Food and Drug Administration
Center for Drug Evaluation and Research

Oncologic Drugs Advisory Committee
62nd Meeting

Town Center Hotel
Silver Spring, Maryland

Tentative Agenda — June 7-8, 1999

9:30	Call to Order and Opening Remarks	Janice Dutcher, M.D. Chair, ODAC
	Introduction of Committee	
	Conflict of Interest Statement	Karen M. Templeton-Somers, Ph.D. Executive Secretary, ODAC
9:45	Open Public Hearing	

Is Time-to-Progression an acceptable primary efficacy endpoint in breast cancer or is survival the only acceptable primary endpoint?

10:15	Presentations	John R. Johnson, M.D. Medical Officer, FDA
		Sandra Swain, M.D. ODAC Consultant
11:00	Break	
11:15	Committee Discussion and Vote	
12:30	Lunch	

June 7, 1999 – Afternoon Session

1:30	Open Public Hearing	
	NDA 21-010, epirubicin hydrochloride for injection, Pharmacia and Upjohn Company	
	- indicated for use as a component of adjuvant therapy in patients with evidence of axillary-node-tumor involvement following resection of primary breast cancer (Stage II & III). Epirubicin is indicated for the therapy of patients with locally advanced or metastatic breast cancer.	
1:45	**Sponsor Presentation**	Pharmacia & Upjohn Company
	Randomized, well-controlled studies supporting approval of epirubicin hydrochloride as adjuvant therapy for early breast cancer and as therapy for advanced disease	Langdon L. Miller, M.D. Vice President Clinical Development Oncology Pharmacia and Upjohn Company
2:45	Questions from the Committee	
3:15	Break	
3:30	**FDA Presentation**	Susan Honig, M.D. FDA Reviewer
4:30	Questions from the Committee	
5:00	Committee Discussion and Vote	
5:30	Adjourn	

June 8, 1999 - Morning Session

8:00	Call to Order and Opening Remarks	Janice Dutcher, M.D. Chair, ODAC
	Introduction of Committee	
	Conflict of Interest Statement	Karen M. Templeton-Somers, Ph.D. Executive Secretary, ODAC
8:15	Open Public Hearing	

NDA 50-718/S-006, Doxil® (doxorubicin HCl liposome injection), ALZA Corporation

- indicated for the treatment of patients with metastatic carcinoma of the ovary who are refractory to both paclitaxel- and platinum-based chemotherapy regimens and who may also be refractory to topotecan. Refractory is defined as a patient having progressive disease while on treatment, or within 6 months of completing treatment.

8:30	**Sponsor Presentation**	ALZA Corporation
	Introduction	Edward Schnipper, MD
	Unmet Medical Need in Advanced Metastatic Ovarian Cancer	Maurie Markman, MD The Cleveland Clinic
	STEALTH™ Liposome Background and Doxil Pharmacology	Frank Martin, PhD
	Doxil Efficacy in Advanced Metastatic Ovarian Cancer	Edward Schnipper, MD
	Doxil Safety Review	Ken Cunningham, MD
	Concluding Remarks	Edward Schnipper, MD
9:30	Questions from the Committee	
10:00	Break	
10:15	**FDA Presentation**	Gregory Frykman, M.D. FDA Reviewer
11:15	Questions from the Committee	
11:45	Committee Discussion and Vote	
12:15	Lunch	

June 8, 1999 - Afternoon Session

1:15	Open Public Hearing	
	NDA 20-221/S-012, Ethyol® (amifostine) for injection, U.S. Bioscience, Inc.	
	- indicated for use to reduce the incidence and severity of radiation induced xerostomia	
1:30	**Sponsor Presentation**	U.S. Bioscience, Inc.
2:30	Questions from the Committee	
3:00	Break	
3:15	**FDA Presentation**	Isagani Chico, M.D. FDA Reviewer
4:15	Questions from the Committee	
4:45	Committee Discussion and Vote	
	ODAC Discussants	Andrew Harwood, M.D. ODAC Consultant
		Scott Lippman, M.D. ODAC Consultant
5:15	Adjourn	