FDA’s Clinical Trial Inspections in China
Including FDA Overall Goals

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Overview

- Budget
- China Initiative
- Recent 483 Observations
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FDA FY 2014 Budget Request

Source: FDA FY 2014 Budget Request

• Request: $4.7 million
• Top priorities:
  • Transforming Food Safety
  • Medical Product Innovation and FDASIA Implementation
• Oversight of Global Supply Chain: Safety Inspections in China

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Medical Product Innovation and FDASIA Implementation

Source: FDA FY 2014 Budget Request

• User fees
  – Continuation of fees (FY 2012 enacted) for food imports, food facility registration and inspections, cosmetics, medical product re-inspection, international courier, food contact notification

• White Oak Consolidation
  – Outfitting and Required Certification and Operation of two largest FDA laboratories (buildings 52/72, Life Sciences Biodefense Complex (LSDC))

• Medical Countermeasures
  – Chemical, biologic, radiological, and nuclear (CBRM), counter deliberate attack or naturally occurring epidemic
China Initiative (1 of 2)

Source: FDA FY 2014 Budget Request

• Strengthen global supply chain for foods, drugs, and ingredients manufactured in China – safety inspections in China

• Work with Chinese regulators (CFDA) and industry, and train CFDA colleagues and staff

• Goal:
  – Fewer import safety emergencies
  – Less foodborne illness
  – Earlier identification of safety problems associated with food, drugs, and ingredients manufactured in China

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China Initiative (2 of 2)
Source: FDA FY 2014 Budget Request

- **FY 2014**
  - **In-country human drug inspections**
    - Hire and train 9 FTE in 2014
    - Increase to 120 in-country inspections in FY 2016
  - **In-country food inspections**
    - Hire and train 7 FTE in 2014
    - Increase to 135 inspections by FY 2016
  - **Training and outreach of Chinese colleagues (CFDA)**
  - **Risk Modeling and Risk Analysis**
    - 3 FTE
      - Additional overseas inspections of facilities manufacturing product with greatest risk to patient
  - **Program Support**
Office of Global Regulatory Operations and Policy

Led by John M. Taylor III, J.D., Counselor to Commissioner and Acting Deputy Commissioner of Office of Global Regulatory Operations and Policy

• Office of Regulatory Affairs (ORA)
• Office of International Programs (OIP)
• Associate Commissioner and Deputy Director: Mary Lou Valdez, M.S.M.
• Assistant Commissioner and Deputy Director: Leslie Ball, M.D., FAAP
  • From 2003-2012, oversaw clinical investigations of human drug trials

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FDA China Office

- Led by Dr. Chris Hickey, Country Director, China
- Three offices: Beijing, Shanghai, Guangzhou
- FDA Country Management in Beijing office; FDA investigators in Shanghai and Guangzhou
- Began in 2008
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FDA Offices Overseas (1 of 2)

Source: www.fda.gov

• Asia Pacific (Silver Spring, MD)
  – With Canada
  – Excluding India and China

• China Office

• Europe Office
  – Silver Spring, MD, and with EMA in London and EFSA in Parma, Italy

• India
  – New Delhi
  – Mumbai

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FDA Offices Overseas (2 of 2)

Source: www.fda.gov

• **Latin America**
  – Regional headquarters in U.S. Embassy in San Jose, Costa Rica
  – Posts in Santiago, Chile and Mexico City, Mexico
  – Brazil office: Silver Spring, MD

• **Middle East and North Africa**
  – Amman, Jordan

• **Sub-Saharan, Africa post**
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Inspections in China

www.fda.gov

• Foodborne Biological Hazards
• Drug Quality Assurance
• Post-market Assurance of Devices
• Compliance of Devices
• Bioresearch Monitoring
• Radiation Control and Health Safety
• Monitoring of Marketed Animal Drugs, Feed, and Devices
• Food Composition, Standards, Labeling
• Recent past: devices, foodborne biological hazards

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Common Concerns
Source: Dr. Leslie Ball, Training in China 2013

- Concerns for rights and safety of those who participate in trials
- Soundness of design of trial
- Qualifications of clinical investigators
- Appropriate monitoring
- Accuracy of results
  - More and more trials are being conducted outside Europe and U.S., including in China
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Recent Clinical 483 Observations (all BIMO inspections)

www.fda.gov

- FD-1572, protocol compliance
- Inadequate case history records, including informed consent and data
- Minutes of IRB Meetings
- Accountability records
- Initial and continuing reviews by IRBs
- Consent form not approved/signed/dated
- List of members of IRBs
- General responsibilities of sponsors
- Problems not reported to IRB
- Informed consent

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Training
www.fda.gov

- Dr. Leslie Ball, Assistant Commissioner and Deputy Director, Office of Global Regulatory Operations and Policy, visited China May 2013
- Gave seminar on FDA’s regulation of clinical trials to colleagues in China Food and Drug Administration
- Training began in 2010. FDA experts provided three-part training program with CFDA
  - Train the Trainer approach
  - 30 Chinese technical experts and inspectors
    - 2010 Classroom Training
    - 2011 Mock inspections with clinical trial sites in China with FDA experts giving advice and oversight
    - 2012 Chinese staff performed the training with FDA experts providing supervision and oversight
Future Goals

• Movement toward global coalitions with regulators
• Development of global data information systems to share real-time information across markets
• Expansion of capabilities in gathering information about risk
• Increased leveraging of combined efforts of government, industry, public and private sectors
Review

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