CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

216820Orig1s000

STATISTICAL REVIEW(S)

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Translational Sciences
Office of Biostatistics

STATISTICAL REVIEW AND EVALUATION

CLINICAL STUDIES - MEMO

NDA Number:	216820/00
Product Name:	Kit for the Preparation of Technetium Tc 99m Mertiatide
Indication:	Diagnosis of congenital & acquired abnormalities, renal failure, urinary tract obstruction, & calculi in adults & pediatric patients. Diagnostic aid in providing renal function, split function, renal angiograms, & renogram curves for whole kidney & renal cortex.
Applicant:	Jubilant DraxImage Inc.
Dates:	Receipt Date: 3/30/2022 PDUFA Goal Date: 1/30/2023
Review Priority:	Standard
Biometrics Division:	Division of Biometrics I
Statistical Reviewer:	Jyoti Zalkikar, PhD.
Concurring Reviewers:	Sue-Jane Wang, PhD, Division Deputy Director
Medical Division:	Division of Imaging and Radiation Medicine
Clinical Team:	Stephanie Coquia, M.D., Primary Clinical Reviewer Shane Masters, M.D, Clinical Team Leader
Project Manager:	Modupe Fagbami

This memo closes the NDA assignment in DARRTS for the statistics team. The Reference Listed Drug (RLD) for this application is Technescan MAG3TM, NDA# 019882, manufactured by Curium US LLC as indicated in the active list of FDA approved drug products with therapeutic equivalence evaluations (Orange Book). Therefore, this application does not contain any pharmacological /toxicological and clinical data for review. From statistical perspective, this NDA receives “No Action Intended”.

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/s/

JYOTI ZALKIKAR
05/31/2022 10:35:14 AM

SUE JANE WANG
05/31/2022 01:06:56 PM