



## Memorandum

Date: April 5, 2004  
To: Oncologic Drugs Advisory Committee Members and Guests  
From: Richard Pazdur, M.D.  
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Subject: FDA Background Package for afternoon of May 4, 2004 Meeting

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This memo outlines the purpose of the afternoon session of the May 4, 2004 meeting of ODAC and describes the content of this briefing package.

The Food and Drug Administration is undertaking a project to evaluate potential endpoints for cancer drug approval. Endpoints will be examined for the most common cancers, such as lung cancer, colon cancer, etc. For each cancer, FDA will hold public workshops to identify important issues, and these issues will be discussed in meetings of the Oncologic Drugs Advisory Committee (ODAC). Subsequently, guidance documents will be published describing FDA's current thinking on endpoints for cancer drug approval.

The afternoon session of May 4, 2004 will focus on endpoints in colorectal cancer. This session will include presentations from participants in the colorectal cancer endpoint workshop held November 12, 2003. ODAC discussions will center on FDA written questions.

Documents in this background package include:

**General background document:**

TAB 1 Endpoints that have supported cancer drug approval (JCO article)

**Colorectal Cancer Endpoints**

TAB 2 Executive summary of workshop discussion

Please also refer to the FDA endpoints web page for additional background documents and slides from the November 2003 colorectal cancer workshop presentations  
[http://www.fda.gov/cder/drug/cancer\\_endpoints/default.htm](http://www.fda.gov/cder/drug/cancer_endpoints/default.htm).