

FDA Inspections Tissue/Cell Establishments

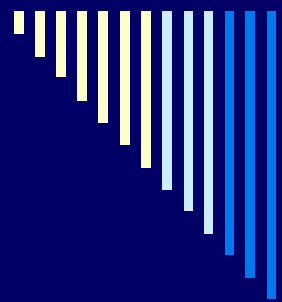
Martha A Wells, MPH

**Office of Cellular, Tissue, and Gene
Therapies**

**Center for Biologics Evaluation and
Research (CBER), FDA**

WHO Meeting, June 2006





Inspections and Enforcement

21 CFR Part 1271, Subpart F

- ❑ Required by regulation
 - ❑ Frequency at Agency discretion
 - ❑ Generally unannounced
 - ❑ Performed by trained investigators from FDA's District Offices
 - ❑ Investigator may take samples, review and copy records
 - ❑ List of observations generated if practices are not in compliance
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Focus for FDA Inspections - Tissue Establishments

- Record review
 - Donor eligibility determination -Screening and testing
 - All manufacturing steps
 - Standard operating procedure review
 - For all steps in manufacture
 - Focus on preventing circumstances that might increase risk of introduction, transmission, or spread of communicable disease
 - Personnel and Training
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Focus for FDA Inspections - Tissue Establishments

- Quality program
 - Facility issues
 - Environmental control
 - Storage/Equipment
 - Supplies and reagents
 - Labeling and labeling controls
 - Processing - controls and validation
 - Tracking
 - Complaint files and tracking system
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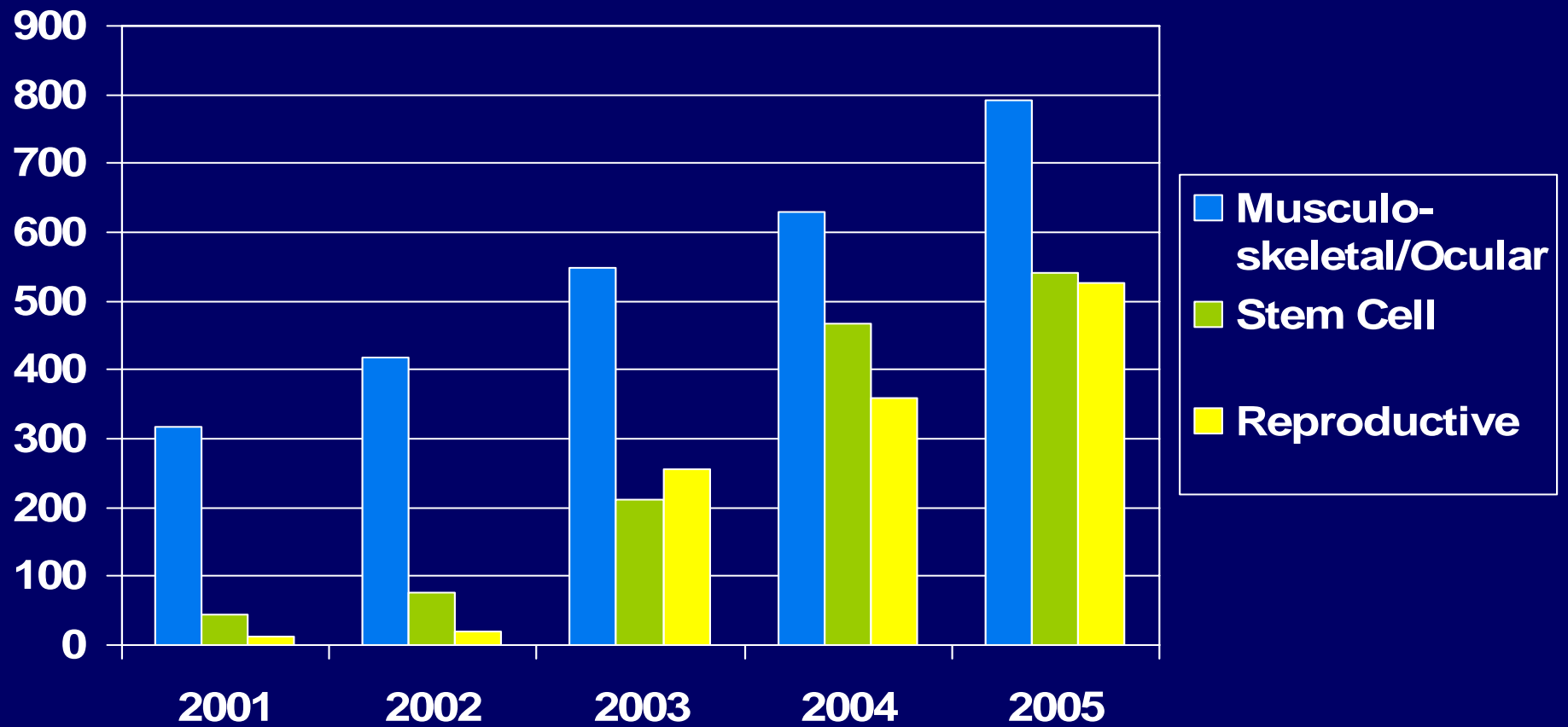


Enforcement Actions by FDA

- Can order establishment to recall, destroy or retain products
 - Can take possession of and/or destroy the violative tissue/cells
 - Can order establishment to cease manufacturing
 - Other actions
 - Untitled and warning letters
 - Regulatory meeting with FDA
 - Prosecution and fines
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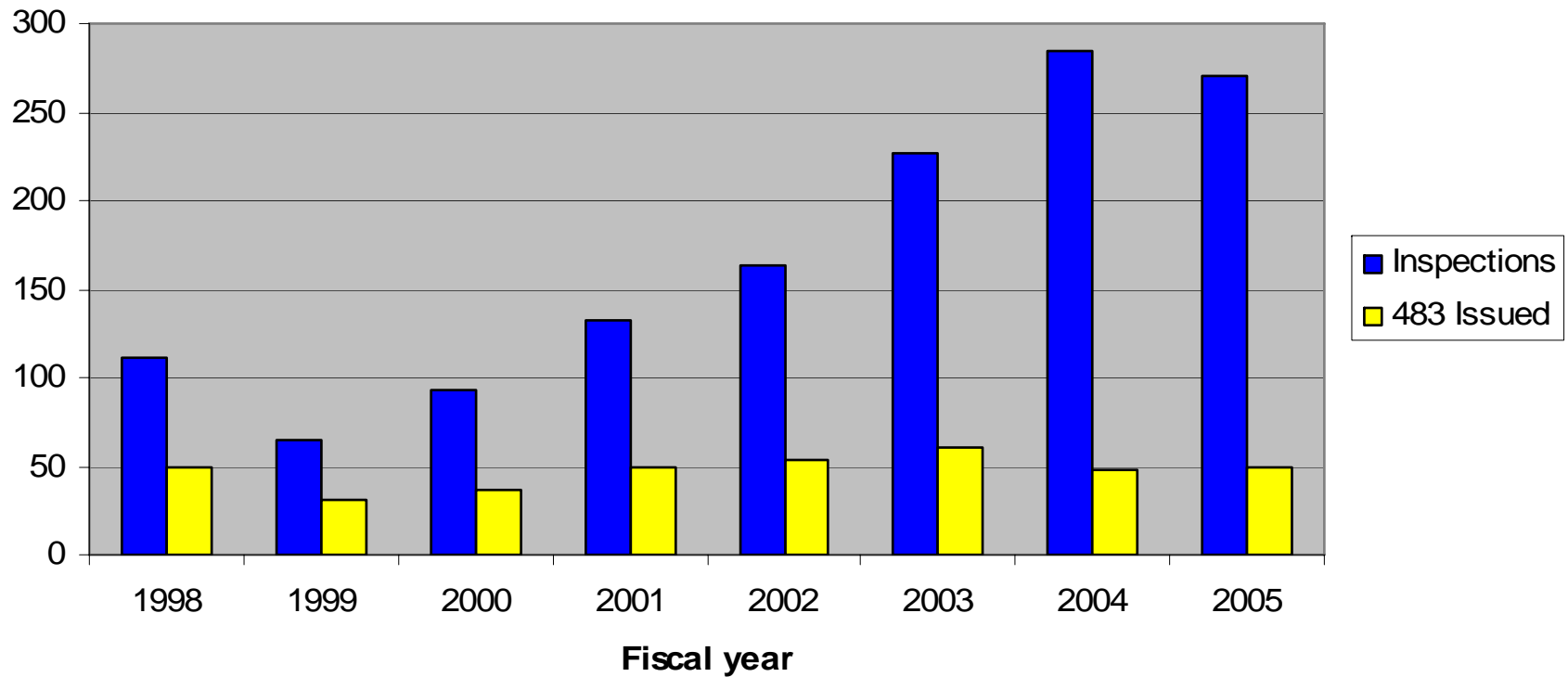


Registered Establishments



Tissue Inspections

Inspection of Tissue Establishments





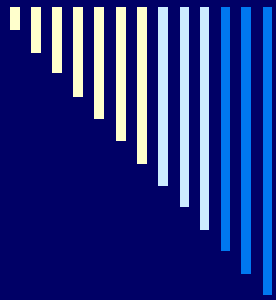
Inspections: Role of Professional Associations

- ❑ Accreditation may be taken into consideration for FDA inspectional planning
 - ❑ Professional association accreditation focused more on education than on compliance/enforcement - voluntary
 - ❑ Development of standards and accreditation programs – may enhance establishment's probability of being in compliance with FDA requirements
 - ❑ Associations assist in training FDA investigators
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Third Party Inspections?

- Might be considered by CBER in the future for tissue establishments
 - First need baseline inspectional history
 - Other FDA models
 - Mammography Quality Standards Inspections
 - Inspection of certain facilities performed by some states under contract with FDA
 - Device manufacturers inspection by FDA accredited persons
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U.S. Food and Drug Administration



CENTER FOR BIOLOGICS EVALUATION AND RESEARCH

CONTACT INFORMATION

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