DHHS

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Docket No. 2004S–0233]

Stimulating Innovation in Medical Technologies; Public Meeting

AGENCY: Department of Health and Human Services.

ACTION: Notice of public meeting.

SUMMARY: The Department of Health and Human Services (HHS) is announcing a public meeting to weigh new ideas and promote new solutions to encourage innovation in health care and to speed the development of effective new medical technologies, such as drug and biological products and medical devices. A high level task force has been formed within HHS and is charged with issuing a report this year on appropriate steps that can be taken across HHS to speed the development and availability of new medical technologies. The purpose of this public meeting is to obtain input from interested persons on what steps HHS can take to create or enhance coordination across HHS agencies in order to stimulate the development of new technologies. HHS will consider presentations made at the public meeting and comments submitted to the docket before and after the meeting when developing the report.

Dates: The public meeting will be held on Monday, November 8, 2004, from 9:30 a.m. to 4 p.m. Submit electronic requests to speak by October 29, 2004 (see *Registration and Request for Presentations).* Submit written or electronic comments by November 15, 2004, to the Division of Dockets Management (see *Addresses).*

Location: The public meeting will be held at the Hubert H. Humphrey Building, rm. 800, 200 Independence Ave. SW., Washington, DC 20201.

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Addresses: Submit written comments concerning this document to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. Follow the instructions for submitting comments.

Contact: Nancy Stanisic, Food and Drug Administration, rm. 9–64, 5600 Fishers Lane, Rockville, MD 20852, 301–827–1660, FAX: 301–443–9718, e-mail: *stanisicn@cder.fda.gov*. or Tom Kuchenberg, Office of the Secretary, Department of Health and Human Services, 200 Independence Ave. SW., Washington, DC 20201, 202–205–8644.

Registration and Request for Presentations: Send registration information and requests to speak electronically (including name, title, firm name, address, telephone, fax number, and presentation abstract, as well as requests to make oral presentations and approximate amount of time requested to make the presentation, to Nancy Stanisic (see *Contact*) by October 29, 2004. Registration is required to attend the meeting. Seating is limited to 120 people. If you need special accommodations due to a disability, please contact Nancy Stanisic by October 29, 2004.

Transcripts: Transcripts of the meeting may be requested in writing from the Freedom of Information Office (HFI–35), Food **and** Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, approximately 15 working days after the meeting at a cost of 10 cents per page. Transcripts of the public meeting will also be available for review at the Division of Dockets Managment (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

SUPPLEMENTARY INFORMATION:

I. Background

During the past decade, an increased awareness of medical technology innovation and its promise and progress has revealed critical problems in the path from discovery through development to delivery. This spring, Secretary of Health and Human Services Tommy G. Thompson appointed a top-level task force to present new ideas on how HHS can coordinate its efforts to help stimulate medical innovation. The task force members include: Centers for Disease Control and Prevention, Director, Julie Gerberding; Centers for Medicare and Medicaid, Administrator, Mark B. McClellan; Acting Commissioner of Food and Drugs, Lester M. Crawford; and National Institutes of Health, Director, Elias A. Zerhouni. Commissioner Crawford will serve as the task force's Chair.

Secretary Thompson asked the task force to look for opportunities across HHS to promote speedier access to new innovative medical technologies that can improve people's health and save lives. He asked the task force to report to him by the end of the year on ways that better coordination across HHS could streamline the way we do business and make safe, effective medical technologies more quickly and readily available to Americans.

On May 24, 2004, a **Federal Register** notice (69 FR 29544) was published asking for comments on how to stimulate innovation in medical technologies, such as drug and biological products and medical devices.

Comments have been received and are being evaluated and condensed into material suitable for a report. On November 8, 2004, we will not only focus on opportunities presented at the public meeting, but those promising ideas that HHS has already received and plans to highlight. The ideas will be posted

1 week before the public meeting in the electronic docket (Docket No. 2004S–0233) located at *http://www.fda.gov/ohrms/dockets/dockets/04S-0233.htm.*

II. Registration and Presentations

Registration is required to attend the meeting. Seating is limited to 120 people and will be on a first come, first served basis. If you need special accommodations due to a disability, please inform Nancy L. Stanisic by October 29, 2004.

If you wish to present information at the public meeting, submit your electronic request and an abstract of your presentation by close of business on October 29, 2004, to Nancy Stanisic (see *Contact*).

The request to participate should contain the following information: (1) Presenter's name; (2) address; (3) telephone number; (4) e-mail address; (5) affiliation, if any; (6) abstract of the presentation; and (7) approximate amount of time requested for the presentation.

We request that persons and groups having similar interests consolidate their comments and present them through a single representative. We will allocate the time available for the meeting among the persons who request to present. Because of limited time, we will accept only one presenter per organization. We reserve the right to deny requests if the proposed topic is not germane. After reviewing the requests to present and the abstracts, we will schedule each appearance and notify each participant by e-mail or telephone of the time allotted to the person and the approximate time the person's presentation is scheduled to begin. Presenters planning to use electronic presentation in Microsoft PowerPoint, Microsoft Word, or Adobe Acrobat (pdf) must send them to us by close of business on November 4, 2004. Presenters

who do not meet this deadline may provide handouts of their presentations at the meeting.

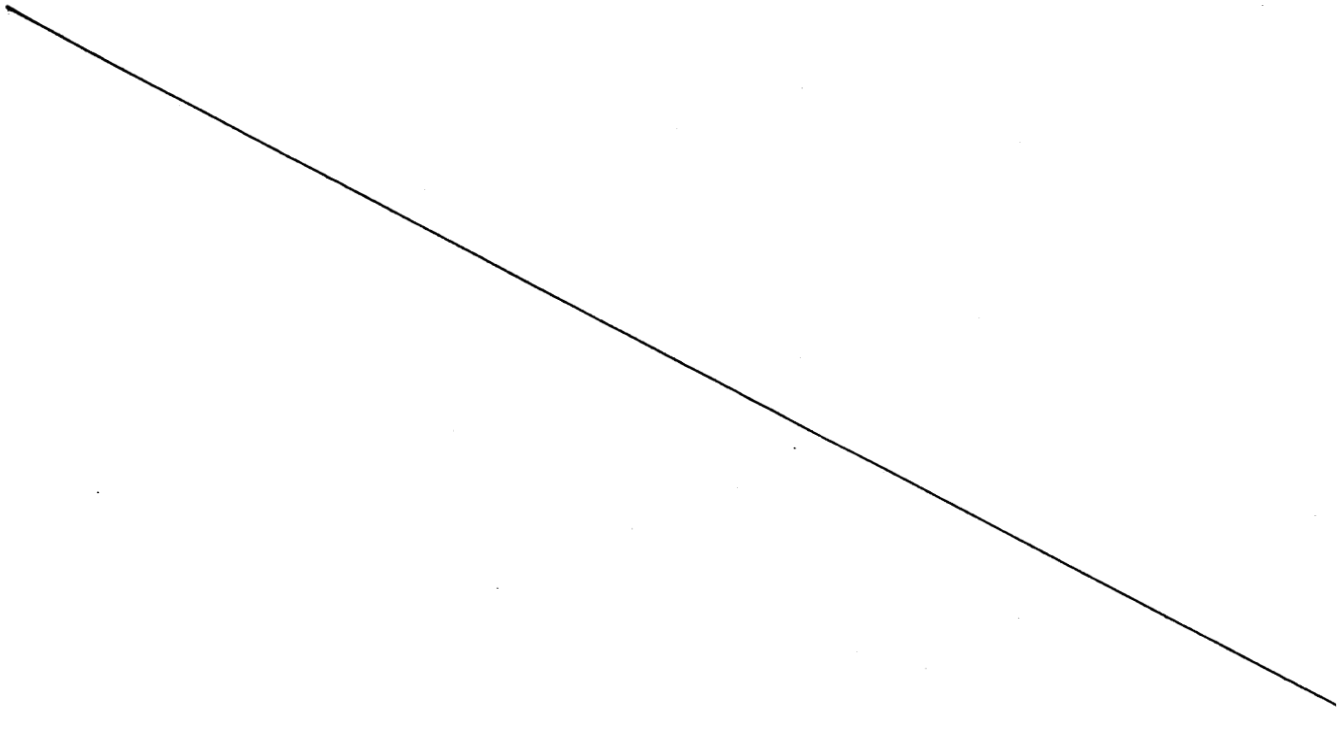
After the meeting, the schedule and presentations will be placed on file in the Division of Dockets Management (see *Addresses)* under the docket number listed in the heading of this document.

111. Comments

Interested persons may submit written or electronic comments to the Division of Dockets Management (see *Addresses).* You must submit two copies of comments identified with the docket number found in brackets in the heading of this document. The received comments may be seen in the Division of Dockets Management Monday through Friday, between 9 a.m. and 4 p.m.

IV. Transcript

Approximately **30** days after the public meeting, you can examine a transcript of the meeting on the Internet at *http://www.fda.gov./ohrms/dockets/default.htm* or at the Division of Dockets Management (see *Addresses)* Monday through Friday, between 9 a.m. and 4 p.m. You may also request a copy of the transcript from the Freedom of Information Office (HFI–35), Food and Drug



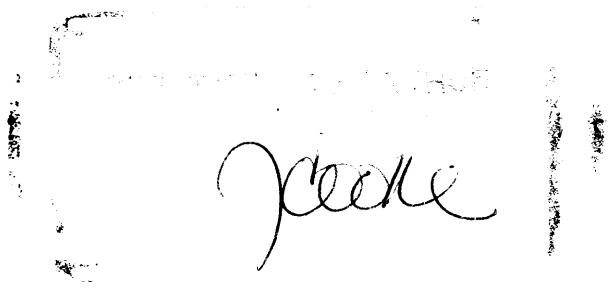
Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, at a cost of 10 cents per page or on CD at a cost of $14.25 each.

Dated: 10/8/04

October 8, *2004.*

Jeffrey Shuren

Jeffrey Shuren,
Assistant Commissioner for Policy.



[FR Doc. 04–????? Filed ??–??–04;8:45 am]

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