



✓ Site: Chicago, IL

# 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)

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Title (required)

First Name (required)

Last Name (required)

- Dr.  Mr.
- Mrs.  Ms.

JERRY

BAUMAN

Organization UNIVERSITY

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 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

Will the FDA attempt to more rigorously regulate "herbals" or natural remedies (eg. St. John Wort, Saw Palmetto) that are not regulated as drugs but are currently being promoted used and advertised as such. I feel this is a public health hazard because safety/efficacy has not been shown & their popularity threatens the legitimacy of the current process.

99N-0386

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