



## Science Board Review of FDA Intramural Research

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1



## Prior Reviews

- Agency-Wide
  - 1955, 1962 Citizens Advisory Committee
  - 1991 Edwards Commission
  - 1997 Korn Subcommittee Report on FDA Research
  - 2007 Science Board Subcommittee on Science and Technology
- Center-Specific
  - Many Centers periodically undergo review, including a recent Centers review by the 2007 Subcommittee on Science and Technology
  - CDRH
  - CFSAN
  - CBER
  - NCTR
- Program-Targeted
  - ORA Pesticide Program
  - National Center for Toxicological Research
  - NARMS Program

*Common theme: FDA looks for the advice of the Science Board on  
Specific and technical issues.* 2



## **FDAAA of 2007\* – Chief Scientist's Intramural Research Responsibilities**

- Oversee, coordinate, ensure quality and regulatory focus
- Track and coordinate
- Develop and advocate budgetary support
- Develop a peer review process
- Identify and solicit intramural research proposals

\*<http://www.fda.gov/oc/initiatives/fdaaa/PL110-85.pdf>

3



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4



## Review Objectives

- Science and technology advances
- Prioritization process
- Senior Management oversight
- Impact – policy and guidance
- Appropriate/available science
- Communication – publications
- Infrastructure quality availability
- Center Director needs

5



## Science Board Review Process

- Establish Subcommittee
  - Members (2 or more)
  - Add'l Subject Matter Experts (Consultants)
- Draft a Work Plan
- Collect Data
- Interim Report to the Science Board
- Final Report to the Science Board

6



## 5 Year Review Cycle of FDA Intramural Research

Calendar Year	Focus Center
2009	CVM
	CFSAN
2010	CDER
2011	CDRH
2012	CBER
2013	NCTR

7



## Center for Veterinary Medicine Mission

The Center for Veterinary Medicine is a consumer protection organization that fosters public and animal health by approving safe and effective products for animals and by enforcing applicable provisions of the Federal Food, Drug, and Cosmetic Act (FFDCA) and other authorities.

8



## Center for Veterinary Medicine Activities

- Animal drug review
- Compliance-related actions
- Post-approval monitoring
- Animal feed safety

9



## CVM Review Timeline

- March
  - Charge to the Subcommittee, Roster, Work Plan
- April
  - Collect Data
- May
  - Interim Report to the Science Board
- June
  - Incorporate additional comments by the Science Board
- July
  - Draft Report
- August Meeting
  - Final Report to the Science Board

10



## Center for Food Safety and Applied Nutrition Mission

CFSAN, in conjunction with the Agency's field staff, is responsible for promoting and protecting the public's health by ensuring that the nation's food supply is safe, sanitary, wholesome, and honestly labeled, and that cosmetic products are safe and properly labeled.

11



## Center for Food Safety and Applied Nutrition Activities\*

- Food and seafood safety
- Food additive review
- Colors and cosmetic safety
- Dietary supplement safety
- Infant formula regulations
- Compliance-related actions
- Foodborne disease outbreak response

\* *Not an inclusive list*

12



## CFSAN Review Timeline

- August
  - Charge to the Subcommittee, Roster, Work Plan
- September
  - Collect Data
- October
  - Interim Report to the Science Board
- November
  - Incorporate additional comments by the Science Board
- December
  - Draft Report
- February
  - Final Report to the Science Board

13



## Next Steps

- Establish Subcommittees

14



## Review Importance

- Mission of Science Board
- Science expertise of Board
- Outside review focused on FDA science
- Focus on science
- Advisory to Commissioner on Science status