



# 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)

✓ Site: Atlanta, GA

Title (required)    First Name (required)    Last Name (required)

Dr.     Mr.    \_\_\_\_\_

Mrs.     Ms.    George Bachmann

Organization    GRADY Health System

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

### 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

The drug manufacturer's claim that the high cost of getting a new drug product through the FDA directly impacts the marketed drug cost to the consumer. With the growing number of uninsured in America, what is the FDA's plan to limit or control the cost of the new drug process? Remember, often the end consumer must decide if they can afford a product or not even though the product may best help a patient.

99N-0386