

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N-0366]

From Concept to Consumer: Center for Biologics Evaluation and Research Working With Stakeholders on Scientific Opportunities for Facilitating Development of Vaccines, Blood and Blood Products, and Cellular, Tissue, and Gene Therapies; Public Workshop; Reopening of the Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; reopening of the comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening until *[insert date 365 days after date of publication in the **Federal Register**]*, the comment period for the notice of public workshop and request for comments published in the **Federal Register** of August 31, 2004 (69 FR 53077). FDA is reopening the comment period to allow interested persons additional time to submit comments and to receive any new information.

DATES: Submit written or electronic comments by *[insert date 365 days after date of publication in the **Federal Register**]*.

ADDRESSES: Submit written comments 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>*.

FOR FURTHER INFORMATION CONTACT: Astrid Szeto, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-6210.

SUPPLEMENTARY INFORMATION:**I. Background**

In the **Federal Register** of August 31, 2004 (69 FR 53077) (August 2004 notice), FDA announced a public workshop entitled “From Concept to Consumer: Center for Biologics Evaluation and Research Working With Stakeholders on Scientific Opportunities for Facilitating Development of Vaccines, Blood and Blood Products, and Cellular, Tissue, and Gene Therapies.” The public workshop was held on October 7, 2004. The goal of the public workshop was to provide a forum for stakeholders to discuss opportunities for and potential approaches to the development of innovative scientific knowledge and tools to facilitate the development and availability of new biological products including vaccines, blood and blood products, and cellular, tissue, and gene therapies.

Interested persons were originally given until September 23, 2004, to comment on the topic of the workshop.

II. Request for Comments

Following publication of the August 2004 notice, FDA received several requests to allow interested persons additional time to comment. The requesters asserted that the time period of 23 days was insufficient to respond fully to FDA’s specific requests for comments and to allow potential respondents to thoroughly evaluate and address pertinent issues.

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 *http://www.fda.gov/dockets/ecomments* 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.

Dated: January 19, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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