

Center for Veterinary Biologics: Current Program and Emerging Issues October 2007

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United States Department of Agriculture
Ames, Iowa USA



Safeguarding Animal Health



APHIS/Veterinary Services

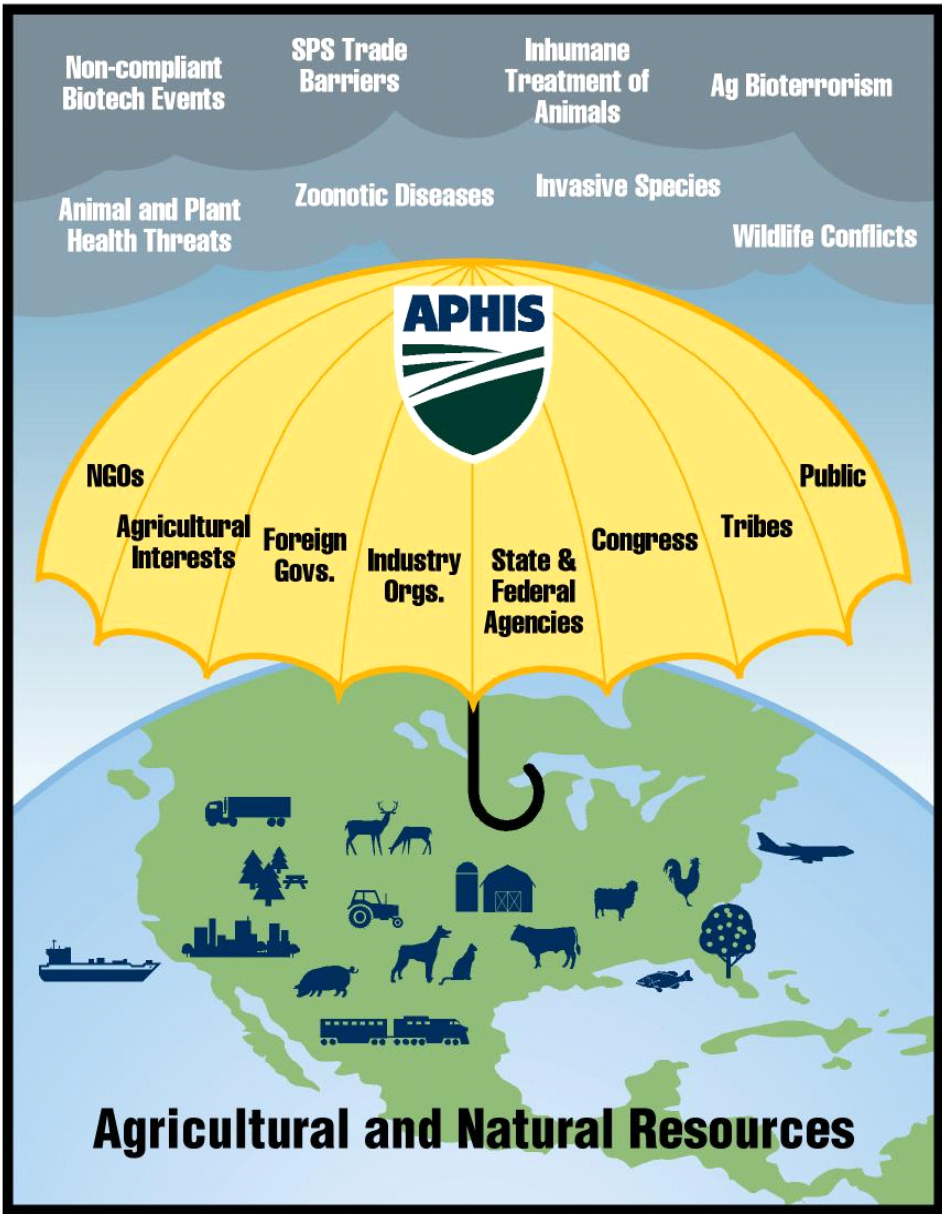
Current/Emerging Issues

- ▶ APHIS Leadership
 - Cindy Smith, Administrator
 - Kevin Shea, Associate Administrator
- ▶ Republication of the Select Agent & Toxin list
 - Proposed Rule for comment
- ▶ Animal Disease Traceability (discussion DRAFT)
- ▶ APHIS Strategic Plan
 - http://www.aphis.usda.gov/about_aphis/strategic_plan.shtml



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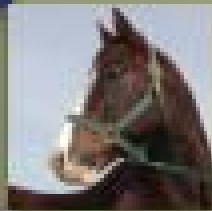
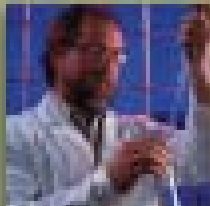
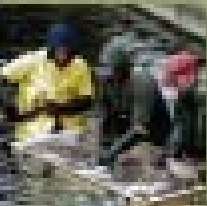
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2006 UNITED STATES Animal Health Report

United States Department of Agriculture
Animal and Plant Health Inspection Service
APHIS Information Bulletin No. 101



Safeguarding Animal Health

United States Animal Health Report

<http://www.aphis.usda.gov/publications>





Protecting American Consumers Every Step of the Way:

A strategic framework for continual improvement in import safety



U.S. Food and Drug Administration



[FDA Home Page](#) | [Search FDA Site](#) | [FDA A-Z Index](#) | [Contact FDA](#)

Pet Food Recall (Melamine)/Tainted Animal Feed

A Report to the President

Interagency Working Group on Import Safety
September 10, 2007



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APHIS/Veterinary Services Current/Emerging Issues

- ▶ Strategic Framework for Import Safety
 - International Trade Data System
 - Interagency Working Group on Import Safety is requesting public comments on Import Safety
 - Veterinary Services represented on APHIS Steering Committee
 - www.importsafety.gov



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APHIS/Veterinary Services

Current/Emerging Issues

- ▶ Biologics discontinuance following successful eradication/control Programs
 - Pseudorabies/*Brucellosis* (examples)
 - Vaccine/Test Kit use & timeline for discontinuing
 - Domestic production of vaccines for export
 - Emergency preparedness (domestic use)
 - Select Agent status and biosecurity
 - Wildlife reservoirs
 - Vaccine/antigen/seed banks
- ▶ White paper: *Vaccine Use Following Brucellosis and Pseudorabies Eradication*
- ▶ http://www.aphis.usda.gov/vs/cvb/PDFs/10_10_06_VaccineUseWhitePaper.pdf



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United States
Department of
Agriculture

Marketing and
Regulatory
Programs

Animal and Plant
Health Inspection
Service

Veterinary Services

Center for Veterinary
Biologics
Suite 104
510 South 17th Street
Ames, IA 50010
(515) 232-5785
FAX (515) 232-7120

Vaccine Use Following Brucellosis and Pseudorabies Eradication



Center for Veterinary Biologics
August 2006



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Center for Veterinary Biologics Activity Summary

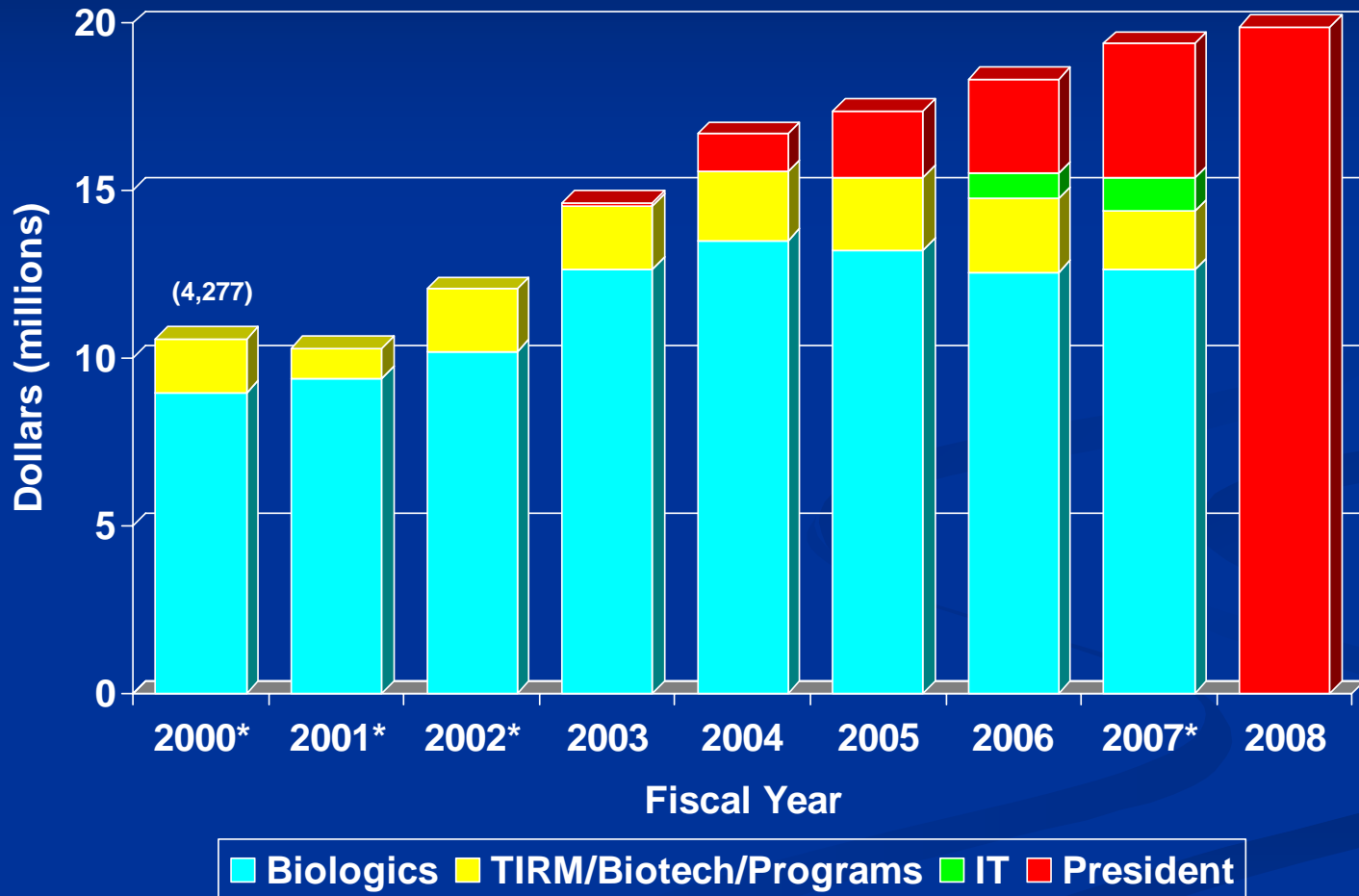
	FY05	FY06	FY07
Submissions	6993 (+48)	6646 (-347)	6656 (+10)
Product Licenses & permits Issued	97 (-27)	76 (-21)	63 (-13)
New Antigen Combinations	16 (-1)	11 (-5)	18 (+7)
Serials Released Eligible (%Tested)	16178 11,685 (13.5)	15945 11,634 (8.46)	16021 11,938 (6.51)
Inspections	88	85	85
Investigations/ Regulatory Actions	47/145	53/113	30/113



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CVB Biologics Allocation History



2008 Forecast

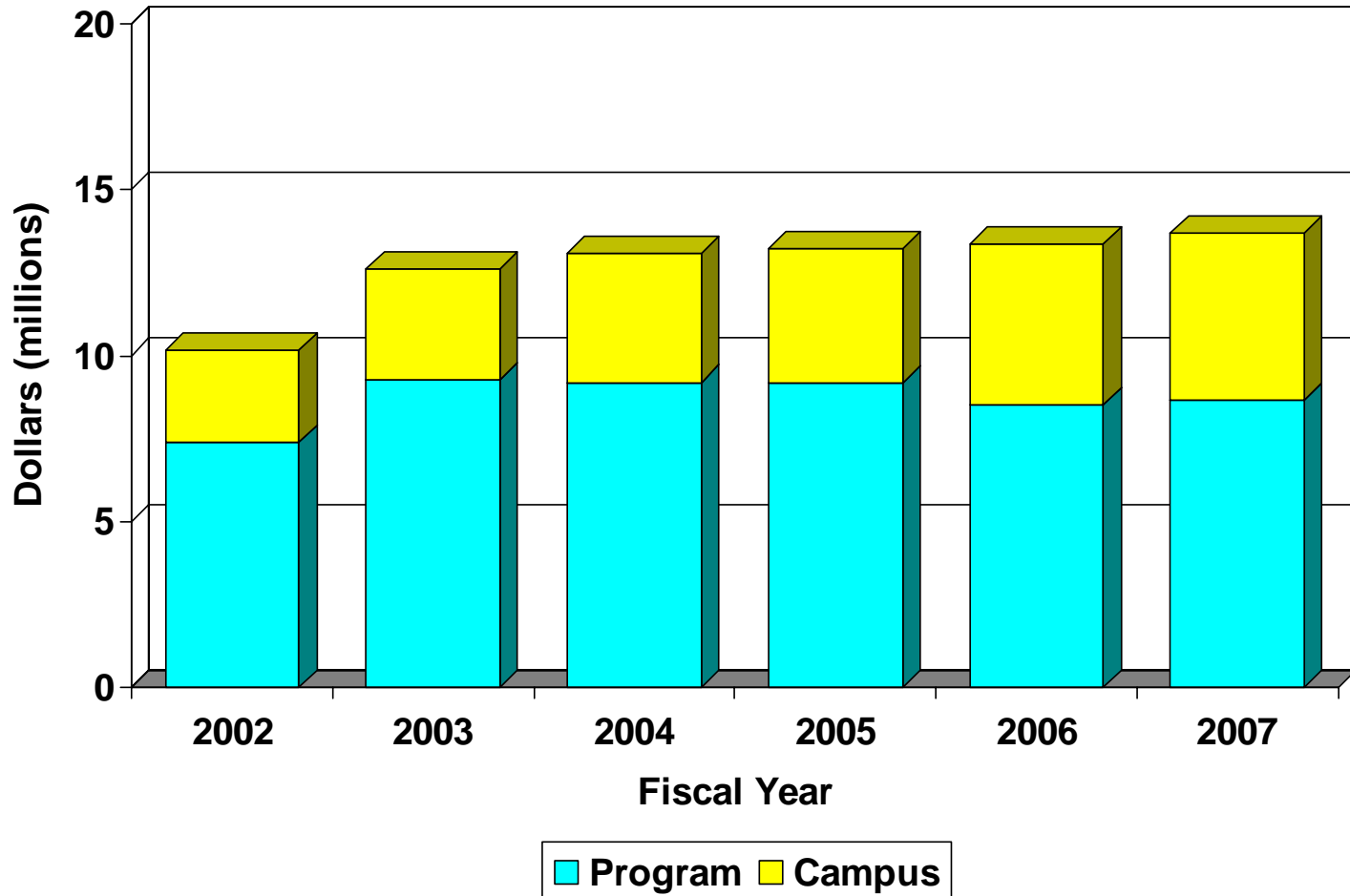
2007 (Cont. res.)	07 President	07 House mark-up	07 Senate mark-up
15, 658	19,867	17,569	18, 156



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Planning for 2008



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Vacancy Impact

(Vacancies / Total Number of Positions)

▶ Reviewers	7/17
▶ Specialists	6/16
▶ Epidemiologists	2/2
▶ Lab VMO/Micro	6/17
▶ Technicians	3/30
▶ Asst./Assoc. Directors	1/2
▶ Support Staff	8/32
▶ Safety & Security Unit	11/23
▶ Information Management Unit	8/42

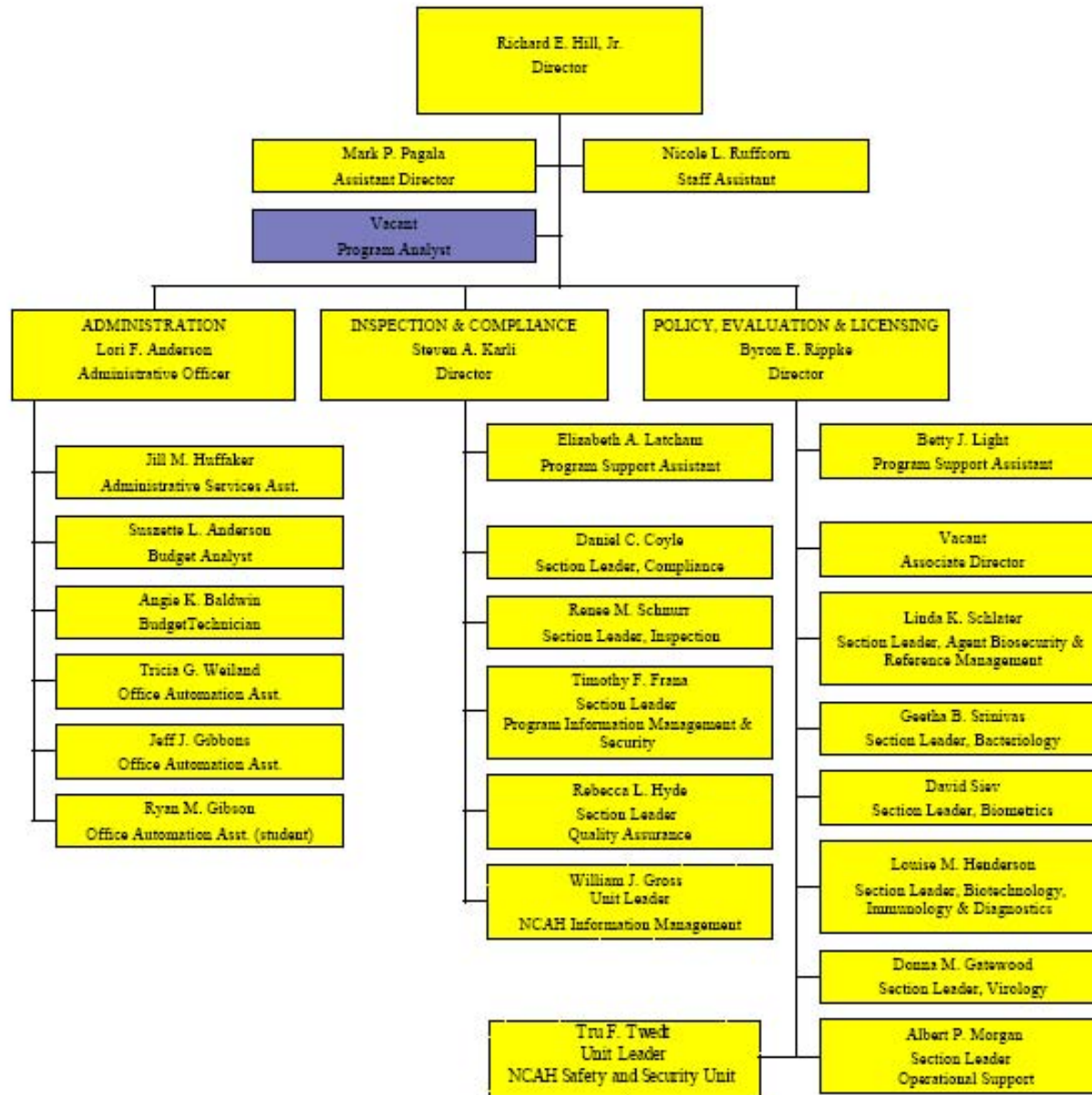


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Center for Veterinary Biologics



September 30, 2007

2008 Summary

- ▶ Continuing Resolution
- ▶ Increased campus costs
- ▶ Equipment and operational expenses and activities
- ▶ Program activity impact



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Center for Veterinary Biologics

Current/Emerging Issues

- ▶ Pharmacovigilance agreements
- ▶ Epizootic hemorrhagic disease
- ▶ *In vitro* policies and guidance documents
- ▶ International Reports:
 - Benchmarking the Competitiveness of the Animal Health Industry
- ▶ *E. coli* Coalition
- ▶ Certification to ISO 9001:2000 Standards



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Certificate of Registration

USDA, APHIS, VS
Center for Veterinary Biologics
1800 Dayton Avenue
Ames, IA 50010

Is hereby granted the right and license to use the QSR® Registered Firm Symbol and to be listed in the Quality Systems Registrars, Inc. "Register of Certified Quality Systems" under the conditions specified in QSR®'s Contract and ISO 9001:2000 (ANSI/ISO/ASQ Q9001-2000) for the following scope:

The Center for Veterinary Biologics, USDA, APHIS, VS is responsible for implementing the provisions of the Virus-Serum-Toxin Act to assure that pure, safe, potent, and effective veterinary biologics are available for the diagnosis, prevention, and treatment of animal diseases. The CVB exercises Federal authority to inspect facilities and review preclicensing data submitted in support of licensure; issue establishment and product permits and licenses; produce testing aids and evaluate product at the CVB laboratory; write standards and procedures for product release; and provide inspection and compliance oversight for firms producing or distributing Veterinary Biologics in the United States. These activities take place at the 1800 Dayton Avenue, Ames, IA 50010 and the 510 S. 17th Street, Ames, IA 50010 locations.

Exclusions: 7.3 Design and development.

The period of registration is from September 4, 2007 to September 3, 2010.

Certificate Number: QSR-858

Scott R. Kleckner
President

September 24, 2007
Date



QUALITY SYSTEMS REGISTRARS, INC.
22630 Davis Drive, Suite 220 • Sterling, Virginia 20164
Ph 703-478-0241 • Fx 703-478-0645
www.qsr.com



Center for Veterinary Biologics Meetings

- ▶ 14th Veterinary Biologics Public Meeting
 - April 7-11, 2008
- ▶ Other meetings of interest
 - Global Animal Health Conference, November 15-6, 2007, London
 - Ploufragen II (follow-up to 1st Harmonization meeting '92) 2008??



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