Rec'd 9/10/98

Welcome

To the

Center for Veterinary Medicine's Stakeholder Meeting

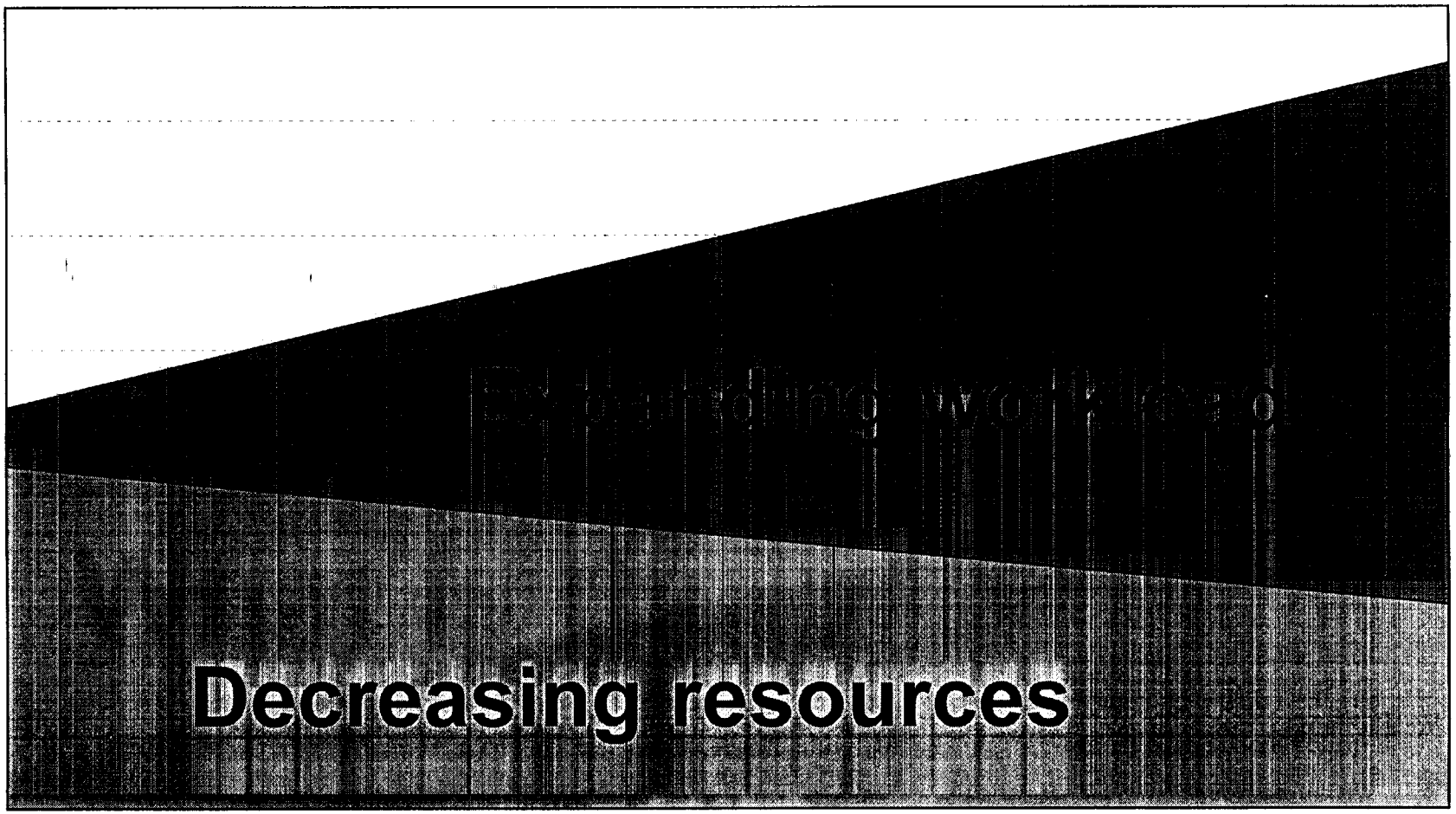
August 19, 1998

Department of Health and Human Services
Hubert H. Humphrey Building
Penthouse Conference Room (Room 800)
200 Independence Avenue, SW
Washington, DC 20201

98N-339V

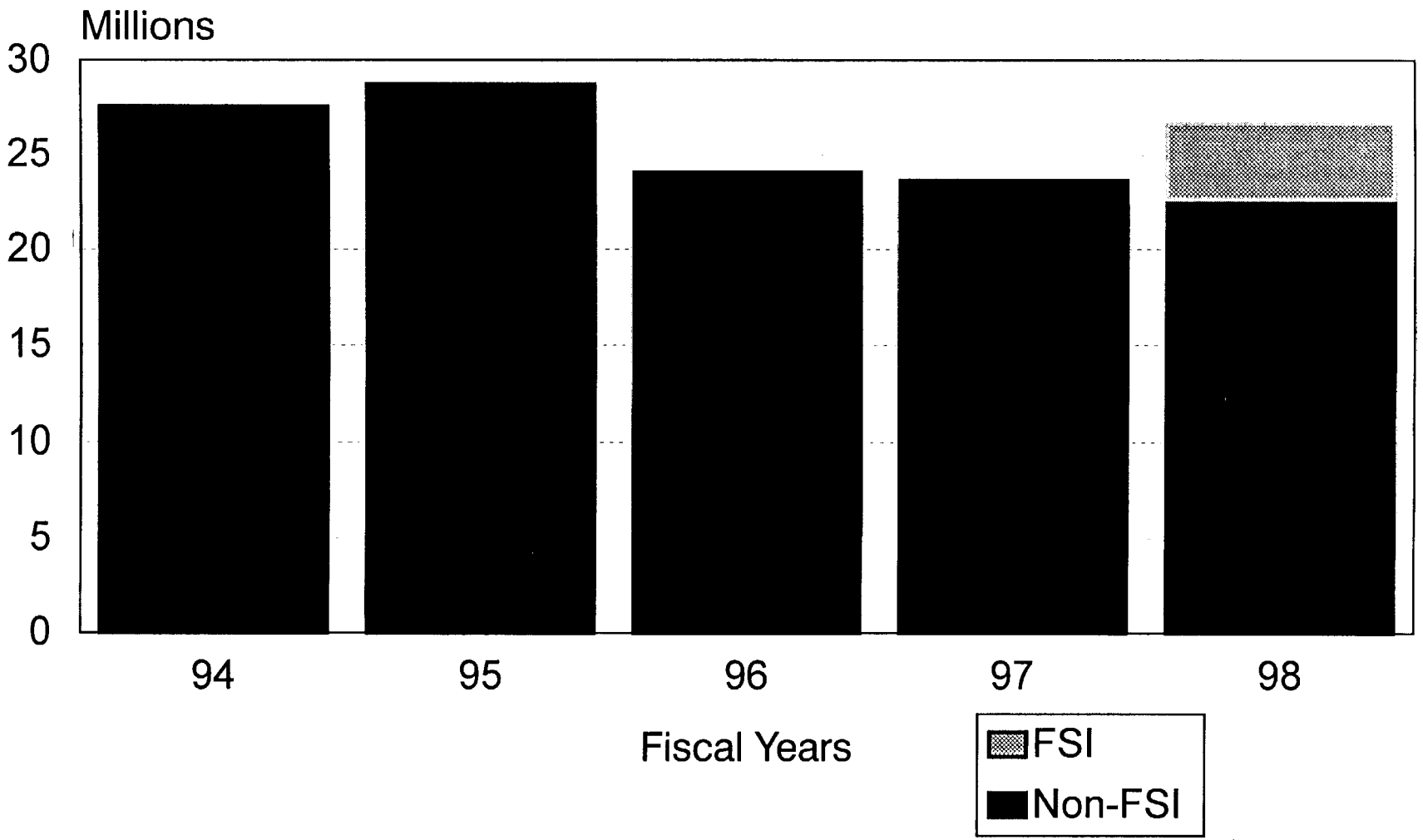
TS3

What is the problem?



FY 1992 FY 1996 FY 2000

Center for Veterinary Medicine's Budget Over Last 5 Years



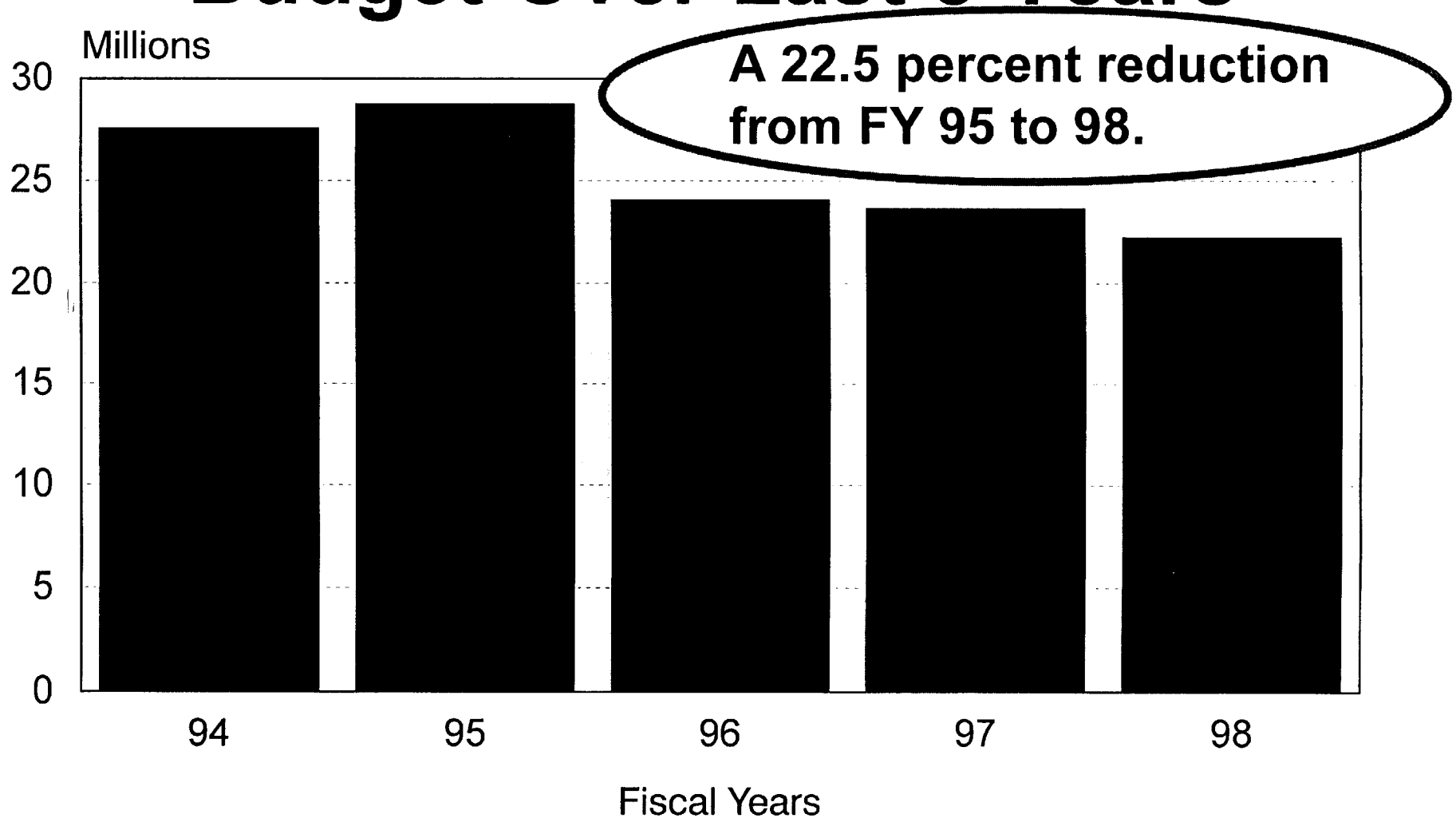
In Constant 1994 Dollars

CVM's Part of the President's Food Safety Initiative (FSI)

Antimicrobial Susceptibility Monitoring

- The National Program
- Related Surveillance
- Related Research

Center for Veterinary Medicine's Budget Over Last 5 Years



In Constant 1994 Dollars

Causes of Decreasing Resources

- Government Downsizing and Streamlining
- Flatline* FDA Budgets
- User Fee Protections

* Flatline = no money appropriated to cover cost-of-living increases or increased cost of goods and services due to inflation.

Causes of Expanding Workload

- Growth of Traditional Work
- Unfunded Mandates
- Increasing Complexity of Products
- New Initiatives
- Unexpected High Priority Work

Growth of Traditional Work

- Premarket Submissions have grown by 33% in the last 5 years
- DERs received annually have increased by more than 180% in the last 5 years
- ADEs received annually have increased by more than 250% in the last 5 years

Unfunded Mandates

- Animal Drug Availability Act of 1996
- FDA Modernization Act of 1997
- Animal Medicinal Drug Use Clarification Act of 1994

Increasing Complexity of Products

- rBST
- Post-Approval Monitoring Programs (PAMPs)
- Risk Assessment Models

New Initiatives

- President's Food Safety Initiative - To Reduce Food Borne Illness
- National Antimicrobial Resistance Monitoring System - To Identify Emerging Resistance and Act to Prevent the Problem
- Joint Institute for Food Safety and Applied Nutrition (JIFSAN) - Collaboration with CFSAN and University of MD to Make Food Supply Safer

- International Activities - VICH and Codex - To Ensure Level Playing Field for Trade and Safet Food Supply

- CVM Strategic Plan - Focus Efforts on Highest Priority Work

- High Performance Organization (HPO) - More Productive Staff

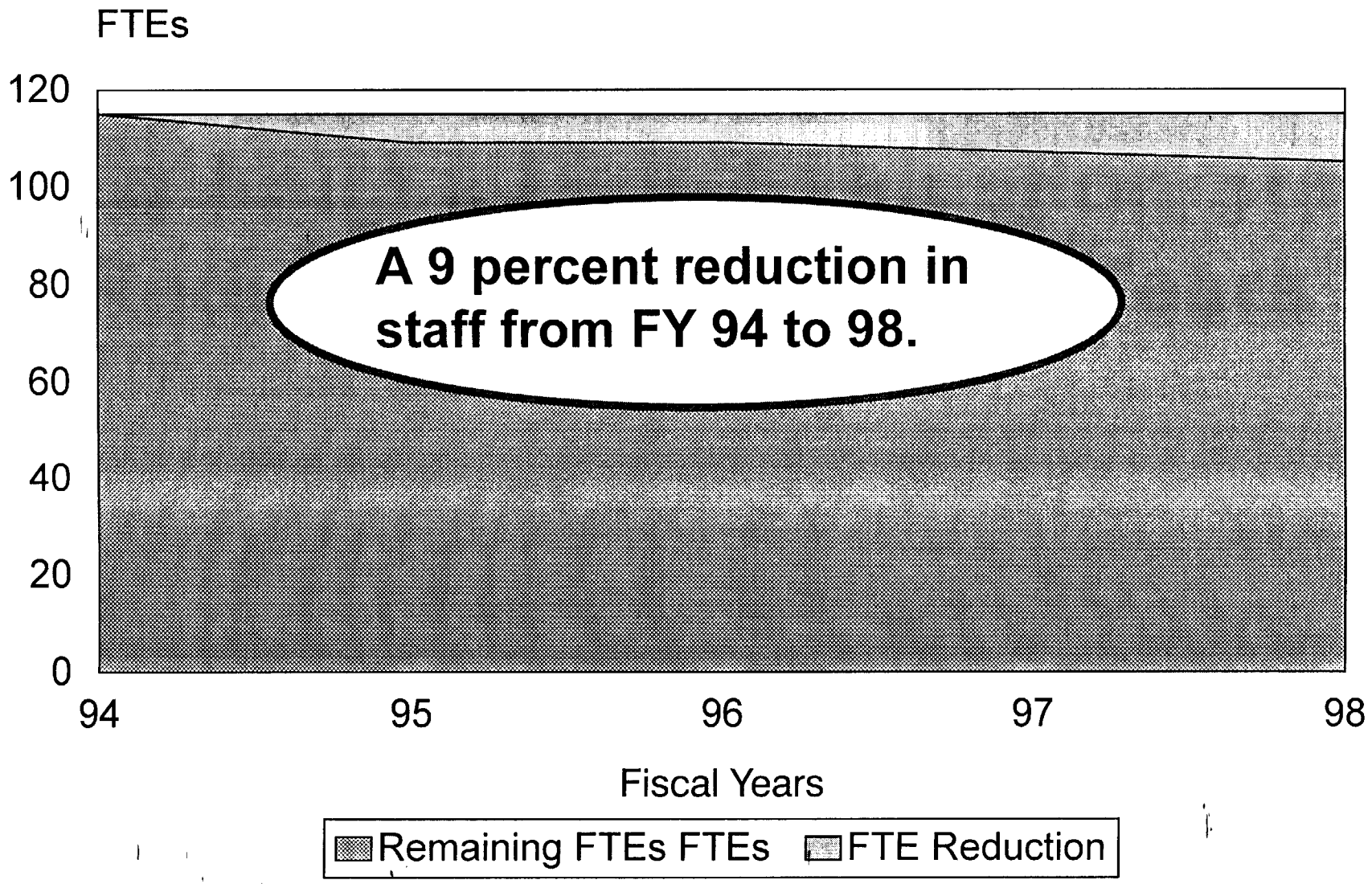
Unexpected High Priority Work

- Bovine Spongiform Encephalopathy (BSE)
- Antimicrobial Resisatance

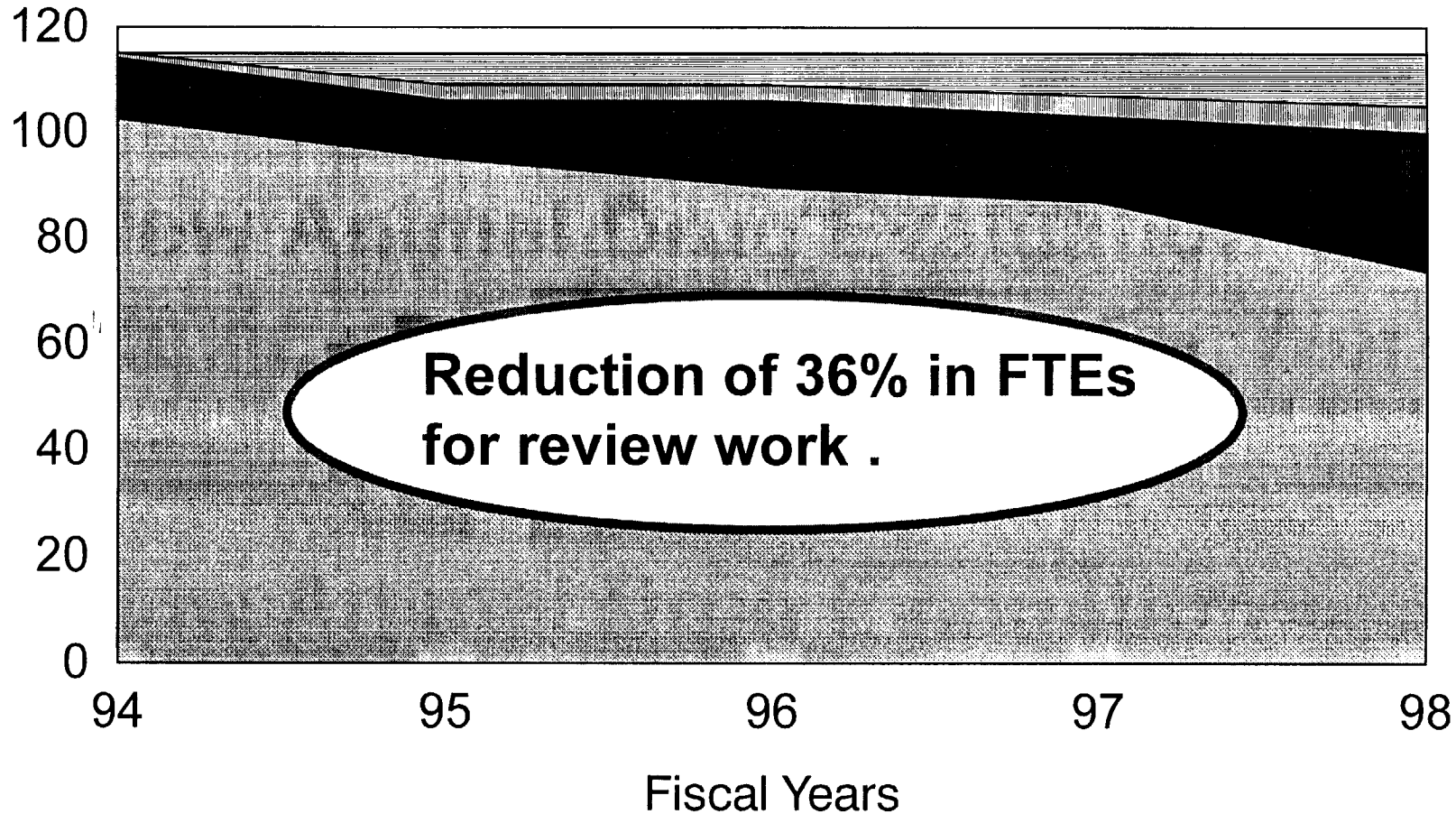
Efficiencies

- ReGo
- Strategic Plan
- Technology
- Electronic Submissions
- HPO

New Animal Drug Evaluation Staff Reductions Over Last 5 Years

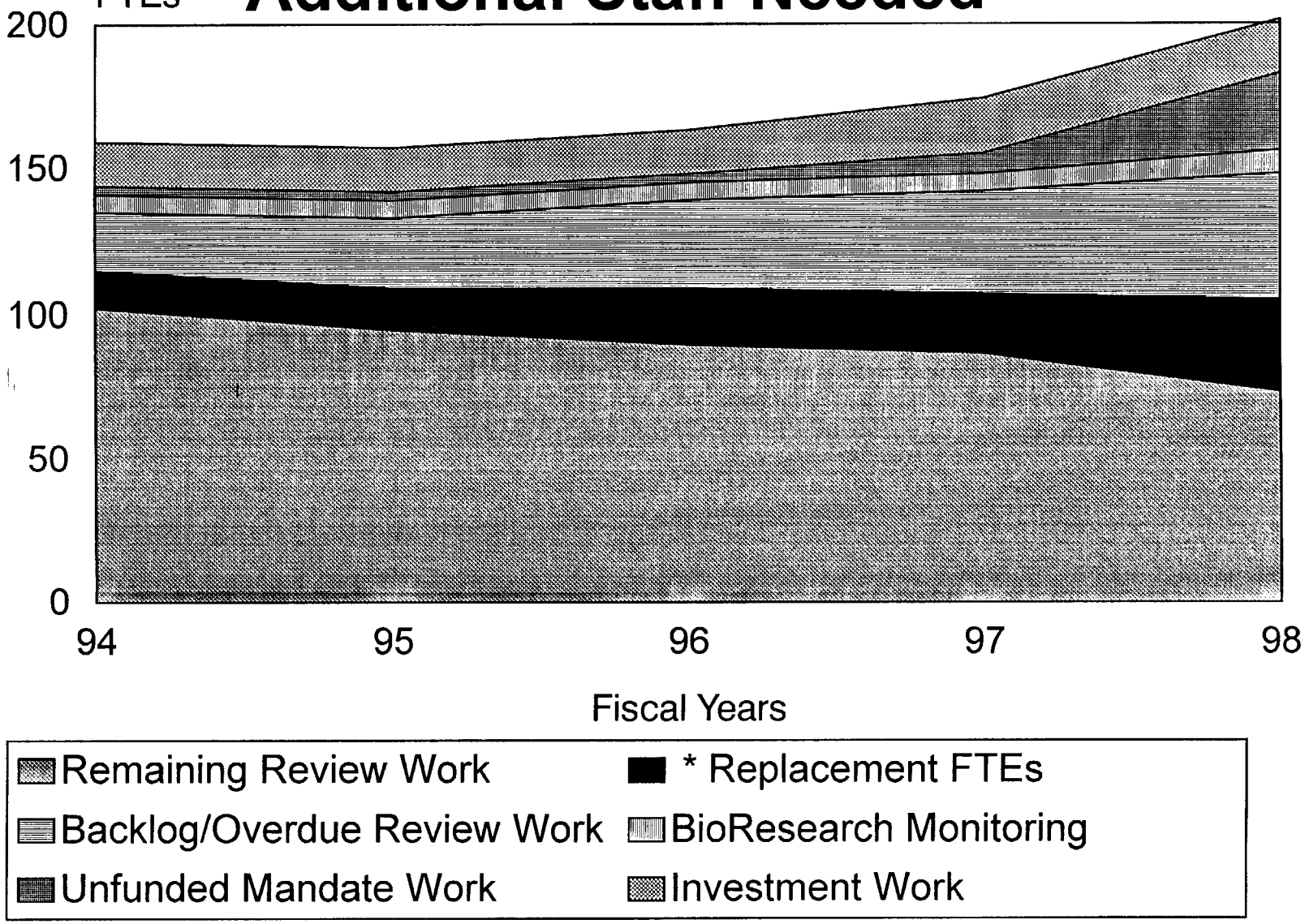


New Animal Drug Evaluation Staff Review versus Non-Review Work



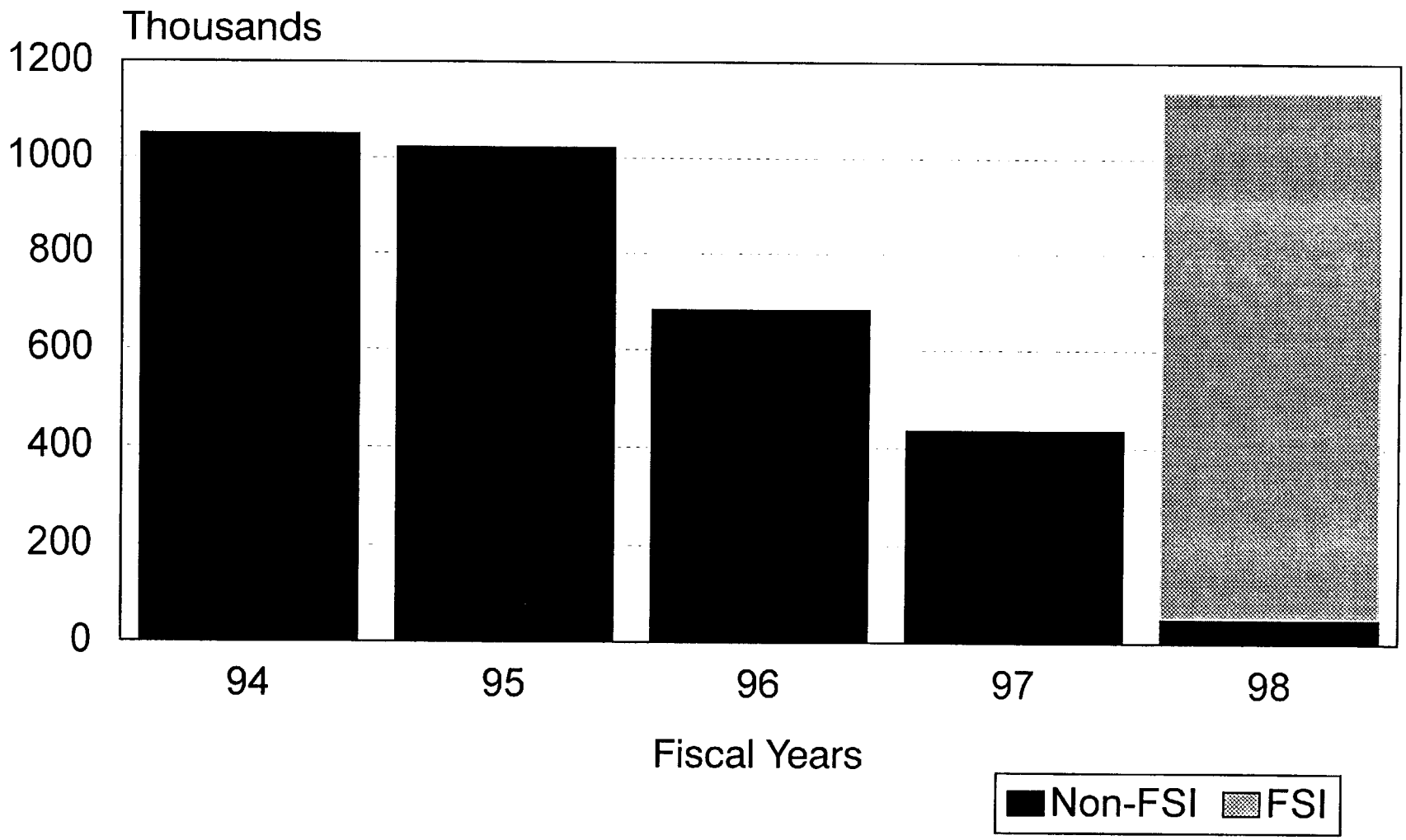
* Investment work = development of guidelines and workshops to educate the industry about premarket requirements.

New Animal Drug Evaluation
Additional Staff Needed



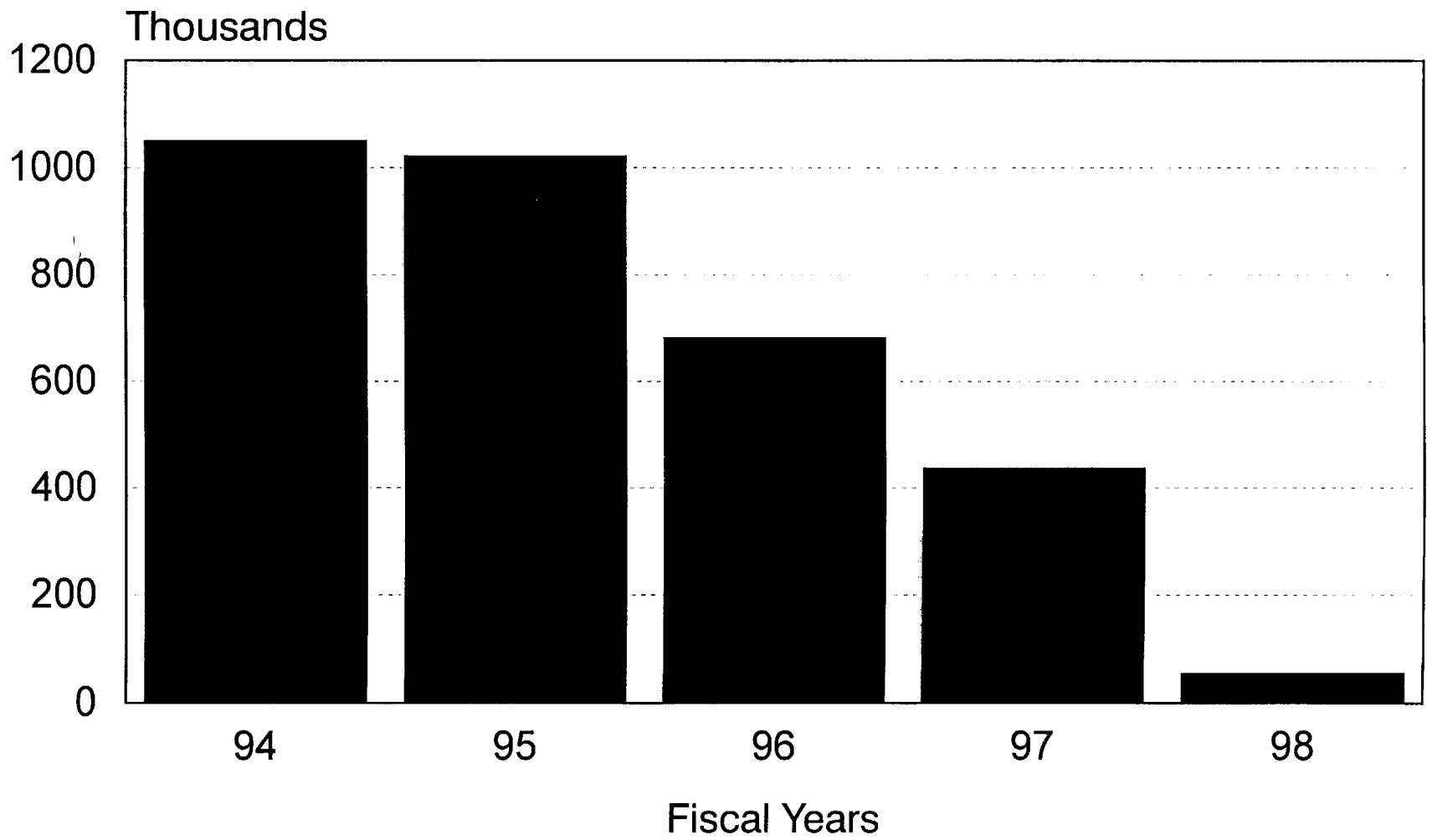
* Replacement for FTEs already being spent on unfunded mandates and Investment work.

Center for Veterinary Medicine Extramural Research - Last 5 Years



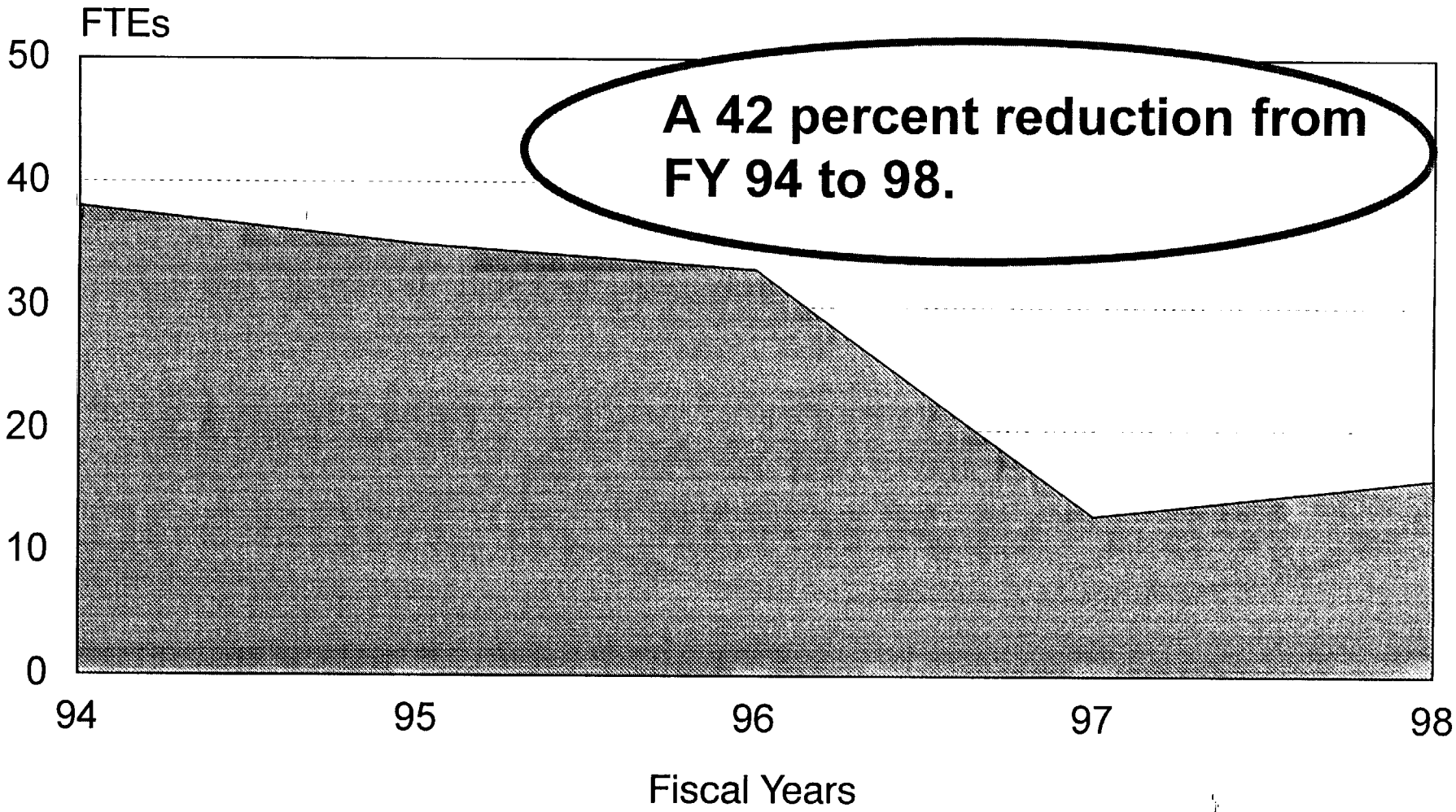
In Constant 1994 Dollars

Center for Veterinary Medicine Extramural Research - Last 5 Years

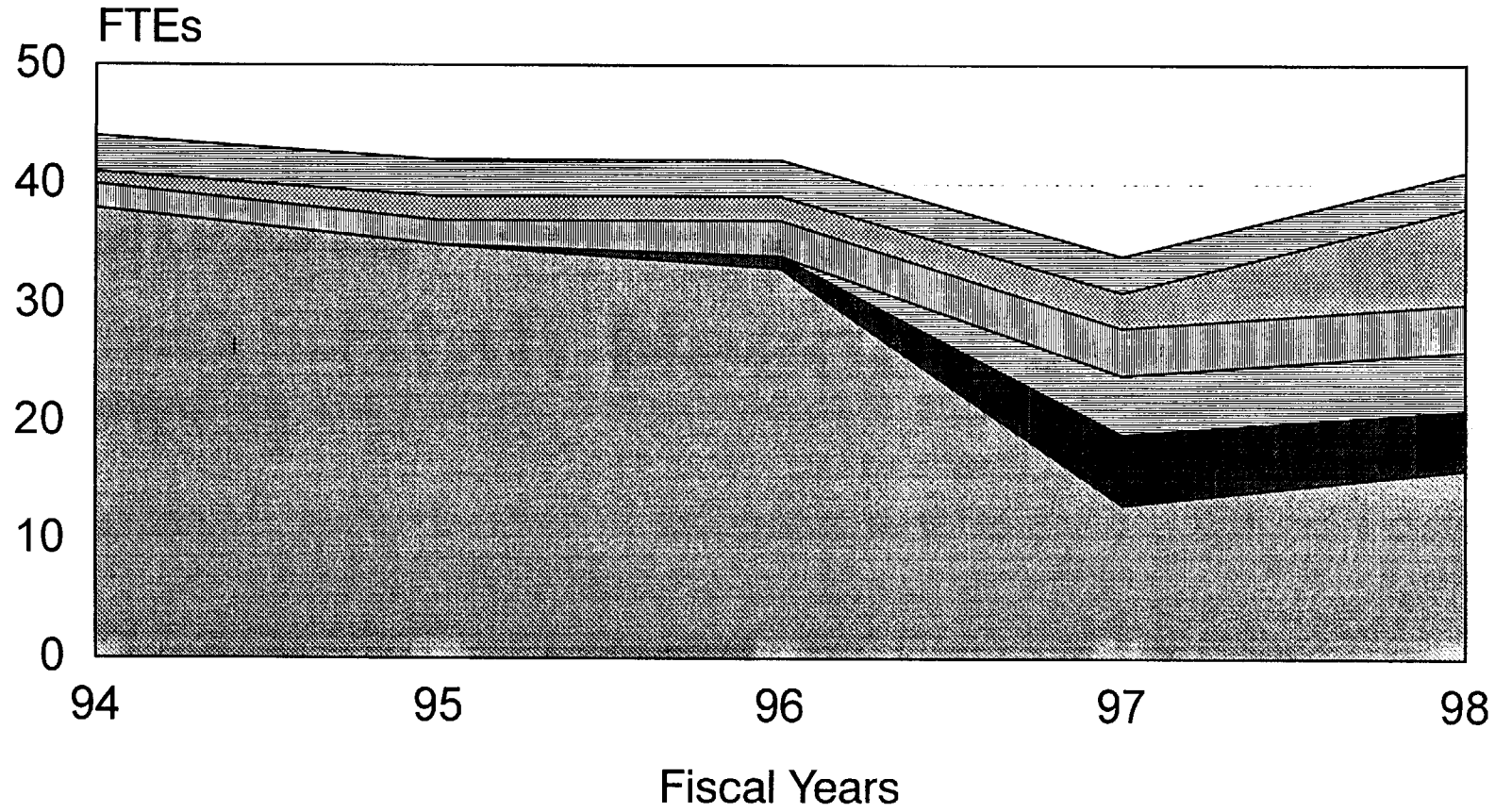


In Constant 1994 Dollars

Division of Compliance Reductions in Staff Over Last 5 Years



Division of Compliance Staff Needed



In your responses and presentations please address the FDA questions listed below both from the CVM and the Agency perspective, as well as, the CVM specific questions also included below.

FDA Questions

To help focus your comments, the FDAquestions have been developed in the context of the objectives described in section 406 (b) of FDAMA.

1. What can FDA do to improve its explanation of the Agency's submission review processes, and make explanations more available to product sponsors and other interested parties?

2. How can the Agency maximize the availability and clarity of information concerning new products?

3. How can FDA work with its partners to ensure that products--domestic and foreign--produced and marketed by the regulated industry are of high quality and provide necessary consumer protection; and how can FDA best establish and sustain an effective, timely, and science-based postmarketing surveillance system for reporting, monitoring, evaluating, and correcting problems associated with use/consumption of FDA-regulated products?

4. What approach should FDA use to ensure an appropriate scientific infrastructure with continued access to scientific and technical expertise needed to meet its statutory obligations and strengthen its science-based decision-making process?

5. What do you believe FDA should do to adequately meet the demands that are beginning to burden the application review process, especially for non-user fee products, so that it can meet its statutory obligations to achieve timely product reviews?

6. What suggestions do you have for the Agency to eliminate backlogs in the review process?

7. What other objectives related to the Agency's statutory obligations or public expectations -- beyond the six objectives -- should be included in the FDA plan?

CVM Questions

1. Thinking about the many consumer protection functions performed by CVM (a listing of the functional activities performed by each of the offices in the Center was included in the information package mailed to you), are there some that should be changed? If so, how? Are there some that could be eliminated? Are there functions not included that you would add?

2. Which of these functions do you believe it would be acceptable for CVM to charge fees?

3. For which of these functions could, and should, CVM rely more on the efforts of third parties, such as testing laboratories, veterinary organizations, standards (domestic or international) setting organizations, states, or regulated industry?

4. Which of these functions do you see as having the best potential for CVM to collaborate with its external stakeholders? Please be specific and name both the functions and the collaborating stakeholder.

5. Which of these functions do you believe offers the greatest opportunities for CVM to place more emphasis on non-regulatory approaches -- such as education, technical assistance, and collaborative problem solving -- to protect and promote public health?

6. In the international arena, CVM is faced with similar questions on the allocation of its resources. Currently, the Center's international resources are split among: international standard setting, such as the establishment of veterinary drug residue standards; efforts to internationally harmonize veterinary drug registration requirements; involvement in Agency efforts to develop mutual recognition agreements between the U.S. and other nations; offering technical assistance to foreign regulatory officials; and providing technical support to U.S. trade agencies. Would you maintain the current mix of effort, or change it? If you would change it, how?

We have established a docket to receive any input that you may have on the six objectives outlined in section 406(b) of FDAMA. The more specific and concrete you can be in your suggestions, the more helpful they will be in developing the 406(b) plan. The docket number is 98N-0339. Comments may be sent via hard copy to the following address:

Food and Drug Administration
Dockets Management Branch
Room 1061, HFA-305
5630 Fishers Lane
Rockville, Maryland 20852

Comments can also be provided on line at http://www.fda.gov or sent via E-mail to the following address, FDADOCKETS@BANGATE.FDA.GOV.