

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

The Food and Drug Administration (FDA), is announcing 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 goal of the public workshop is 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.

Date and Time: The public workshop will be held on October 7, 2004, from 8:30 a.m. to 5 p.m.

Location: The public workshop will be held at The Gaithersburg Marriott Washingtonian Center, 9751 Washingtonian Blvd., Gaithersburg, MD.

Contact Person: Melanie Whelan, Center for Biologics Evaluation and Research (HFM-43), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-3841, FAX: 301-827-3079, e-mail: Whelan@cber.fda.gov.

Registration: Mail, fax, or e-mail the registration information (including name, title, affiliation, address, and telephone and fax numbers) to Melanie Whelan (see *Contact Person*) by September 30, 2004. Because seating is limited, we recommend early registration. There is no registration fee for the workshop. If you need special accommodations due to a disability, please contact Melanie Whelan (see *Contact Person*) at least 7 days in advance.

Comments: Regardless of attendance at the public workshop, interested persons may submit to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852 written or electronic comments by September 23, 2004. Submit electronic comments to <http://www/fda.gov/dockets/ecomments>. Submit a single copy of electronic comments or two 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.

SUPPLEMENTARY INFORMATION: The goal of this workshop is to provide a public forum for input and discussion concerning opportunities for the enhancement of scientific knowledge and tools for safety, efficacy, and product quality that can be used to more effectively and efficiently develop and evaluate new biological products in the areas described.

On March 16, 2004, FDA released a report addressing the recent slowdown in innovative medical therapies submitted to FDA for approval entitled “Innovation/Stagnation: Challenge and Opportunity on the Critical Path to New Medical Products” at <http://www.fda.gov/oc/initiatives/criticalpath/>. That report describes the urgent need to create the scientific and technological “tools” to modernize the medical product development process—the Critical Path—to make medical product development more predictable and less costly.

The Center for Biologics Evaluation and Research (CBER) is seeking input from government and nongovernment research organizations, medical professional organizations, health care practitioners, patients, disease interest groups, pharmaceutical and biological product manufacturers and their industry organizations, and others with interests in facilitating development of the biological products that CBER regulates. The workshop will cover delineation of opportunities in key technologies and medical science knowledge needed to contribute to science based evaluation of the safety and efficacy of those biological products, and innovative development processes to manufacture them. FDA will discuss and welcomes input concerning all applicable areas of science including, but not limited to, bench laboratory investigations, clinical research and clinical trial design and execution, facility and manufacturing process research, statistical and epidemiological research, and computer science and computer modeling research. The workshop will not cover discussions of biological product discovery and invention or regulatory policies. The workshop will include presentations by FDA speakers and breakout sessions with panels composed of both FDA staff and non-FDA stakeholders, with an opportunity for public questions and comments.

FDA will post the agenda for this public workshop, when finalized on CBER's Web sites at <http://www.fda.gov/cber/scireg.htm> and <http://www.fda.gov/cber/minutes/workshop-min.htm>.

Transcripts: Please note that transcripts of the workshop will not be prepared.

Dated: August 24, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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