

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

**Oncologic Drugs Advisory Committee**

68<sup>th</sup> Meeting

Holiday Inn - Bethesda, Maryland

**Proposed Agenda**

**September 10-11, 2001**

8:00	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	

*Clinical Trial Designs for First-Line Hormonal Treatment of Metastatic Breast Cancer*

8:30	FDA presentation	Susan Honig, M.D. FDA Medical Reviewer
		Patricia Cortazar, M.D. FDA Medical Reviewer
		Rajeshwari Sridhara, Ph.D. FDA Statistical Reviewer
9:30	Questions from the Committee	
10:00	Break	
10:15	Committee Discussion	
12:30	Lunch	

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**September 10, 2001 – Afternoon Session**

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<b>1:30</b>	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 21-236, IntraDose® (cisplatin/epinephrine) Injectable Gel, Matrix Pharmaceutical, Inc.**  
- indicated for the treatment of recurrent or refractory squamous cell carcinoma of the head and neck in patients who are not considered curable with surgery or radiotherapy

2:00	<b>Sponsor Presentation</b>	<b>Matrix Pharmaceuticals, Inc.</b>
	Introduction	Stephen B. Howell, M.D. University of California, San Diego
	Current Management of Head and Neck Cancer	Glenn Mills, M.D. Louisiana State University
	Pharmacologic rationale and challenges associated with demonstration of clinical benefit	Stephen B. Howell, M.D.
	Clinical Study Results, Efficacy and Safety	Richard D. Leavitt, M.D. Senior Vice President, Medical Affairs
		John Mackowiak, Ph.D. Center for Outcomes Research
	Risk/Benefit and Conclusions	Glenn Mills, M.D.
3:00	Questions from the Committee	
3:30	Break	
3:45	<b>FDA Presentation</b>	Grant Williams, M.D. Medical Team Leader, FDA
		Gregory Frykman, M.D. FDA Medical Reviewer
		Rajeshwari Sridhara, Ph.D. FDA Statistical Reviewer
4:30	Questions from the Committee	
5:00	Committee Discussion and Vote	
5:30	Adjourn	

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**September 11, 2001**

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8:00	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	
	<b>BLA 125019, Zevalin™ (ibritumomab tiuxetan), IDEC Pharmaceuticals Corporation</b>	
	- indicated for the treatment of patients with relapsed or refractory low grade, follicular or CD20+ transformed B cell Non-Hodgkins lymphoma (NHL) and rituximab refractory follicular NHL	
8:30	Introduction	Marjorie Shapiro, Ph.D. FDA Product Reviewer
8:45	<b>Sponsor Presentation</b>	<b>IDEC Pharmaceuticals Corporation</b>
	<b>Ibritumomab Tiuxetan (Zevalin™) Radioimmunotherapy of Non-Hodgkin's Lymphoma</b>	
	Opening Remarks	Leslie L. Shelly, Ph.D. Associate Director, Regulatory Affairs
	Scientific and Medical Summary of Zevalin™	Christine A. White, M.D. Vice President, Medical Affairs
9:30	Questions from the Committee	
10:00	Break	
10:15	<b>FDA Presentation</b>	Philippe Bishop, M.D. FDA Medical Reviewer
11:00	Questions from the Committee	
11:30	Committee Discussion and Vote	
12:15	Lunch	

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**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	<b>Sponsor Presentation</b>	<b>Guilford Pharmaceuticals Inc.</b>
	Introductions	Louise Peltier Senior Director, Regulatory Affairs
	Overview of Primary Malignant Glioma: Clinical Features and Treatment	Alan Hamilton, M.D. University of Arizona School of Medicine
	Phase III Trials (T-301 and C-0190)	Dana Hilt, M.D. Vice President of Clinical Research
	Statistical Analytic Methods	Stephen Piantadosi, M.D., Ph.D. Johns Hopkins School of Medicine
	Phase III Trial (T-301) Efficacy and Safety Results	Dana Hilt, M.D.
2:30	Questions from the Committee	
3:00	Break	
3:15	<b>FDA Presentation</b>	Alison Martin, M.D. Medical Team Leader, FDA
		Alla Shapiro, M.D. FDA Medical Reviewer
		Ning Li, Ph.D. FDA Statistical Reviewer
4:30	Questions from the Committee	
5:00	Committee Discussion and Vote	
5:30	Adjourn	