

FOOD AND DRUG ADMINISTRATION (FDA)

Center for Drug Evaluation and Research (CDER)

Medical Imaging Drugs Advisory Committee (MIDAC) Meeting

FDA White Oak Campus, Building 31 Conference Center, the Great Room (Rm. 1503)

10903 New Hampshire Avenue, Silver Spring, Maryland

May 10, 2017

DRAFT AGENDA

The committee will discuss new drug application (NDA) 208-630 for 5-Aminolevulinic Acid Hydrochloride [5-ALA HCl], Powder, for oral solution, submitted by NX Development Corp., for the proposed indication as an imaging agent to facilitate the real time detection and visualization of malignant tissue during glioma surgery.

8:00 a.m.	Call to Order and Introduction of Committee	Henry D. Royal, MD Chairperson, MIDAC
8:05 a.m.	Conflict of Interest Statement	Jennifer Shepherd, RPh Designated Federal Officer, MIDAC
8:10 a.m.	Introductory Remarks	Alex Gorovets, MD Deputy Director Division of Medical Imaging Products (DMIP) Office of Drug Evaluation-IV (ODE-IV) Office of New Drugs (OND), CDER, FDA
8:15 a.m.	GUEST SPEAKER PRESENTATION	
	Current Practices for Glioma Surgery	Cameron W. Brennan, MD Memorial Sloan Kettering Cancer Center
8:45 a.m.	Clarifying Questions	
9:00 a.m.	APPLICANT PRESENTATIONS	NX Development Corp.
	Introduction	Alan Ezrin, PhD President and Chief Executive Officer NX Development Corporation
	Visualization of Tumor During Glioma Surgery	Constantinos G. Hadjipanayis, MD, PhD Professor and Chair, Department of Neurosurgery Director of Neurosurgical Oncology Professor of Oncological Services Mount Sinai
	Clinical Efficacy	Walter Stummer, PhD, Dr med Department of Neurosurgery University of Münster, Germany
	Safety Results	Walter Stummer, PhD, Dr med
	Benefit/Risk	Constantinos G. Hadjipanayis, MD, PhD

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DRAFT AGENDA (CONT.)

APPLICANT PRESENTATIONS (CONT.)

Conclusion **Alan Ezrin, PhD**

10:30 a.m. Clarifying Questions

10:45 a.m. **BREAK**

11:00 a.m. **FDA PRESENTATIONS**

FDA Clinical Review **Betsy Ballard, MD**
Medical Officer
DMIP, ODE-IV, OND, CDER, FDA

FDA Statistical Analyses **Anthony Mucci, PhD**
Mathematical Statistician
Division of Biometrics I, Office of Biostatistics, Office of
Translational Sciences, CDER, FDA

12:00 a.m. Clarifying Questions

12:15 p.m. **LUNCH**

1:00 p.m. **OPEN PUBLIC HEARING**

2:00 p.m. Questions to the Committee/Committee Discussion

3:00 p.m. **BREAK**

3:15 p.m. Questions to the Committee/Committee Discussion (cont.)

4:00 p.m. **ADJOURNMENT**