FDA Teleconference
and
CDRH Stakeholders Meeting

La Jolla, California
April 28, 1999

Meeting Summary

The Center for Devices and Radiological Health (CDRH), Food and Drug Administration (FDA) held a public meeting with CDRH stakeholders on Wednesday, April 28, 1999. The meeting, which was announced in the Federal Register on March 22, 1999 (64 FR 13804), started at 9:45 A.M. and adjourned at 4:00 P.M., Pacific Time. Participants in the meeting responded to five questions posed by the FDA Commissioner that focus on (1) strengthening FDA's science and (2) improving communication processes with the public.

Approximately 60 individuals attended the meeting. They included consumers, health care professionals, regulated industry, press representatives, and employees from various components of FDA. From 10 a.m. until 12 p.m., the meeting participants viewed a live Satellite FDA Teleconference featuring Dr. Jane Henney, Commissioner of FDA, and Dr. Linda Suydam, Senior Associate Commissioner, FDA. From 1 p.m. to 4 p.m. Pacific Time, CDRH held a local meeting on CDRH-specific issues related to the Commissioner's questions.

The afternoon meeting was opened with remarks by Dr. Elizabeth Jacobson, Acting Director, CDRH. Dr. Jacobson's presentation included a discussion of (1) response to stakeholder input in 1998; (2) regulatory challenges facing CDRH; (3) current resource picture for CDRH; (4) CDRH reengineering and FDAMA initiatives; and (5) the need for public advice on meeting the requirements of the Federal Food, Drug and Cosmetic Act. The slides used during Dr. Jacobson's presentation can be found at http://www.fda.gov/cdrh/modact/stake42899.pdf.

Following Dr. Jacobson's presentation, two groups of FDA stakeholders gave oral presentations or addressed questions and comments to an FDA panel. The FDA panel consisted of Dr. Jacobson; Dr. Susan Alpert, Director, Office of Device

Evaluation, CDRH; and Elaine Messa, Director, Los Angeles District Office, FDA. Dr. Lireka Joseph, Director, Office of Health and Industry Programs, CDRH, moderated the program.

The first group of FDA stakeholders included five individuals who had preregistered with a request to make an oral presentation:

- One individual represented a consumer group;
- Two individuals represented medical device manufacturer's associations; and
- Two individuals were from FDA-regulated industry.

After the five oral presentations, a second group of FDA stakeholders asked questions or made suggestions to the FDA panel during an open session from the floor. This group included:

- Two individuals representing consumer groups; and
- Seven individuals from FDA-regulated industry.

All of the stakeholders offered many suggestions and recommendations. Their complete remarks are included in the transcript of the meeting available at http://www.fda.gov/ohrms/dockets/dockets/99n0386/tr00008.pdf. From these there emerged several recurrent themes:

- Support for Center research and scientific expertise in support of the review process and assessing risks, including suggestions for greater use of consultants and other bodies of scientists to better leverage available resources;
- Continue and increase the use of the Center's web site for information dissemination, both to make "final documents" available and to involve stakeholders in the topics that CDRH proposes to address;
- Increased use of the web site and other communications media to educate the general public about risks and risk assessment, and to encourage communication between consumers and regulated industry;
- Concern about the risks associated with silicone gel-filled breast

implants, patient information, and the procedures and systems used to track the long term consequences of implants; and

- Support for continuing CDRH reengineering and FDAMA initiatives, with an emphasis on the consistency of reviewer decisions.

Other stakeholder suggestions and concerns included making greater use of third parties, improving procedures for obtaining informed consent from patients, specific comments regarding current FDAMA initiatives and guidance documents, and suggestions for additional FDAMA initiatives and guidance documents.

The comments and suggestions received at the meeting underscore the value of stakeholder input as the Center develops initiatives for accomplishing its mandate. Further information on this and other FDA stakeholder meetings, including meeting transcripts, can be found at the FDA web site http://www.fda.gov. For more extensive information on CDRH program activities, please visit the CDRH web site at http://www.fda.gov/cdrh.