

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007N-0489]

DDM

Display Date 01-03-08

Publication Date 01-04-08

Certifier A. Corbin

**Request for Comments on the Science and Technology Report;
Establishment of Docket; Request for Comments**

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of docket; request for comments.

SUMMARY: On March 31, 2006, the Food and Drug Administration (FDA) charged the Science Board to evaluate FDA's science-based capacities to meet current and future public health challenges. The Science Board established a subcommittee on science and technology to perform the review and draft a report of findings and preliminary recommendations. The subcommittee report was presented and discussed at the December 3, 2007, Science Board Advisory Committee meeting, at which time the Science Board decided to obtain comments from the public on the subcommittee report. FDA is soliciting public comment on the subcommittee report on behalf of the Science Board.

DATES: To be considered, written or electronic comments on the subcommittee report must be received on or before *[insert date 30 days after date of publication in the Federal Register]*. All comments received while the docket is open will be forwarded to the Science Board for their review.

ADDRESSES: Electronic comments should be submitted to <http://www.fda.gov/dockets/ecomments>. Select Docket No. 2007N-0489, "FDA Report on Science and Technology" and follow prompts to submit your statement. Written comments should be submitted to the Division of Dockets Management (HFA-

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305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, by close of business on (see **DATES**). All comments should be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday. All comments received will be posted without change, including any personal information provided. All comments received while the docket is open will be forwarded to the Science Board for their review. All comments will also be discussed at the next Science Board Advisory Committee meeting. A notice of the next Science Board Advisory Committee meeting will be published at a later date. See **SUPPLEMENTARY INFORMATION** section for electronic access.

FOR FURTHER INFORMATION CONTACT: Carlos Peña, Office of the Commissioner, Food and Drug Administration (HF-33), 5600 Fishers Lane, Rockville, MD 20857, 301-827-6687, FAX: 301-827-3340, e-mail: *carlos.Peña,@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

On March 31, 2006, FDA charged the Science Board to conduct a broad review of FDA scientific capacities, processes, and infrastructure which support FDA's core regulatory functions including the following: (1) Premarket review and consultation during the development of new FDA-regulated products; (2) oversight of marketed product quality; and (3) postmarket product safety surveillance and risk management. The following is the Commissioner of Food and Drugs' charge to the Science Board: "Review and report the broad categories of scientific and technologic capacities that FDA needs to fully

support its core regulatory functions and decisionmaking throughout the product life-cycle, today and over the next decade.” Specifically:

(1) Are there any important gaps in current scientific capacities in which FDA should substantially increase efforts, to ensure that it can address current or expected scientific demands of FDA’s regulatory mission? In what areas should the agency maintain or strengthen its current level of work and capacity?

(2) Are there areas of science in which the agency should consider refocusing its efforts in order to better address current or anticipated future scientific demands of FDA’s regulatory mission?

(3) What opportunities exist to enhance the overall effectiveness of FDA’s scientific and technologic capacity through coordination of scientific activities and priority setting across FDA components?

(4) What opportunities exist to better leverage FDA’s scientific capacity through collaboration with other public agencies and private organizations? Are there other approaches to resource leveraging that FDA could pursue to better support needed scientific capacities?

The review was initiated to obtain advice regarding current science-based capacities and the degree to which they can prepare FDA for anticipated changes in science, technology and population health needs.

To respond to this request from the agency, the Science Board established a subcommittee on science and technology to perform the review. The subcommittee was supported by 30 outside experts, who were drawn from government, academia, and industry. Their efforts culminated in a subcommittee report of findings and preliminary recommendations. The subcommittee report was presented and discussed at the December 3, 2007,

Science Board Advisory Committee meeting, at which time the Science Board decided to obtain comments from the public on the subcommittee report (an electronic copy of the subcommittee report is available at http://www.fda.gov/ohrms/dockets/ac/07/briefing/2007-4329b_02_00_index.html).

II. Request for Comments

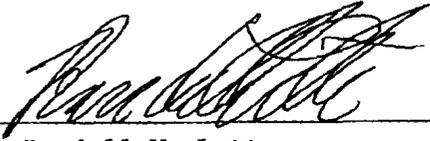
In accordance with 21 CFR 14.35, FDA is soliciting public comment on the subcommittee report, on behalf of the Science Board. Comments received while the docket is open will be forwarded to the Science Board for their review. Comments will also be discussed at the next Science Board Advisory Committee meeting. A notice of the next Science Board Advisory Committee meeting will be published in the **Federal Register** at a later date.

III. Submission of Comments

To help facilitate the public comment process upon the subcommittee report, FDA has established a public docket, on behalf of the Science Board. All comments submitted to the public docket are public information and may be posted to the FDA's Web site at: <http://www.fda.gov> for public viewing. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments received may be reviewed in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that in January 2008, the FDA Web site is expected to transition to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. After the transition date, electronic submissions will be accepted by FDA through the FDMS only. When the exact date of the transition to FDMS is known, FDA will publish a **Federal Register** notice announcing that date.

Dated: DEC 28 2007
December 28, 2007.



Randall W. Lutter,
Deputy Commissioner for Policy.

[FR Doc. 07-????? Filed ??-??-07; 8:45 am]

BILLING CODE 4160-01-S

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