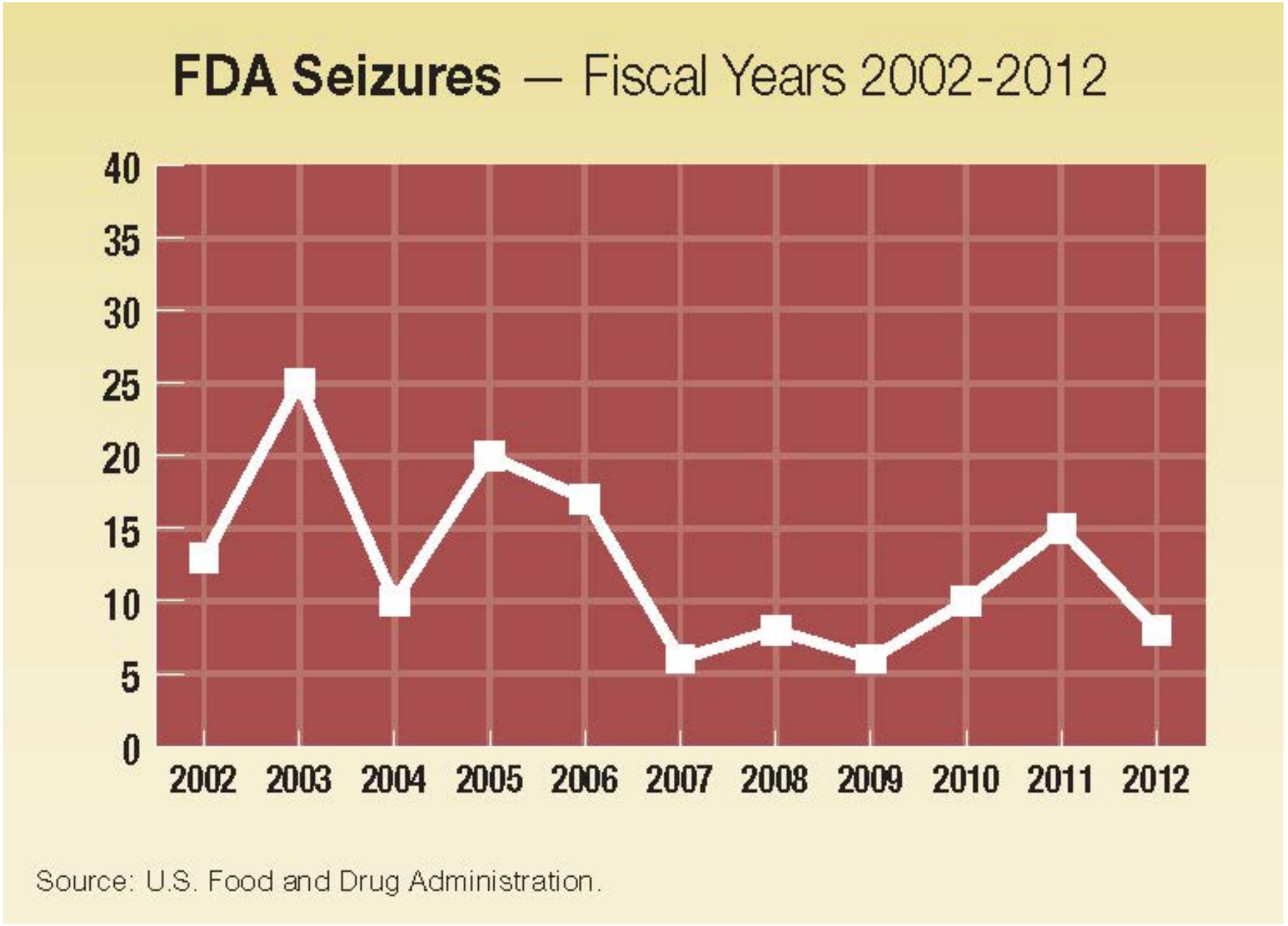

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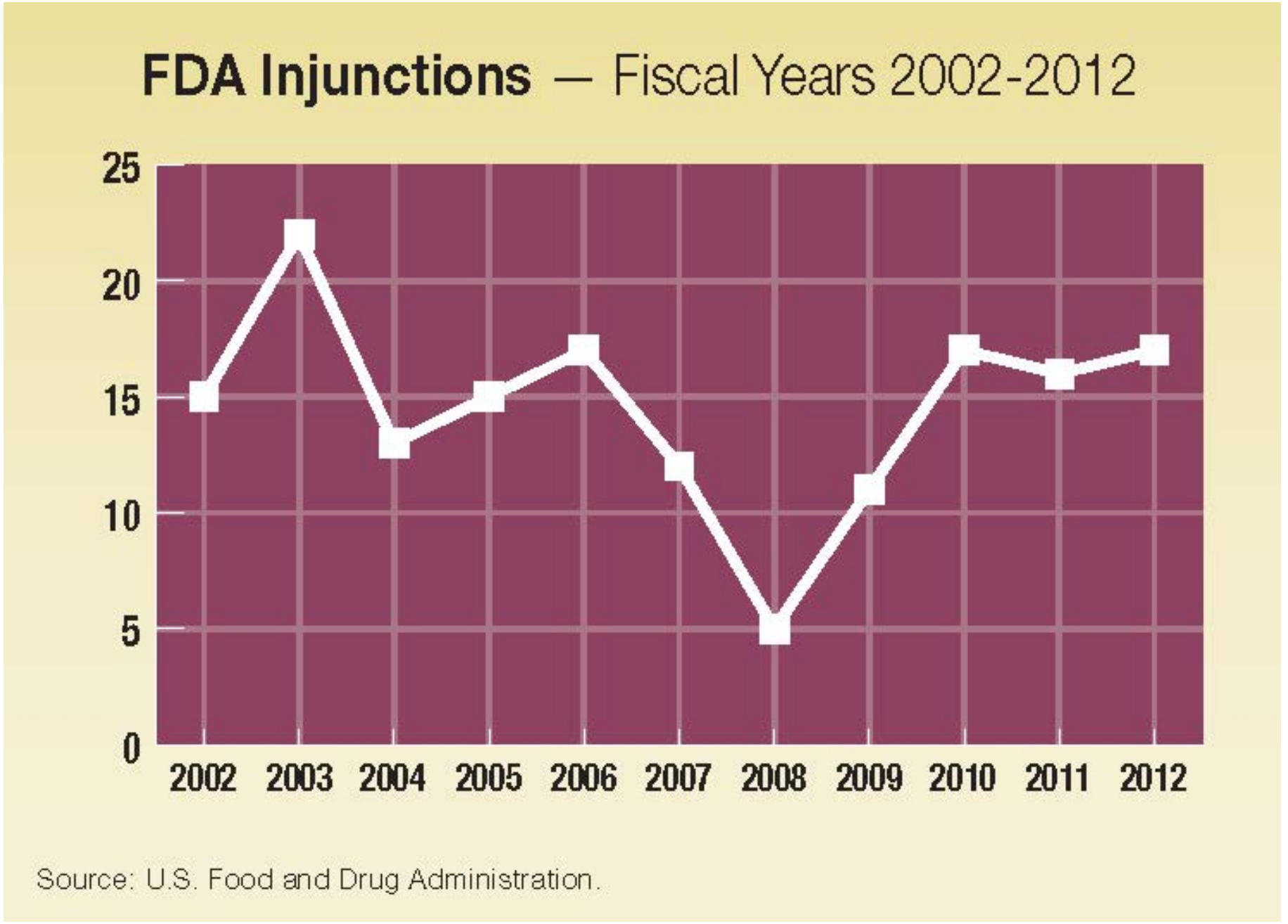

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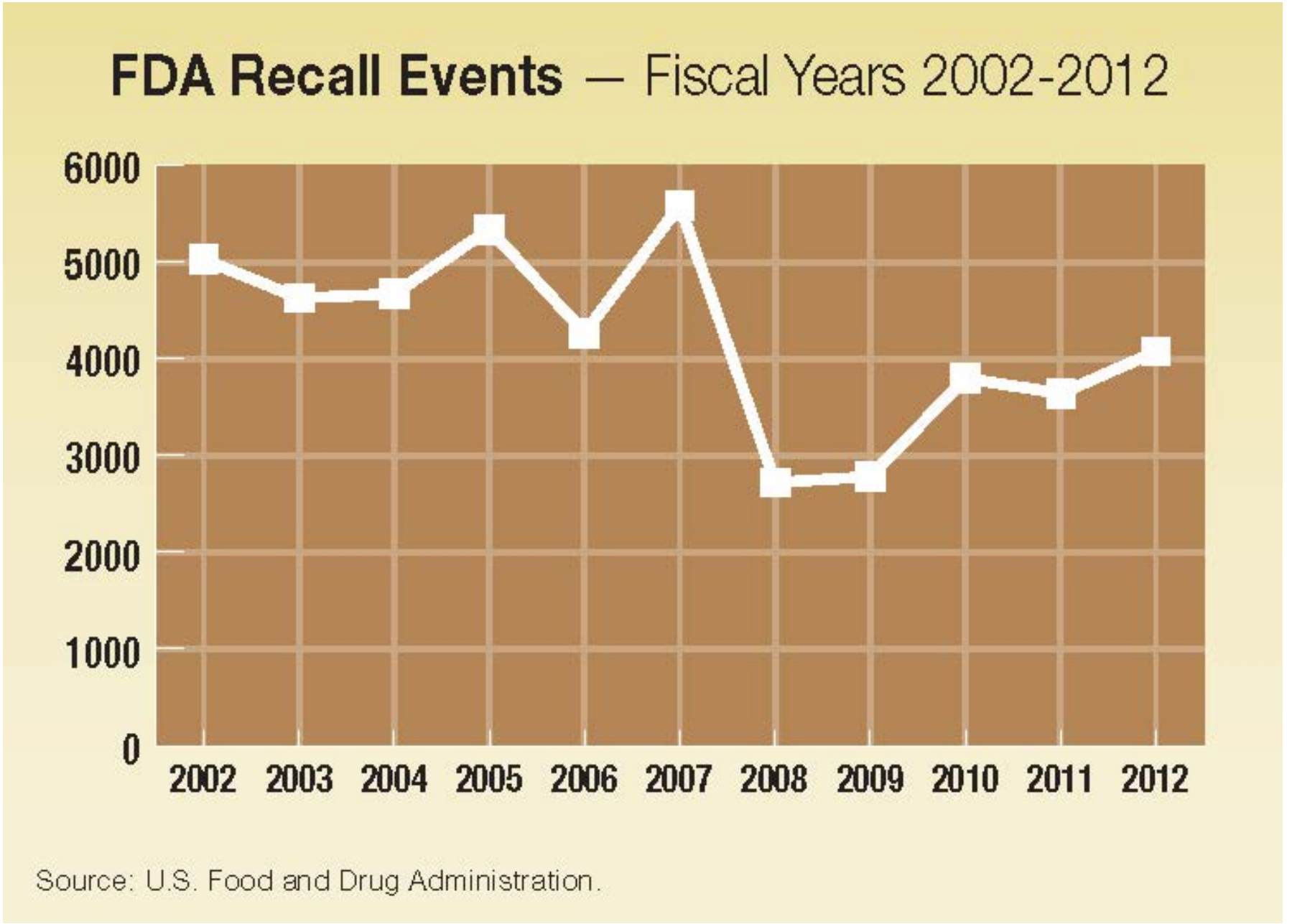

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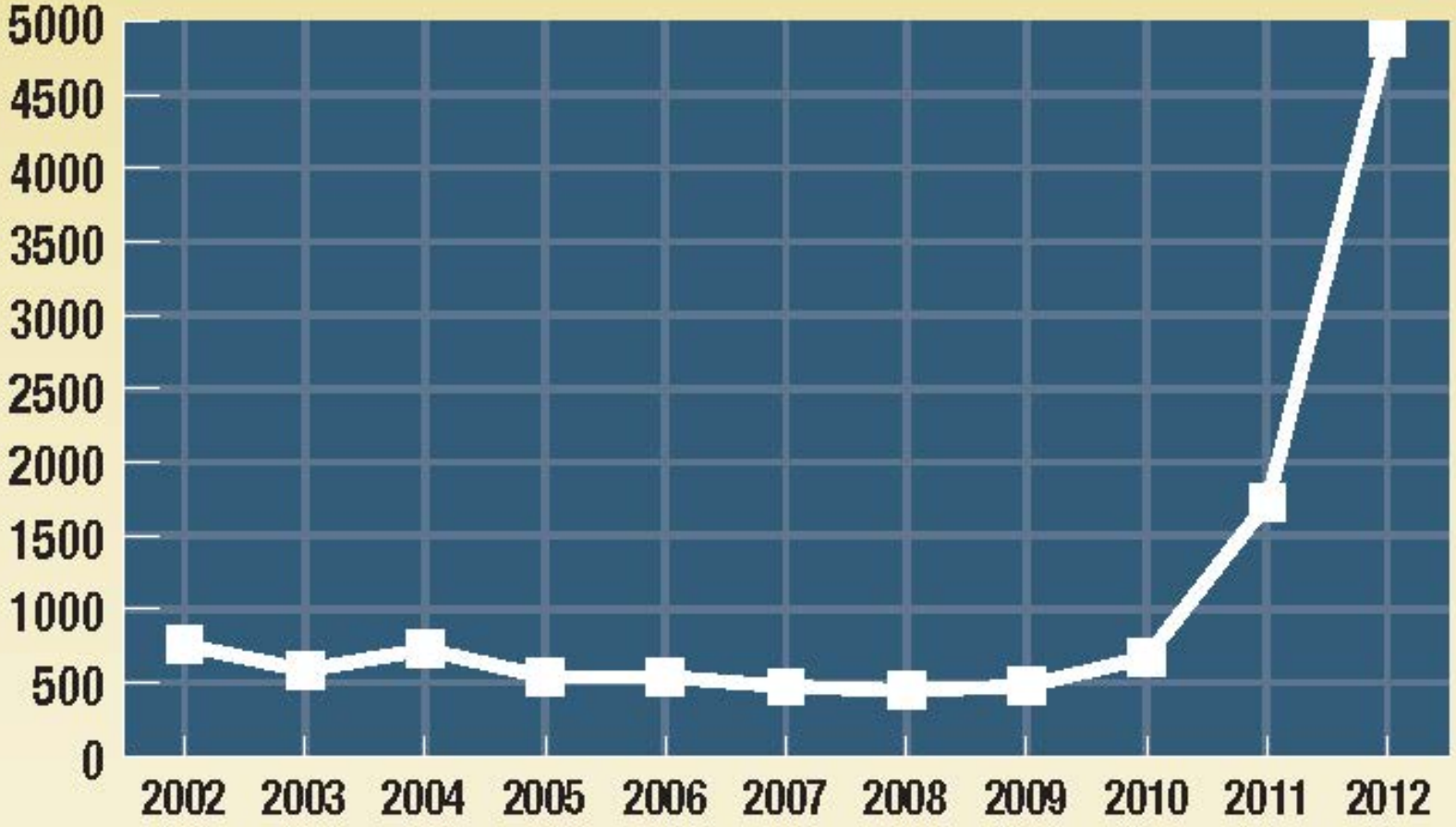
FDA Warning Letters — Fiscal Years 2002-2012



Source: U.S. Food and Drug Administration.

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RECENT LABELING TRENDS AND ISSUES

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Recent labeling trends and issues

- Gluten claims
- “Natural” and other claims for civil suits
- Energy drinks –
  - beverages or dietary supplements?
  - dangerous?
- POM’s life not completely wonderful

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Thank you.

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