Food and Drug Administration
Center for Drug Evaluation and Research

Oncologic Drugs Advisory Committee

63rd Meeting

Holiday Inn
Silver Spring, Maryland

Tentative Agenda — September 16-17, 1999

8:00	Call to Order and Opening Remarks	Richard Schilsky, M.D. Chair, ODAC
	Introduction of Committee	
	Conflict of Interest Statement	Karen M. Templeton-Somers, Ph.D. Executive Secretary, ODAC
	Open Public Hearing	
	Michael Cohen – Institute for Safe Medication Practices	
	Laurence F. Daspit – Spring, Texas	

NDA 21-053, UFT® (tegafur and uracil) Capsules, Bristol-Myers Squibb Company

- indicated with leucovorin calcium tablets for the first-line treatment of metastatic colorectal cancer

8:15	**Sponsor Presentation**	Bristol-Myers Squibb Company
	Introduction	Renzo Canetta, M.D. Vice President, Clinical Oncology
	Chemotherapy for Metastatic Colorectal Cancer	John MacDonald, M.D. St. Vincent's Comprehensive Cancer Center
	UFT Development	Robert Diasio, M.D. University of Alabama
	Pivotal Study – 011	Steven Benner, M.D. M.H.S. Group Director, Clinical Oncology
	Confirmatory Study	James Carmichael, M.D., Ph.D. Nottingham City Hospital, England
	Concluding Remarks	Renzo Canetta, M.D.
9:15	Questions from the Committee	
9:45	Break	

10:00	**FDA Presentation**	Robert M. White, M.D. FDA Reviewer
11:00	Questions from the Committee	
11:30	Committee Discussion and Vote	
	ODAC Discussants	David Kelsen, M.D. ODAC Member
		Kim Margolin, M.D. ODAC Member
		James Krook, M.D. ODAC Consultant
12:00	Lunch	

September 16, 1999 – Afternoon Session

1:00 Open Public Hearing

Michael Cohen – Institute for Safe Medication Practices

Judy Perotti (or TBA) – Y-ME National Breast Cancer Organization

Laura Meeker – Arlington, Virginia

NDA 50-772 Evacet™ (doxorubicin HCl liposome injection), The Liposome Company, Inc.

- indicated for the first-line treatment of metastatic breast cancer in combination with cyclophosphamide

1:15	**Sponsor Presentation**	The Liposome Company, Inc.
2:15	Questions from the Committee	
2:45	Break	
3:00	**FDA Presentation**	Patricia Cortazar, M.D. FDA Reviewer
4:00	Questions from the Committee	
4:30	Committee Discussion and Vote	
	ODAC Discussants	William Gradishar, M.D. ODAC Member
		Stacy Nerenstone, M.D. ODAC Member
5:00	Adjourn	

September 17, 1999 – Morning Session

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

Judy Perotti (or TBA)– Y-ME National Breast Cancer Organization

NDA 20-262/S-033, TAXOL® (paclitaxel) Injection, Bristol-Myers Squibb Company

- indicated for the adjuvant treatment of node-positive breast cancer administered sequentially to standard combination therapy

8:15	**Sponsor Presentation**	Bristol-Myers Squibb Company
	Introduction	David Tuck, M.D. Director, Clinical Oncology
	Breast Cancer Chemotherapy	Larry Norton, M.D. Memorial Sloan Kettering Cancer Center
	Inter-Group 0148 Results	Craig Henderson, M.D. University of California, San Francisco
	Concluding Remarks	Renzo Canetta, M.D. Vice President, Clinical Oncology
9:15	Questions from the Committee	
9:45	Break	
10:00	**FDA Presentation**	James O'Leary, M.D. FDA Reviewer
11:00	Questions from the Committee	
11:30	Committee Discussion and Vote	
	ODAC Discussants	William Gradishar, M.D. ODAC Consultant
		Joyce O'Shaughnessy, M.D. ODAC Consultant
12:00	Lunch	

September 17, 1999 - Afternoon Session

1:00	Call to Order and Opening Remarks	Richard Schilsky, M.D. Chair, ODAC
	Introduction of Committee	
	Conflict of Interest Statement	Karen M. Templeton-Somers, Ph.D. Executive Secretary, ODAC
	Open Public Hearing	
1:15	**Update on the Preliminary Results of EST 1690** (ECOG Intergroup Study of INTRON A for the adjuvant treatment of melanoma)	
		John Kirkwood, M.D. University of Pittsburgh

BLA 97-1001, Roferon®-A, Hoffman-La Roche Inc.

- indicated for use as adjuvant treatment of surgically resected malignant melanoma without clinical evidence of nodal disease, AJCC stage II (Breslow thickness>1.5 mm, N0)

1:30	**Sponsor Presentation**	Hoffman-La Roche Inc.
	Clinical Overview of Malignant Melanoma	Antonia Buzaid, M.D. University of Sao Paulo, Brazil
	Data on Roferon®-A in the Treatment of Stage II Malignant Melanoma	Leon Hooftman, M.D. Director of Oncology
2:30	Questions from the Committee	
3:00	Break	
3:15	**FDA Presentation**	Massimo Cardinali, M.D. FDA Reviewer
		Peter A. Lachenbruch, Ph.D. FDA Reviewer
4:00	Questions from the Committee	
4:30	Committee Discussion and Vote	
	ODAC Discussants	Janice Dutcher, M.D. ODAC Consultant
		(TBA)
5:00	Adjourn	