CDRH Stakeholders Meeting
August 18, 1998
Meeting Summary

The Center for Devices and Radiological Health (CDRH), Food and Drug Administration (FDA) held a public meeting with CDRH stakeholders on Tuesday, August 18, 1998. The meeting, which was announced in the Federal Register on July 24, 1998 (64 FR 39877), started at 9 A.M. and adjourned at 12:30 P.M.

The purpose of the meeting was to involve participants from consumer and scientific groups and the regulated industry in drafting FDA's developmental plan to meet the objectives of the Food and Drug Administration Modernization Act of 1997 (FDAMA). Seventy-five individuals attended the meeting. The participants included consumers, health care professionals, regulated industry, press representatives, and employees from various components of FDA and HCFA (Health Care Financing Administration).

The meeting was opened with remarks by Linda A. Suydam, Associate Commissioner for Strategic Management, FDA. Bruce Burlington, M.D., Director, CDRH, FDA then gave an overview of the program. Following the FDA presentations, ten stakeholder representatives gave oral presentations addressing various aspects of FDA activities:

- Two individuals represented standards groups
- One individual represented a medical device manufacturer's association
- One individual spoke on behalf of the Conference of Radiation Control Program Directors
- Two individuals represented professional groups (the American College of Radiology and the National Patient Safety Foundation)
- One individual spoke on several topics, but specifically consumer representation on agency panels
- Three consumers spoke on behalf of a single issue – silicone and breast implants

After the presentations, an FDA panel consisting of Ms. Suydam, Dr. Burlington and representatives from various CDRH offices asked clarifying questions of the presenters.

Stakeholders offered many suggestions and recommendations. From these there emerged several recurrent themes:

- Increased diversity and participation on Advisory Committees from scientific, professional and consumer stakeholders
- Increased reliance on consensus standards and standards-based guidance documents
- Support for Center research and scientific expertise, including greater use of consultants and more communications with professional societies
- Getting information to consumers and increased use of the Center's WEB site for information dissemination
- Need for a strong FDA, but concern over lack of resources to accomplish everything

Other stakeholder suggestions included making greater use of third parties, adopting the European model for premarket review, increasing consumer involvement in adverse event reporting, improving procedures for obtaining informed consent from patients, eliminating unnecessary Center functions, and giving new initiatives time to work. Support was expressed for maintaining an inspection program based upon a firm's past history and product risk, developing the Sentinel system for postmarket monitoring, and using FDAMA and reengineering tools such as the 510(k) paradigm to meet statutory time frames.

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 website http://www.fda.gov. This website also includes specific information on how to submit written responses to the docket on these issues. For more extensive information on CDRH program activities, please visit the CDRH website at http://www.fda.gov/cdrh.