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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

# Fifth Joint Project Management Workshop on Improving Agency/Industry Communication Throughout the Drug Development Process; Public Workshop

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of public workshop.

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The Food and Drug Administration (FDA) in cosponsorship with the Drug Information Association (DIA) is announcing a public workshop entitled "The Fifth Joint Project Management Workshop: Improve Agency/Industry Communication Throughout the Drug Development Process." The workshop will focus on facilitating the drug development and drug review processes through interactions between industry and FDA to effectively manage risk to expedite products of public benefit to market.

*Date and Time*: The public workshop will be held on May 11, 2004, from 8:30 a.m. to 5 p.m., May 12, 2004, from 8:30 a.m. to 5 p.m., and May 13, 2004, from 8:30 a.m. to 12:30 p.m.

*Location*: The public workshop will be at the Hyatt Regency Bethesda, 1 Bethesda Metro Center, Bethesda, MD.

*Contact Person*: Julieann Dubeau, Center for Drug Evaluation and Research (HFD–180), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD, 301–827–7310, FAX: 301–827–1305, e-mail: *Dubeau@cder.fda.gov*, or Gail Sherman, Center for Biologics Evaluation and Research (HFM–42), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–



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2000, FAX: 301–827–3079, e-mail: *Sherman@cber.fda.gov*, or Camela Pastorius, Drug Information Association, 800 Enterprise Rd., suite 200, Horsham, PA 19044, 215–442–6196, FAX: 215–442–6103, e-mail: *Camela.Pastorius@diahome.org.*

*Registration*: Mail or fax your registration information and registration fee to Drug Information Association (DIA), P.O. Box 827192, Philadelphia, PA 19182–7192. You may obtain registration forms from DIA (see *Contact Person*) or from FDA at *http://www.fda.gov/cber/meetings.htm.* Additional information regarding registration fees and online registration can be found at *http://www.diahome.org/docs/events/events__search__detail.cfm.* (FDA has verified the Web site, but we are not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register.**)

If you need special accommodations due to a disability, please contact Camela Pastorius (see *Contact Person*) by May 4, 2004.

**SUPPLEMENTARY INFORMATION:** FDA (the Center for Biologics Evaluation and Research and the Center for Drug Evaluation and Research) and DIA are cosponsoring a public workshop as part of a continuing effort to develop higher levels of teamwork, communication, and procedural knowledge to facilitate drug development and review in the United States. The workshop's target audience is project directors, leaders, managers, and regulatory affairs representatives from industry; and FDA reviewers, regulatory project managers, and consumer safety officers. At the conclusion of the workshop, the participants should be able to do the following: (1) Identify FDA/industry

cultural differences that influence interactions between the two groups, (2) effectively manage constructive interactions in a changing environment, and (3) manage communication strategies for facilitating drug approvals.

Dated: 4/6/04

April 6, 2004.

Jeffrey Shuren,
Assistant Commissioner for Policy.

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