Year End Report
FY 2010

USDA, APHIS
Veterinary Services
Center for Veterinary Biologics
Inspection and Compliance
LSRTIS Background

- Custom modules developed around the functional components of the CVB
- Retired 1 non-supported application
- Provides flow processing for licensing and pre-licensing of over 124 veterinary biologics manufacturers and more than 2500 products
- Provides serial release processing, tracking, and authorization for over 73 Billion doses of vaccines, and related animal biologic products.
- Incorporates laboratory testing information of samples for the serial release process.
2010 LSRTIS Actions

• LSRTIS Phase II completed and placed into production
  – Provides logical process flow and checks for:
    • Biologics Material Processing - receiving/storing biologic samples for testing
    • Licensing
    • Pre-Licensing
    • Laboratory Testing
    • Serial release tracking for vaccines and other biologic materials.

• Phase III application development initiated

• Certification and Accreditation
  – Phase I C&A completed and approved.
  – Phase II initiated
2011 LSRTIS Actions

• LSRTIS Phase III initiated
  – Merge LSRTIS Phase I and LSRTIS Phase II developments into one application package.
  – Enhance application by adding:
    • Compliance Module – supporting compliance activities associated with veterinary biologics
    • Inspection Module – supporting inspections of veterinary biologics licensed establishments
    • Export Module – supporting certification of licensed veterinary biologics that are exported

• Certification and Accreditation
  – Phase II C&A to be completed and approved.
Pharmacovigilence (PV)

- Improve adverse event reporting and defect tracking of regulated biologics for USDA licensed products
- Improve common interface for veterinary adverse event reporting between USDA and FDA
- Provide CVB with a system that meets international regulatory requirements for pharmacovigilence
2011 PV Actions

• Commercial Off The Shelf (COTS) package purchased
  – PV Works (Vendor: Assured Information Systems)
  – Installation of COTS Package
  – User Acceptance Testing of Application
  – Development of Requirements for any added functionality

• Certification and Accreditation
  – Complete Phase I C&A
  – Initiate Phase II C&A

• Development
  – Initiate customization to prepare for interface with FDA and EPA.
Other Pharmacovigilence Activities

- **VICH Pharmacovigilence Expert Working Group**
  - Open for comment until 21 DEC 2010

- **Rulemaking**
  - Will be developing new proposed rule for adverse event reporting following VICH guidance (estimate late 2011 – early 2012)
  - Final rule to be developed following comments
  - Delayed implementation for firms to come into compliance (estimate 2016-2017) for mandatory reporting to CVB
Export Activities by Serial

Example chart showing export activities by serial, with data points for FY02 to FY10.
Export Activities by Product

- Certificates of L&I

FY02 - FY10 years shown with corresponding activity levels.
Inspections

- In-depth
- Special
- Followup

FY02  FY04  FY06  FY08  FY10
Serial Release Activities

Serials Released
Audits
Serials Destroyed

FY00 FY02 FY04 FY06 FY08 FY10

Serials Released
Audits
Serials Destroyed
Product Inspection Activities – FY 10

The bar chart illustrates the number of approved and rejected items across different categories:

- Facility Documents
- EOD
- Reprocessing
- Rebottling

The chart shows the following counts:

**Approved:**
- Facility Documents: 90
- EOD: 70
- Reprocessing: 50
- Rebottling: 30

**Rejected:**
- Facility Documents: 10
- EOD: 20
- Reprocessing: 10
- Rebottling: 5
Product Inspection Activities

- Facility Documents
- EOD
- Reprocessing
- Rebottling

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Administrative Inspection Review (AIR)

Activity per Year

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- **Sent to Firms**
- **Received back**
Regulatory Actions

![Bar chart showing Regulatory Actions from FY02 to FY10]

- **Investigations Opened**
- **Formal Regulatory Actions**
- **Warning Notices**

Bar chart categories:
- FY02
- FY04
- FY06
- FY08
- FY10