

**Food and Drug Administration
Center for Drug Evaluation and Research**

Oncologic Drugs Advisory Committee

69th Meeting

Holiday Inn – Silver Spring, Maryland

Proposed Agenda

December 5-6, 2001

8:30	Call to Order and Opening Remarks	Stacy Nerenstone, M.D. Chair, ODAC
	Introduction of Committee	
	Conflict of Interest Statement	Karen M. Templeton-Somers, Ph.D. Executive Secretary, ODAC
	Open Public Hearing	

*Development of Diagnostic Assays Intended to Identify Patients
Who Might Benefit from Treatment with a Particular Therapeutic Product:
Characterization and Interpretation of Assay Results*

9:00	Introduction
	Immunohistochemistry Presentation
	Fluorescence <i>in situ</i> Hybridization Presentation
10:45	Break
11:00	Data Presentations
11:20	Panel Discussion
12:00	Committee Discussion and Vote
12:45	Lunch

December 5, 2001 – Afternoon Session

1:45	Call to Order and Opening Remarks	Stacy Nerenstone, M.D. Chair, ODAC
	Introduction of Committee	
	Conflict of Interest Statement	Karen M. Templeton-Somers, Ph.D. Executive Secretary, ODAC
	Open Public Hearing	

December 6, 2001 – Afternoon Session

1:15	Call to Order and Opening Remarks	Stacy Nerenstone, M.D. Chair, ODAC
	Introduction of Committee	
	Conflict of Interest Statement	Karen M. Templeton-Somers, Ph.D. Executive Secretary, ODAC
	Open Public Hearing	

NDA 20-637/S016, Gliadel® Wafer (carmustine), Guilford Pharmaceuticals Inc.

- indicated for use as a treatment to significantly prolong survival and maintain overall function (as measured by preservation of Karnovsky Performance Status) and neurological function in patients with malignant glioma undergoing primary and/or recurrent surgical resection

1:30	Sponsor Presentation	Guilford Pharmaceuticals Inc.
2:30	Questions from the Committee	
3:00	Break	
3:15	FDA Presentation	
4:30	Questions from the Committee	
5:00	Committee Discussion and Vote	
5:30	Adjourn	