Agenda

FDAMA Teleconference and CDRH Stakeholders Meeting
La Jolla, California
April 28, 1999

9:00-9:45	Registration
9:45-10:00	Introduction to the Teleconference, Dr. Lireka Joseph, Director, Office of Health and Industry Programs, CDRH, FDA
10:00-12:00	FDA Teleconference: Dr. Jane Henney, Commissioner of FDA, and Dr. Linda Suydam, Senior Associate Commissioner, FDA
12:00-1:00	Lunch Break
1:00-1:05	Welcome, Overview of the CDRH Program, Dr. Joseph
1:05-1:30	Opening Remarks, Dr. Elizabeth Jacobson, Acting Director, CDRH

The following individuals have submitted a request to make an oral presentation. After their presentations, the Agency panel will engage in a discussion with the presenters. The Agency Panel consists of: Dr. Jacobson; Dr. Susan Alpert, Director, Office of Device Evaluation, CDRH; Elaine Messa, Director, Los Angeles District Office, ORA, FDA; and Dr. Joseph, moderator.

1:30-2:40 **Stakeholders Panel**

- Marlene Keeling, President, Chemically Associated Neurological Disorders
- Steve Northrup, Executive Director, Medical Device Manufacturers Association
- Susan Saiget, CLS, MT(ASCP), PharMingen, Becton Dickinson Biosciences
- Cheryl Shea, Vice President - RA/QA, CryoGen, Inc.
- Susan Zagame, Vice President, Technology and Regulatory Affairs, Health Industry Manufacturers Association

2:40-3:00	Break
3:00-3:45	**Open session:** FDA is seeking your input to the questions listed on the reverse side of this agenda (please use the microphone and identify yourself for the record)
3:45-4:00	Closing Remarks from FDA Panel

Through this teleconference and meeting, FDA is trying to elicit your best and most specific answers to the following questions:

1. Science-based decisions are made throughout the life span of products from initial research, development and testing, through production, marketing and consumption. These decisions require the best science to identify, evaluate and balance product risks and benefits. It is crucial that FDA's staff in collaboration with product sponsors develop a shared understanding of new science and technologies and their effect throughout a product's life span. **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. As the agency attempts to meet its public health responsibilities, the speed of discovery results in an avalanche of new information from government, academic and industry scientists. **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 products life cycle?**

3. Most products in the American marketplace, especially medical ones, have two facets. On one side they benefit users and often improve lives. They are, however rarely without risk and their use can result in known and unknown side effects. Consumers must weigh benefits and risks before using these products, oftentimes with incomplete information. **What actions do you propose for educating the public about the concept of balancing risks against benefits in public health decision-making?**

4. The Agency stated in the FDA PLAN FOR STATUTORY COMPLIANCE, that inflation has eroded real assets that can be applied to meet its public health mission while Congress has increased its responsibilities. **Because the Agency must allocate its scarce resources to achieve the greatest impact, 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. FDAMA requires the agency to continue to meet with stakeholders on key issues. Meetings have ranged from explaining Agency positions to working with sponsors on product applications. Historically, these interactions have benefited both stakeholders, through better knowledge of the FDA, and the Agency, by leading to changes in its operations. **Because the Agency wants to assure that its stakeholders are aware and participate in its modernization activities, what additional actions do you propose for enhancing communication processes that allow for ongoing feedback and/or evaluation of our modernization efforts?**

In addition to the FDA questions, CDRH is seeking input from its stakeholders to the following three questions:

a. FDAMA and Reengineering: The device program has made many changes in the past year in administrative reengineering and implementing FDAMA. **Are there some changes you particularly support? Are there some changes you are concerned about? Are there some opportunities for change that we have missed?**

b. Y2K Readiness or Compliance Status of Device and Radiological Health Industries: **How can industry and FDA work together to communicate the status of Y2K readiness of the industry to their stakeholders?**

c. International Activities: **What kinds of things do you think FDA should do to encourage international harmonization in device regulation? What strategies can industry and government use to address the growing costs of international harmonization?**