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
Neurosurgery for Brain Tumors: A General Overview
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
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