

United States Animal Health Association Biologics & Biotechnology Committee

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Inspection and Compliance



Safeguarding Animal Health

Information Management

- Consolidation of Information Resource Management Services (IRMS), Library and Visual Services from ARS-NADC and APHIS-NVSL/CVB
- APHIS IRMS
 - Moved under CVB direction Sept 1, 2006
- Implementation Teams developing plan
- Target implementation date – Feb 4, 2007



Safeguarding Animal Health

Automated Information Management System (AIMS)

- Phase 2 : Licensing, Serial Release, and Testing (LSRTIS) Project Mission
 - Replace our current information systems with an integrated system that is flexible, reliable, supportable, efficient, adaptable, accessible, secure, cost effective, and tailored to the current and future needs of CVB and their customers/stakeholders.

Automated Information Management System (AIMS)

- Phase II of LSRTIS
 - Replace legacy system and core functions
 - Release 1
 - IC serial Release functions
 - PEL testing & scheduling functions
 - Biological Materials Processing Section (BMPS) CVB functions
 - Future Releases
 - Firm Services
 - Facilities
 - Compliance
 - Export

Automated Information Management System (AIMS)

- Timeline Release 1
 - Phase II project initiated October 2004
 - Business Requirements finalized
 - Functional Requirements 90% complete
 - Additional prototypes developed
 - Implementation testing expected Summer 07
- Enhancements
 - Increased tracking capability
 - User friendly - web application
 - Technological advancements

Automated Information Management System (AIMS)

- Future Challenges
 - APHIS Form 2008 currently a Level 3 application
 - No solution from USDA/APHIS for Level 3 applications
 - Signatures/Authentication
 - No solution from USDA/APHIS for electronic signatures
 - Budget vs end product
 - Project development and release is being phased

Continuity of Operations Plan (COOP)

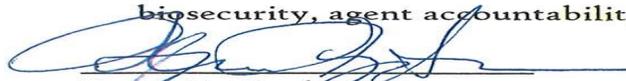
- Mission Critical Business Processes
 - Reviewing Plans
 - Essential Functions
 - Business Recovery Plan
 - Living Disaster Recovery Planning System (LDRPS)
 - Aligning with VS COOP
 - Scanning of Outlines of Production
 - Special Outlines - Completed
 - Outlines of Production – on hold
- VS Business Recovery Plans
 - National Select Agent Registry
 - Maintain tertiary roles at CVB

CVB QUALITY VISION STATEMENT

January 1, 2006

The Center for Veterinary Biologics (CVB) reaffirms its commitment to a quality-based program as an integral component of the CVB Mission and Vision. Quality management is the responsibility and fundamental duty of every employee at the CVB. The CVB Quality goal is to embrace and sustain a documented program of procedures and process improvement which results in services and products that consistently meet or exceed the needs and expectations of its customers and stakeholders.

- The Quality Objective of the Policy, Evaluation, and Licensing (PEL) laboratory staff is to ensure that the testing services and reagents provided are of the highest quality and are well supported by documentation. This will be accomplished by systematically developing a quality structure that ensures and promotes scientific excellence in an environment of well-defined processes.
- The Quality Objective of the PEL review staff is to ensure fair, consistent, and comprehensive review and evaluation of product development and production data submitted by veterinary biologics manufacturers in support of product licensure for compliance with the Virus-Serum-Toxin Act and associated Federal regulations. Policy will be consistent, well documented, and based on sound science.
- The Quality Objective of the Inspection and Compliance staff is to ensure that veterinary biological products are prepared, maintained, and distributed in compliance with the Virus-Serum-Toxin Act and associated Federal regulations. The documentation and processes for the assessment of establishment procedures, facilities, and product distribution will fulfill evolving Federal requirements for biosafety, biosecurity, agent accountability, and environmental protection.



Byron E. Rippke., Director
Policy, Evaluation, and Licensing
Center for Veterinary Biologics



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Richard E. Hill, Jr., Director
Center for Veterinary Biologics



Quality Management

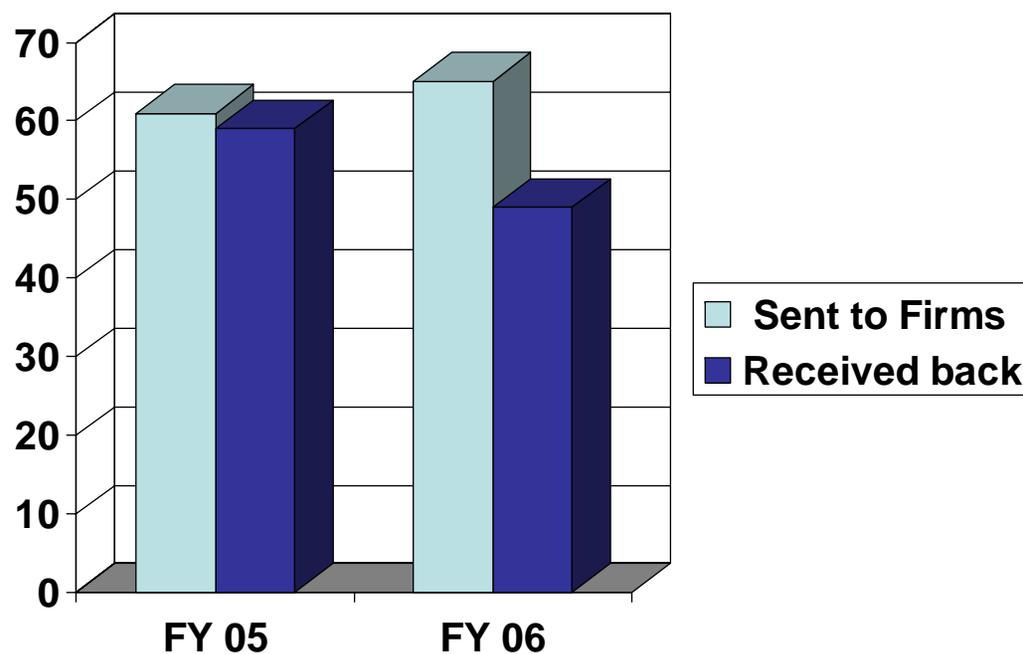
- CVB Quality Management System (QMS) Manual being finalized.
- All CVB personnel received training in ISO 9001 (QMS requirements) and in ISO 17025 (testing and calibration laboratory requirements), Jan-Mar, 2006.
- All IC Biologics Specialists received training in ISO 19011 (auditing guidelines), March, 2006.
- Contract with Quality Systems Registrars, Inc. for ISO 9001 certification/registration--pre-assessment audit scheduled for Nov, 2006.

Administrative Inspection Review (AIR)

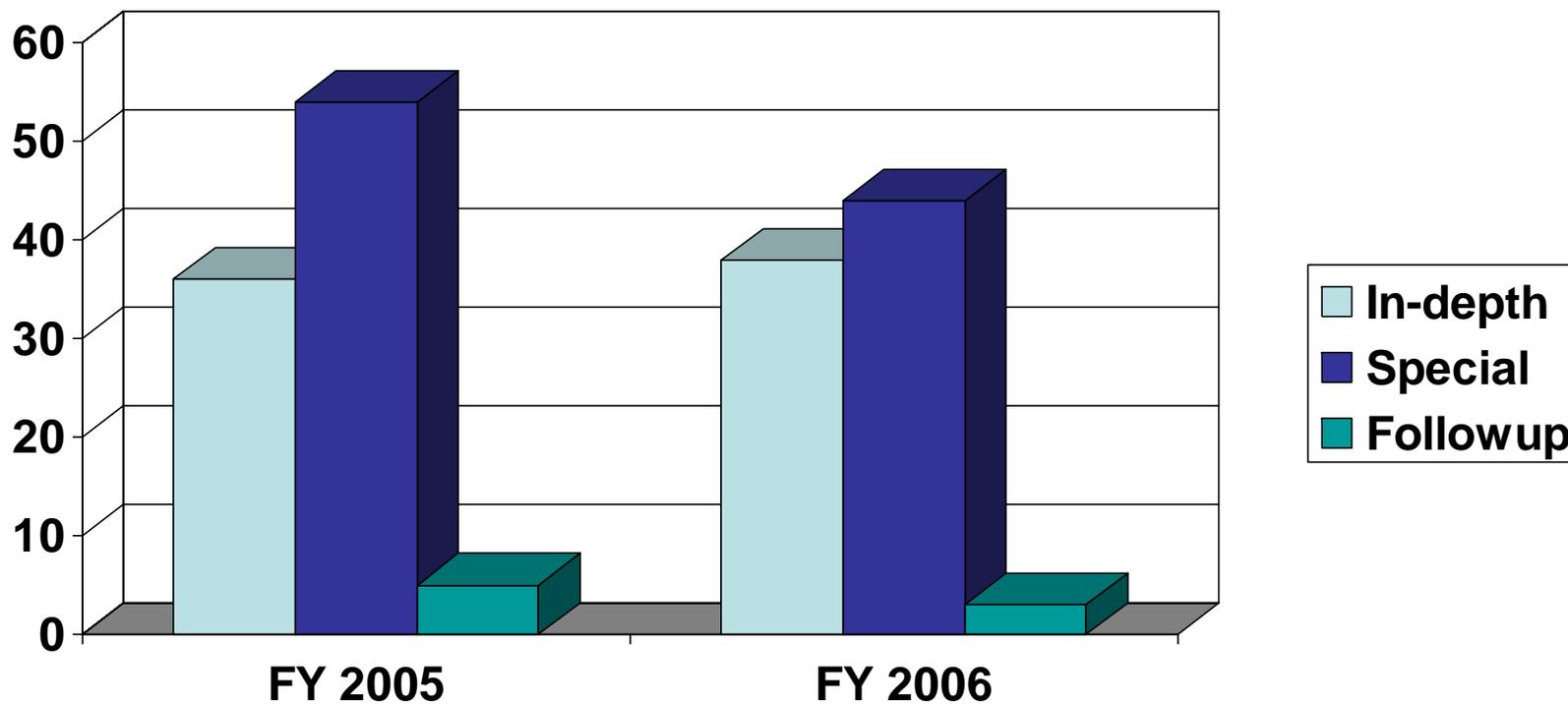
- Starting 3rd Year for AIRs
- Benefits:
 - Firms able to schedule resources
 - Enhances compliance from biologics firms
 - Determine need for Inspections
- Expanding to Include Permittees

Administrative Inspection Review (AIR)

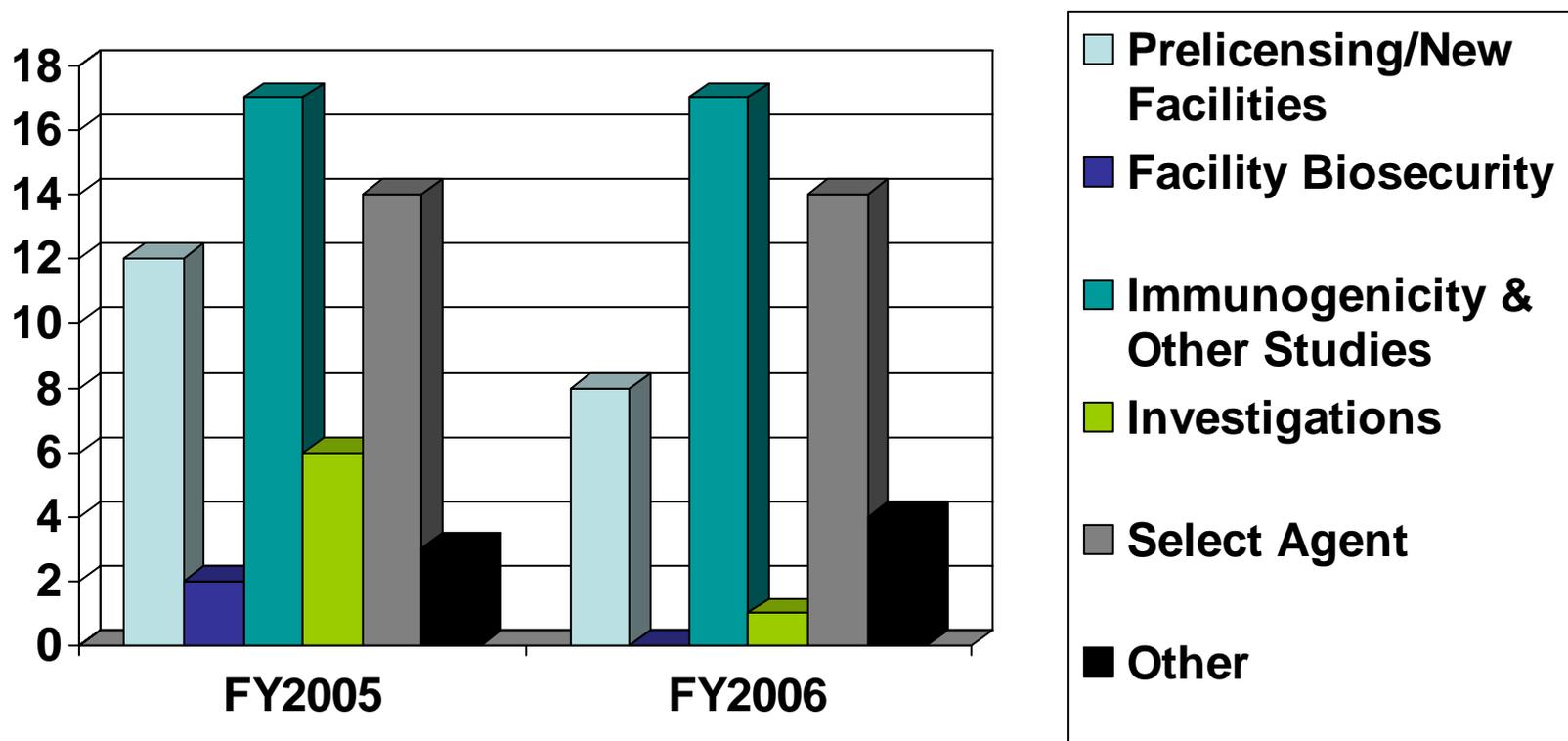
Activity per Year



Inspections



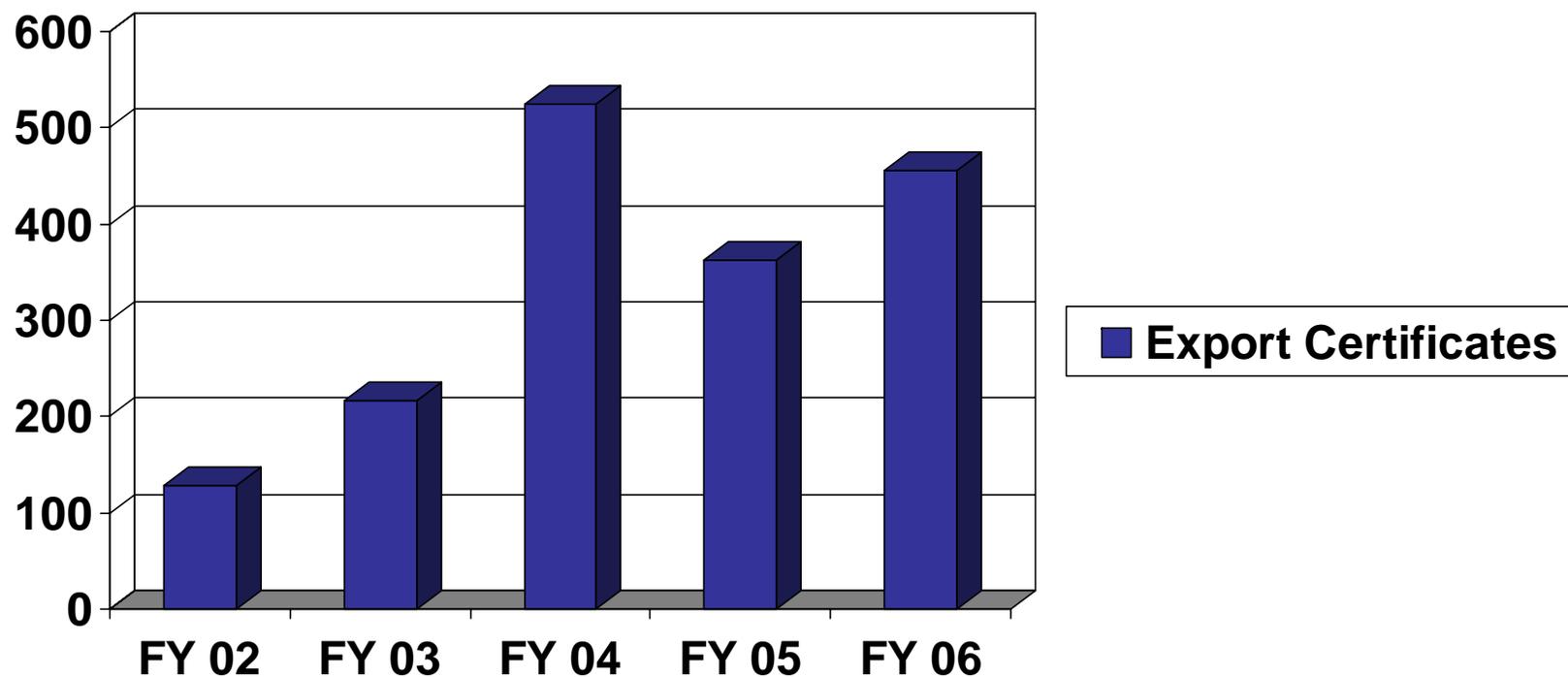
Special Inspections



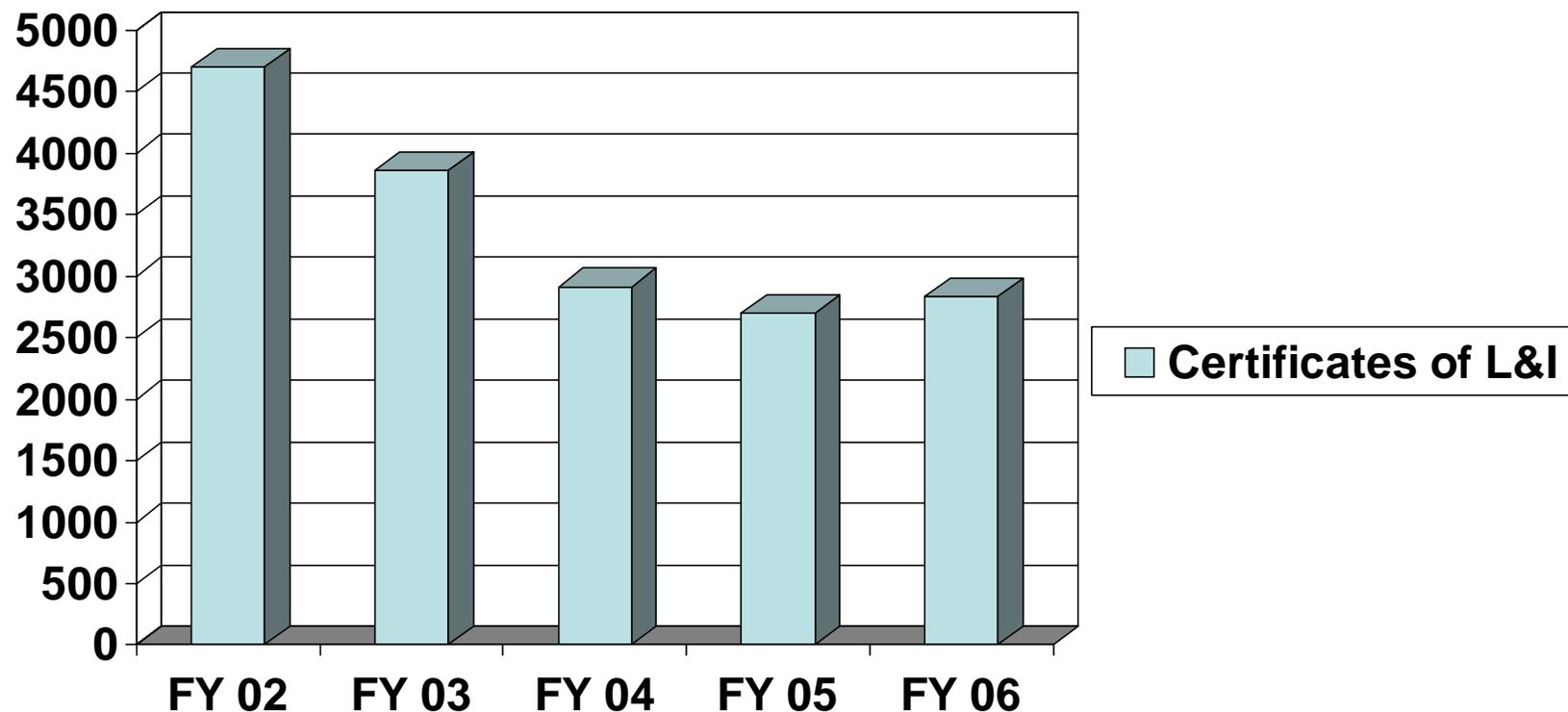
Export Activities

- Following the positive BSE in the US
 - CVB worked with International Services and the National Center for Import and Export to resume the exportation of veterinary biologicals to other countries
 - Current and Resolved Issues
 - Chile, Mexico, Brazil
 - Joint inspection of US Biologics Manufacturers
 - CVB and Brazilian Regulatory Officials

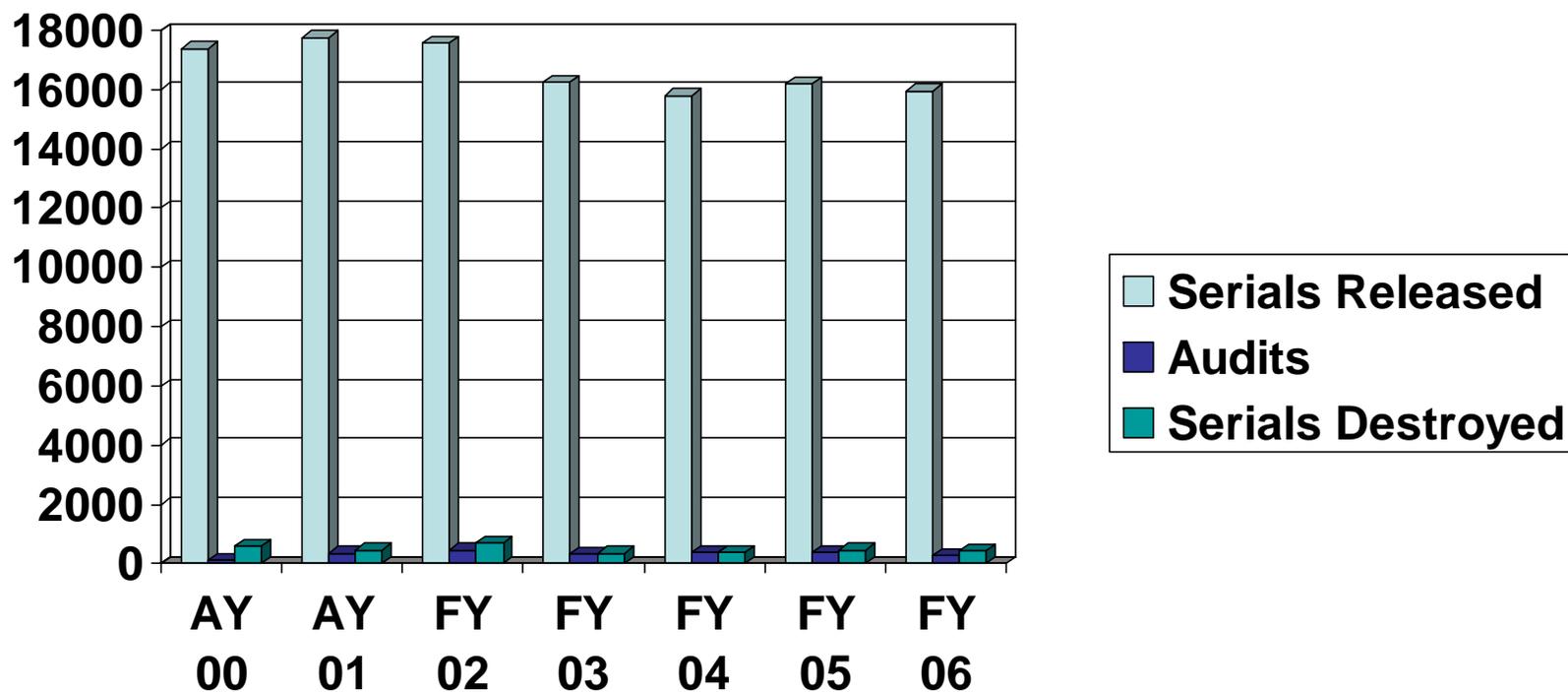
Export Activities by Serial



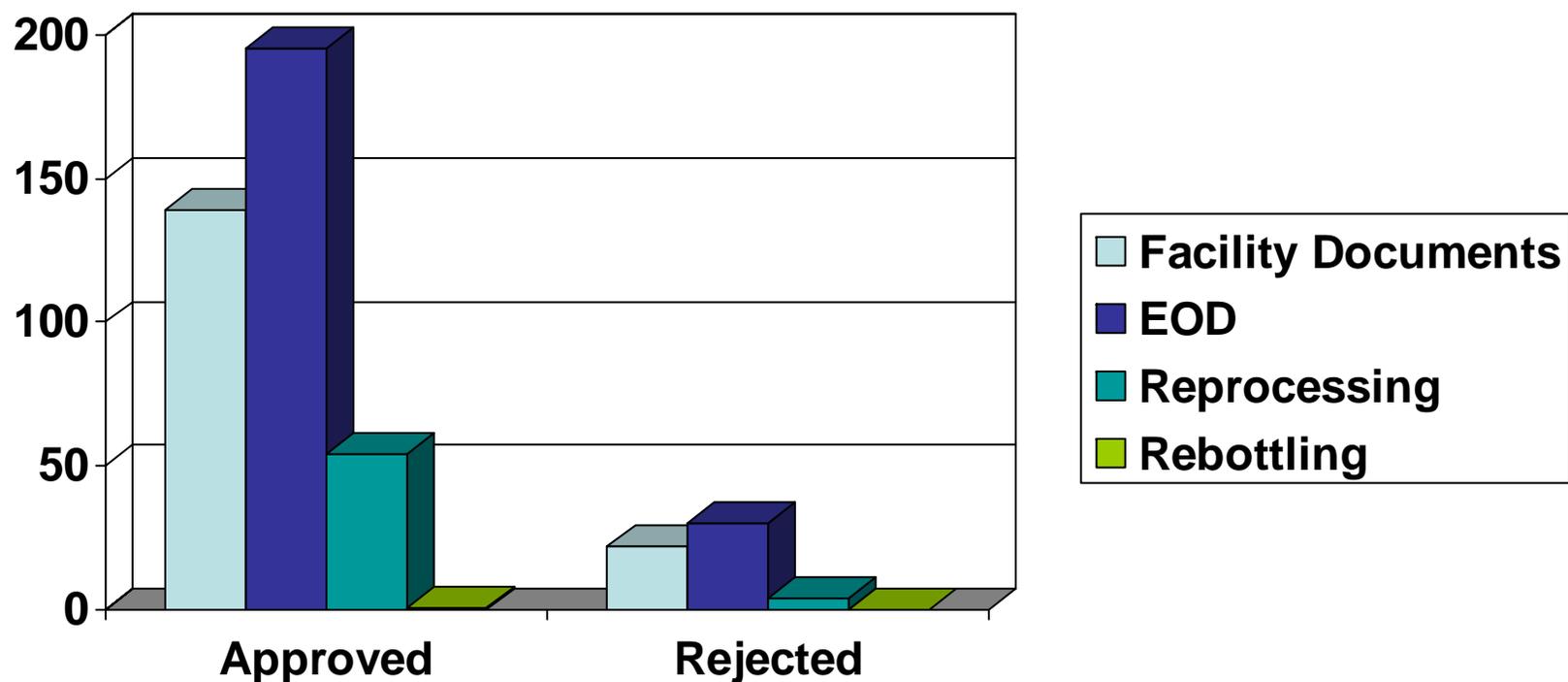
Export Activities by Product



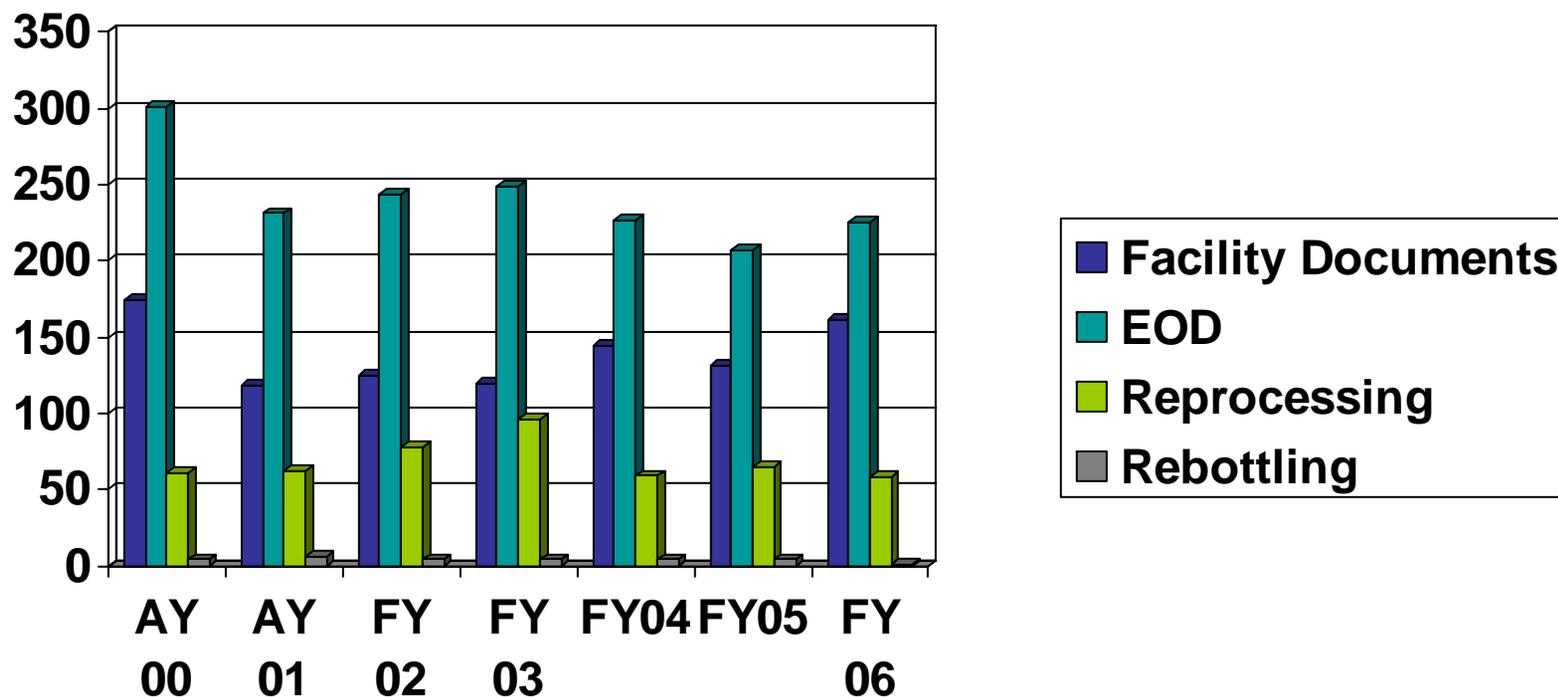
Serial Release Activities



Product Inspection Activities – FY 06



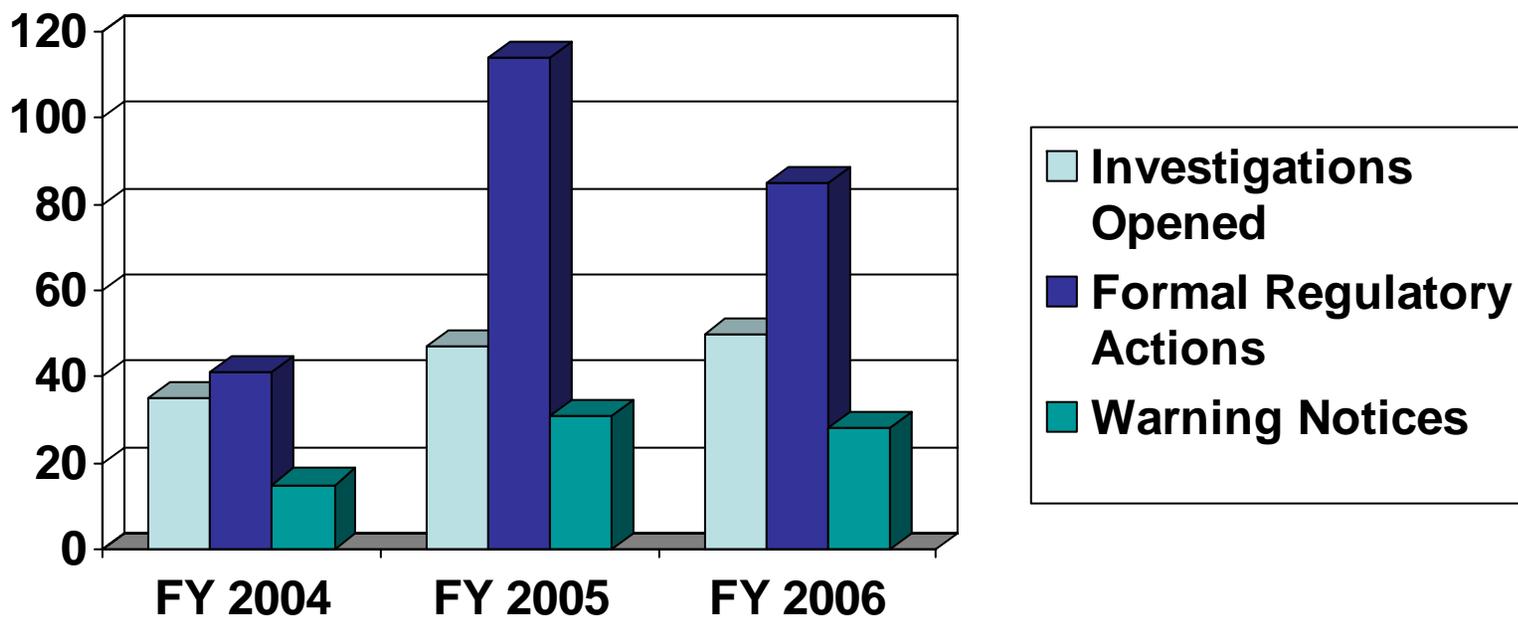
Product Inspection Activities



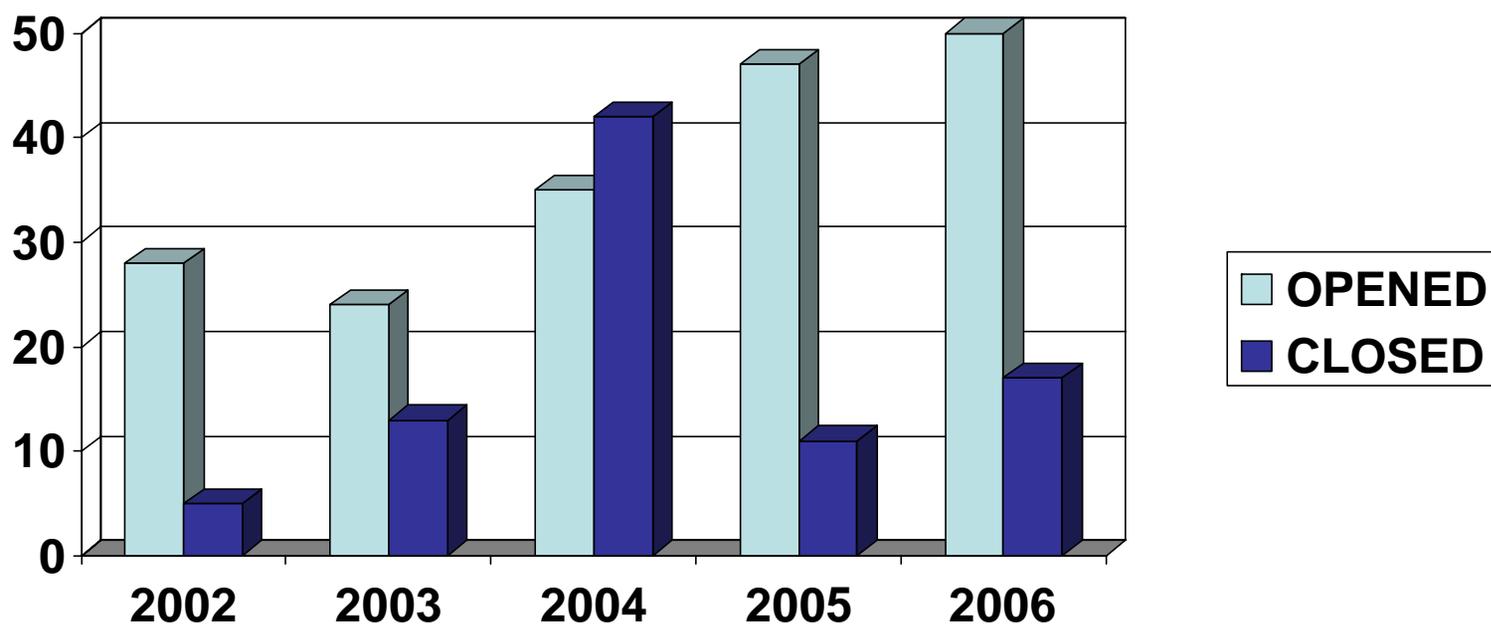
Primary Sources of Compliance Issues- Investigations

- Potency/Stability/Safety
- Unlicensed manufacturing
- Advertising
- Repackaging/Packaging/Labeling

Regulatory Actions



Investigations



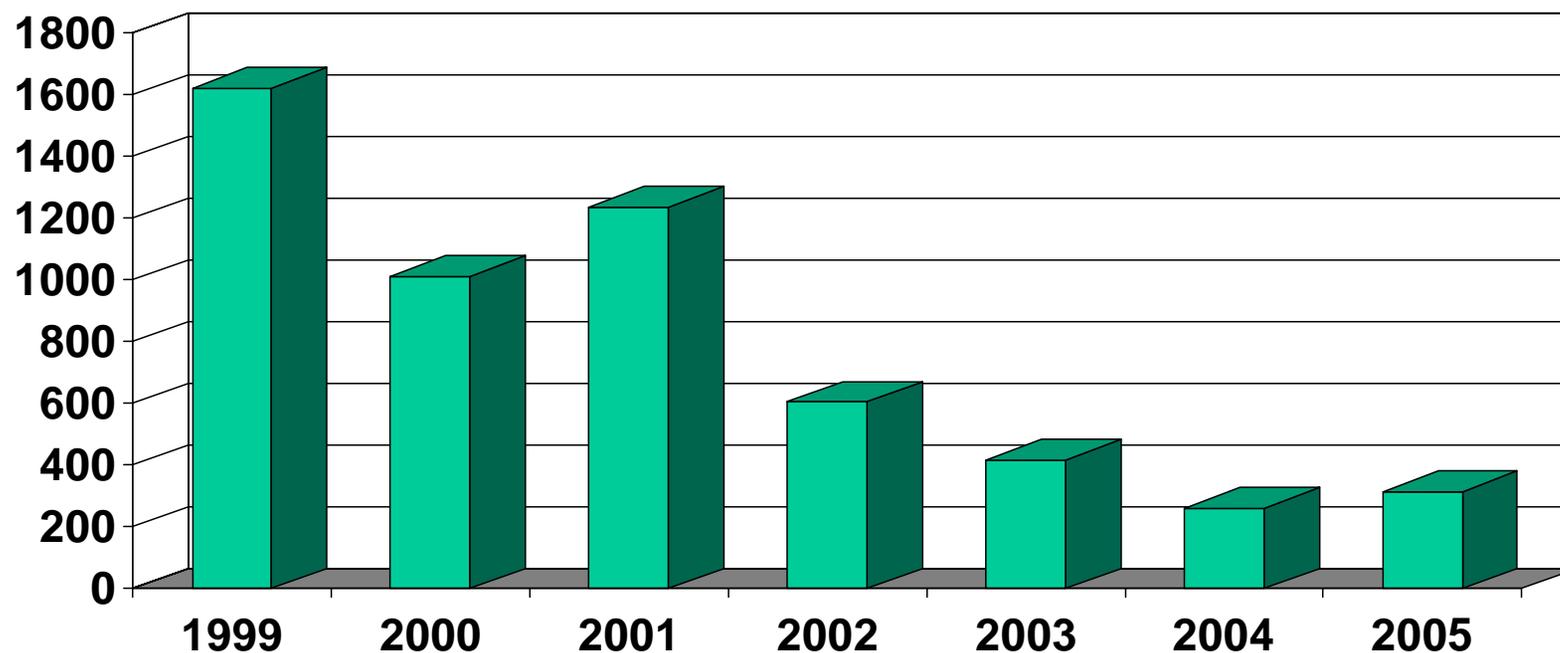
Additional Compliance Issues

- Increase in unlicensed firm investigations
- Focus on Regulation writing
- Collaboration with California Department of Food & Agriculture

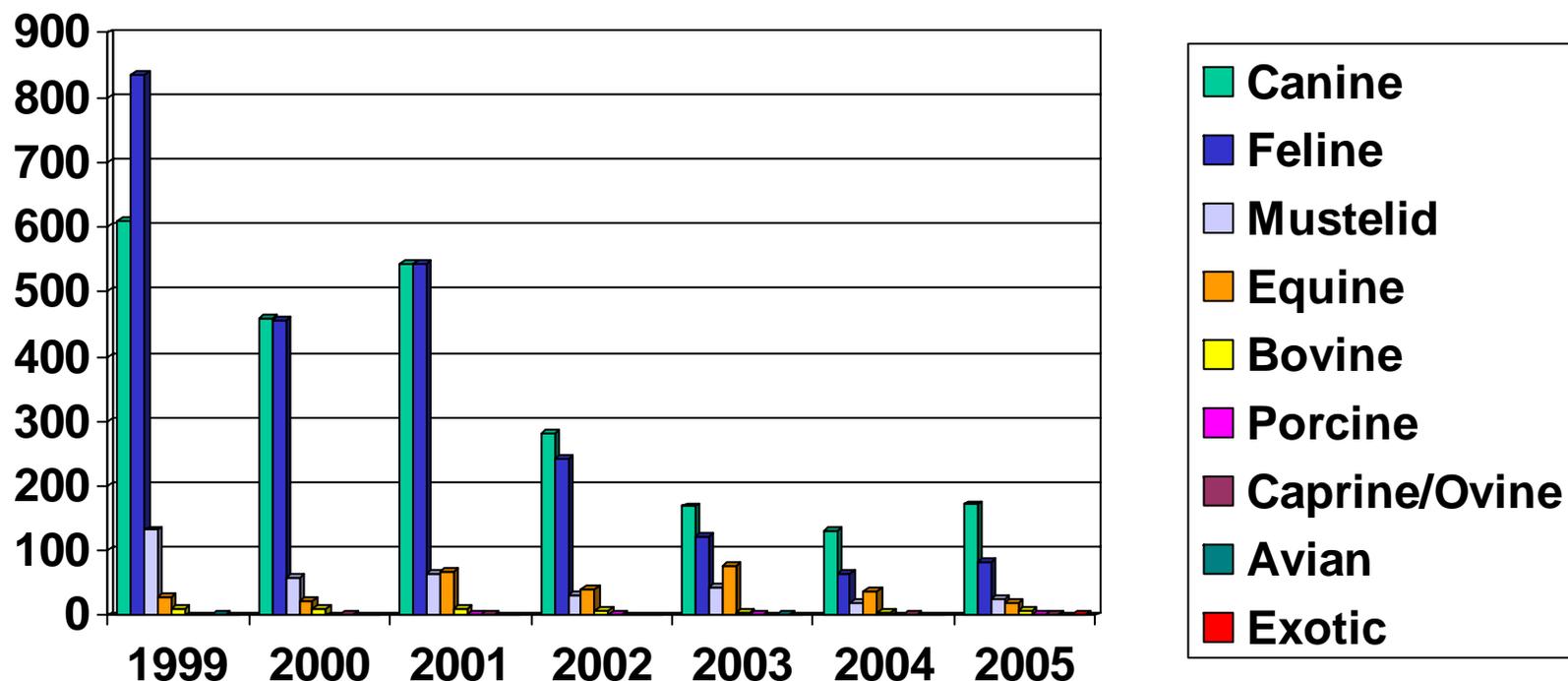
Pharmacovigilance

- Federal Register – Proposed Rule published
 - Comment period closed
 - Evaluating comments for next steps
- VICH Harmonization activities –
 - Meeting held in Tokyo – May 2006
 - Progress made on periodic reporting guideline
 - Issues remain regarding electronic transmission
 - Meeting in early 2007 under consideration

Adverse Event Reports Calendar Year



Adverse Event Reports by Species Calendar Year



CVB Website

- www.aphis.usda.gov/vs/cvb
- To file an Adverse Event Report
 - Click on “Vaccine Adverse Events” button
- CVB guidance documents
- Links to current BSE Surveillance System information