



✓ Site: Boston, MA

FDAMA STAKEHOLDER MEETING

APRIL 28, 1999

Talking with Stakeholders About FDA Modernization

**Your question/comments will become part of Docket Number: 99N-0386

Fax to: 1-888-361-4011 (on April 28 only)

Title (required) First Name (required) Last Name (required)
 Dr. Mr. _____
 Mrs. Ms. John Rider
 Organization Committee of Ten Thousand

Stakeholder Group ✓ stakeholder group you represent

Consumer Consumer Group Health Professional Industry Association Other

Center ✓ the center/product area your comments address

Center for Biologics Evaluation and Research Center for Drug Evaluation and Research
 Center for Devices and Radiological Health Center for Food Safety and Applied Nutrition
 Center for Veterinary Medicine Office of Regulatory Affairs
 FDA General

Questions to Stakeholders

Please check the box next to the stakeholder question/s from the March 22, 1999, Federal Register notice which your question/comment addresses

- 1. What actions do you propose the Agency take to expand FDA's capability to incorporate state-of-the-art science into its risk-based decision-making?
- 2. What actions do you propose to facilitate the exchange and integration of scientific information to better enable FDA to meet its public health responsibilities throughout a product's life cycle?
- 3. What actions do you propose for educating the public about the concept of balancing risks against benefits in public health decision-making?
- 4. What actions do you propose to enable FDA and its product centers to focus resources on areas of greatest risk to the public health?
- 5. What additional actions do you propose for enhancing communication processes that allow for ongoing feedback and/or evaluation of our modernization efforts?
- 6. Additional Comments on FDA Modernization Efforts

YOUR COMMENT/QUESTION

1) How does the FDA utilize ~~on~~ post market surveillance in relation to drugs treating HIV/AIDS in relation to overall risk analysis - and in adverse reporting to consumers of products used to treat HIV/AIDS.

2) How is drug ~~reaction~~ toxicity measured as opposed to overall benefit analysis? How far do longitudinal studies go in tracking adverse long term reactions to medications.

3) How ~~are~~ many studies are being done that combine alternative therapies with traditional treatments in relation to HIV/AIDS treatments. C/6