



# 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: Philadelphia

Title (required)    First Name (required)    Last Name (required)  
 Dr.    Mr.    ASHOK    KATDARE  
 Mrs.    Ms.

Organization International Pharmaceutical Excipients Council (IPEC)

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

C. IPEC, an organization with broadbased membership of scientific experts and industry professionals from pharmaceutical (Pharma and generic) and excipient industry (Total worldwide membership ~300) proposes to collaborate/assist the agency in the review of excipient quality based on known safety considerations and relative risk analysis of excipients. This should ensure consistent, standard procedures across the divisions.

99N-0386 Q What are FDA's plans to 'stay ahead of the curve' in new technologies? C18

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