

ACTION: Notice; reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening until February 8, 2008, the comment period for the draft guidance for industry entitled "Antibacterial Drug Products: Use of Noninferiority Studies to Support Approval," published in the **Federal Register** of October 15, 2007 (72 FR 58312). The draft guidance informed industry of FDA's current thinking regarding appropriate clinical study designs to evaluate antibacterial drugs, and asked sponsors to amend ongoing or completed studies accordingly. FDA is taking this action in response to a request for an extension of the comment period to allow interested persons additional time to review the draft guidance and submit comments.

DATES: Submit written or electronic comments by February 8, 2008.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD-240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests.

Submit written comments on the draft guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to either <http://www.fda.gov/dockets/ecomments> or <http://www.regulations.gov>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Edward Cox, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 6412, Silver Spring, MD 20993-0002, 301-796-1300.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of October 15, 2007 (72 FR 58312), FDA published a notice announcing the availability of a draft guidance for industry entitled "Antibacterial Drug Products: Use of Noninferiority Studies to Support Approval." The purpose of the guidance is to inform industry of FDA's current thinking regarding appropriate clinical study designs to evaluate antibacterial drugs, and to ask sponsors to amend ongoing or completed studies accordingly. The guidance is in response to a number of public discussions in recent years regarding the

use of active-controlled studies designed to show noninferiority as a basis for approval of antibacterial drug products. Some of these discussions have focused on specific diseases such as acute bacterial sinusitis, acute bacterial otitis media, and acute bacterial exacerbation of chronic bronchitis. These public discussions have contributed to FDA's evolving understanding of the science of clinical trials and, in particular, the appropriate role of active-controlled studies designed to show noninferiority in the development of antibacterial drug products.

The draft guidance recommends that sponsors provide justification for the treatment effect size and the proposed noninferiority margin for all antibacterial development programs for which approval will rely on noninferiority studies. The initial comment period for this guidance closed on December 14, 2007.

II. Reopening of Comment Period

On November 13, 2007, the Pharmaceutical Research and Manufacturers of America requested an extension beyond the December 14, 2007, deadline for the submission of comments. FDA recognizes the effect this guidance may have on the development of new antimicrobial products and that additional time may be needed for comment. Therefore, FDA has decided to reopen the comment period on the draft guidance until February 8, 2008, to allow the public more time to review and comment on its contents.

III. How to Submit Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments to or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to 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.

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.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/cder/guidance/index.htm> or <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: December 27, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7-25601 Filed 1-3-08; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007N-0489]

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 February 4, 2008. 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-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: December 28, 2007.

Randall W. Lutter,

Deputy Commissioner for Policy.

[FR Doc. E7-25607 Filed 1-3-08; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Public Law 104-13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, call the HRSA Reports Clearance Officer on (301) 443-1129.

Comments are invited on: (a) The proposed collection of information for the proper performance of the functions of the agency; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Sickle Cell Disease Treatment Demonstration Program (SCDTDP), Health Resources and Services Administration (HRSA): NEW

In 2004 Congress enacted and the President signed into law Pub. L. 108-