Food and Drug Administration
Center for Drug Evaluation and Research

Oncologic Drugs Advisory Committee Meeting
December 16, 2003

Briefing Material

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Overview Memo:
Richard Pazdur, M.D., Director, Division of Oncologic Drug Products

Published Documents:

Tab 1: Johnson, John R., Williams, Grant & Pazdur, Richard. (2003) Endpoints and United States Food and Drug Administration: Approval of Oncology Drugs. *Journal of Clinical Oncology*, 21 (7), pp 1404-1411.

Tab 2: Department of Health and Human Services, Food and Drug Administration. (May 1988). Guidance for Industry: Providing Cinical Evidence of Effectiveness for Human Drug and Biological Products.

Tab 3: Department of Health and Human Services, Food and Drug Administraton. (December 1998). Guidance for Industry: FDA Approval of New Cancer Treatment Uses for Marketed Drug and Biological Products.

Tab 4: Workshop Summary on Endpoints for Approval of cancer Drugs for Lung Cancer

Tab 5: Department of Health and Human Services, Food and Drug Administration. Guidance for Industry: FDA Requirements for Approval of Drugs to Treat Non-Small Cell Lung Cancer.