

MEMORANDUM

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

DATE: 1/24/2024

TO: Division of Biometrics I, Office of Biostatistics, OTS, and
Division of Imaging and Radiation Medicine, OND

THROUGH: Deputy Division Director and Signer, Sue-Jane Wang, PhD

FROM: Primary Statistical Reviewer, Zhipeng Huang, PhD
Secondary Statistical Reviewer and Signer, Jyoti Zalkikar, PhD

SUBJECT: NDA 021064 Statistical review memorandum

APPLICATION/DRUG: NDA 021064/DEFINITY®, Vial for Injectable Suspension

Lantheus Medical Imaging, Inc. (LMI) have submitted this supplemental application for the approved drug DEFINITY®, Vial for (Perflutren Lipid Microsphere) Injectable Suspension to support the expanded indication in the use of DEFINITY® in pediatric patients. The primary statistical reviewer's comments in the filing review are as follows: *Since the indication expansion of the sNDA is for pediatric use and there is no clinical data submitted, Statistical review is not needed for this sNDA submission.*

This is based on the information currently in the administrative record. If review staff of Division of Biometrics I must review information that is subsequently added to the administrative record, they will update the statistical content of the multidisciplinary review and evaluation document accordingly.

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

JYOTI ZALKIKAR
01/24/2024 08:54:20 PM

SUE JANE WANG
01/25/2024 09:26:13 AM