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APPLICATION NUMBER:

216820Orig1s000

CLINICAL PHARMACOLOGY REVIEW(S)

Clinical Pharmacology NDA Review-Memorandum

NDA Number (SDN)	216820 (4)
Link to EDR	\\CDSESUB1\evsprod\NDA216820\0003
Submission Date	March 30, 2022
Submission Type	Standard
Generic Name	Kit for the Preparation of Technetium Tc-99m Mertiatide Injection
Dosage Form and Strengths	1 mg betiatide as lyophilized powder in 10 mL multiple-dose vial
Route of Administration	Intravenous
Proposed Dose	(b) (4) Adults (b) (4) 185 MBq (5 mCi) to 370 MBq (10 mCi) Pediatrics: 2.6 MBq/kg (70 µCi/kg) to 5.2 MBq/kg (140 µCi/kg) with a minimum dose of 37 MBq (1 mCi)
Proposed Indications	(b) (4) agent for use in the diagnosis of congenital and acquired abnormalities, renal failure, urinary tract obstruction, and calculi in adults and pediatric patients
Applicant	Jubilant Draximage
OCP Review Team	Sriram Subramaniam, PhD; Christy John, PhD (TL)
OCP Final Signatory	Olanrewaju Okusanya, PharmD, MS

Jubilant Draximage Inc., d.b.a. Jubilant Radiopharma, has submitted a 505(b)(2) application for its 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 is proposed for the same indications, has the same dosage form (lyophilized powder for solution), contains the same active ingredient (betiatide) at the same amount (1 mg), and the same route of administration following reconstitution as the LD. Also, the proposed doses in terms of radioactivity are the same as the LD [(b) (4) Adults (b) (4) 185 MBq (5 mCi) to 370 MBq (10 mCi), and Pediatrics: 2.6 MBq/kg (70 µCi/kg) to 5.2 MBq/kg (140 µCi/kg) with a minimum dose of 37 MBq (1 mCi)].

Per the Applicant, there are no other differences between Applicant's proposed drug product and the LD other than the difference in the 'hydration form' of stannous chloride used in the product formulation (prior to lyophilization), whereas the finished product (lyophilized form) composition is same as LD. The LD used (b) (4)

The Applicant requests a waiver of in-vivo bioavailability or bioequivalence studies for its proposed drug product Kit for the preparation of Technetium Tc 99m Mertiatide. The Applicant is relying on a scientific bridge between its proposed drug to the listed drug to support reliance on the Agency's previous findings of safety and effectiveness for the LD.

CMC/Biopharmaceutics review for this application concluded that "Based on the totality of the information provided, the proposed drug product, NDA 216820 (Kit for the Preparation of Technetium Tc 99m Mertiatide Lyophilized Powder for Solution) for intravenous administration is adequately bridged to the listed drug (LD), NDA 019882 (Technescan MAG3™) in accordance with 21 CFR §320.24(b)(6) and an in vivo pharmacokinetic study is not needed." (for details refer to the CMC/Biopharmaceutics review).

There are no clinical pharmacology studies and no clinical pharmacology summary module in this submission for clinical pharmacology review. Thus, a clinical pharmacology review is not warranted for this application.

Recommendation:

This NDA is approvable from a clinical pharmacology perspective, pending the Applicant and the Agency come to an agreement regarding the labeling language.

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/

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