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## THE NEW QSR/GMP *COMPLIANCE* ENVIRONMENT

PCF  
Washington DC  
November 3, 2011

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# WHY QSR IS NOW COMPLIANCE

- GMP/QSR structurally not just Quality Concern
- Serious FDCA civil and criminal exposure
- Fraud and Abuse; selling defective device for which government agencies pay
- Potential CIA/Exclusion exposure
- Can hold up other product approvals pending resolution of Warning Letter QSR concerns
- State AG concern

# Current FDA Enforcement Environment

- **FDA prioritizing follow-up inspections after Warning Letters and recalls**
  - Sharing laboratory and enforcement data with local and foreign governments
- **Increased focus on individuals: criminal and civil strict liability for responsible corporate officers**
- **Pressure from Congress**
  - Device Hearings
  - GAO report re: FDA's Office of Criminal Investigations

# Recalls and Warning Letters

- **Recalls: Increase in device recalls in all classes**

CY 2009	CY 2010
626	717

- **Warning Letters: FDA Continues Significant Quality-Related WLs**
  - 93 in 2010 and 92 in 2009
  - Frequently Cited Issues in 2010 Quality-Related WLs
    - CAPAs (55%)
    - Complaint Handling (53%)
    - MDRs (50+%)
    - Design Controls (44%)
    - Process Validation (30%)

# Injunctions / Seizures / Consent Decrees

- FDA expediting decision-making process for seizures and injunctions
- All involve major third-party oversight
- Recent consent decrees
  - Genzyme (2010)
  - Terumo Cardiovascular Systems (2011)
    - Halts production of two heart-lung bypass systems and other cardiovascular devices
    - Significant previous WLs
    - \$35 million in disgorgement of profits
  - J&J (2011)
    - Multiple sites

# Criminal: Guidant LLC

- Guidant charged with:
  - Violating FDCA by making materially false and misleading statements in its annual report for the PRIZM device
  - Violating FDCA by failing to promptly notify FDA of correction it made to the RENEWAL device to reduce health risk
- Penalties:
  - \$42,079,675 in criminal forfeiture
  - \$253,962,251 in criminal fines