CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

216820Orig1s000

SUMMARY REVIEW

MEMORANDUM
Division of Imaging and Radiation Medicine January 29, 2023
Division Director Summary

NDA: 216820/Original
PRODUCT: Kit for the Preparation of Technetium Tc 99m Mertiatide Injection
APPLICANT: Jubilant Draximage

Jubilant Draximage (Applicant) has submitted a 505(b)(2) application for a Kit for the Preparation of Technetium Tc-99m Mertiatide. The listed drug (LD) is Technescan MAG3 (technetium Tc-99m mertiatide: NDA 019882). The Applicant's mertiatide kit contains the same active ingredient in the same quantity, and has the same dosage form, the same route of administration following reconstitution, the same proposed doses of radioactivity, and the same indications as the LD.

The differences between the Applicant's product and the LD consist of the hydration state of the stannous chloride (dihydrate for the Applicant's drug, anhydrous for the LD) and the lack of sodium hydroxide for pH adjustment (only HCl is needed). (b) (4) The quantity and hydration state of the stannous chloride in the finished product (lyophilized form) is identical to that of the LD. The application contains no Clinical Pharmacology, Toxicology, or Clinical studies. I concur with the reviewers from these scientific disciplines that no new studies are needed.

I concur with the assessment by Biopharmaceutics and Clinical Pharmacology that based on the totality of the information provided, the proposed drug product is adequately bridged to the LD, in accordance with 21 CFR §320.24(b)(6) and an in vivo pharmacokinetic study is not needed.

I concur with the Pharmacology Toxicology reviewer that no new nonclinical studies are needed. Studies conducted to support the approval of the LD included a biodistribution study in rats, acute toxicity studies in mice and rabbits, and subacute toxicity studies in rats and rabbits. There were no mortalities or toxic effects in the species tested.

I concur with the Clinical reviewer's assessment that reliance on FDA's findings of safety and effectiveness for Technescan MAG3 provides sufficient support to this application from a clinical perspective.

I concur with the assessments by the Chemistry, Manufacturing and Controls reviewers that the product quality is acceptable. The Applicant has provided adequate information, data, and controls, including specifications and analytical methods, for the betiatide active ingredient. The Applicant has justified and qualified the quality of the components used in the drug product, including excipients. Controls and specifications for critical quality attributes are established, acceptance criteria are justified, and analytical methods are verified as suitable to

assess the quality attributes. Assessment of potential impurities has been performed and control strategies are established. The Applicant provides adequate validation data to support the sterility of the product. Manufacturing process and controls are adequate. All the facilities are acceptable based on compliance status, inspection history, and experience with the proposed operations. The labeling, as finalized, contains adequate information for radiolabeling and for confirming the radiochemical purity by the user of the kit.

I concur with the final product labeling as revised by the review disciplines, including medication error prevention (DMEPA), and pediatric and maternal health (DPMH), and the division's associate director for labeling (ADL). The prescribing information (PI) for the LD is currently not in physician-labeling-rule (PLR) format. The Applicant changed the PI for their product to be consistent with PLR and PLLR (pregnancy and lactation labeling rule) format.

In conclusion, I concur with the unanimous recommendation by the review team that the application be approved.

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/

LIBERO L MARZELLA
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