CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

216820Orig1s000

ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS

NDA 216820

GENERAL ADVICE

Jubilant DraxImage Inc. dba Jubilant Radiopharma
Attention: Theresa Broomall (US Agent)
Syneos Health, LLC
1030 Sync Street
Morrisville, NC 27560

Dear Ms. Broomall:

Please refer to your pre-assigned new drug application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Kit for the Preparation of Technetium Tc 99m Mertiatide.

We also refer to your October 15, 2021, correspondence, received October 15, 2021, requesting a meeting to confirm the following:

- That the Application can be submitted as a 505(b)(2)
- That the Application can rely on Technescan MAG3™ from Curium, NDA 019882, as the RLD for the evidence of safety and efficacy derived from nonclinical, clinical and postmarketing findings
- That *in vivo* bioavailability or bioequivalence of JDI's proposed product with the RLD is self-evident and hence, a bio-waiver based on the FDA 21CFR 320.22(b)(ii) requirement will be granted to their Application.

We furthermore refer to our meeting granted letter dated October 25, 2021, and our meeting cancellation letter dated December 23, 2021.

We also refer to your January 12, 2022, submission, containing your response to our information request dated January 7, 2022.

We have reviewed the referenced material and have the following comments:

BACKGROUND

Jubilant DraxImage Inc. dba Jubilant Radiopharma, Sponsor of NDA 216820 Kit for the Preparation of Technetium Tc 99m Mertiatide, requested a meeting on October 15, 2021, to confirm the following with the Agency:

- That the Application can be submitted as a 505(b)(2)
- That the Application can rely on Technescan MAG3™ from Curium, NDA 019882, as the RLD for evidence of safety and efficacy derived from nonclinical, clinical, and postmarketing findings

- That *in vivo* bioavailability or bioequivalence of JDI's proposed product with the RLD is self-evident and hence, a bio-waiver based on the FDA 21CFR 320.22(b)(ii) requirement will be granted to their Application.

DISCUSSION

Question 1:

Does FDA agree that JDI's proposed product Kit for the Preparation of Technetium Tc 99m Mertiatide prepared as per the proposed formulation (Table 1) can be submitted as 505(b)(2) and FDA will not "refuse to receive" this NDA?

FDA Response:

Based on the information you have provided, and after consulting with the Office of Generic Drugs, the formulation proposed in Table 1 may be submitted as a 505(b)(2) application.

Note that this pathway will require inclusion of sufficient information in the NDA to establish a scientific bridge between your product and the listed drug (LD). See additional comments from FDA in the responses to Questions 2 and 3, below.

Determination of whether the application is filed will be made after submission and filing review.

Question 2:

Does the FDA agree that evidence of safety and efficacy derived from non-clinical, clinical and post marketing findings for the approved NDA 019882 (Technescan MAG3™ from CURIUM US LLC) is sufficient to support JDI's 505(b)(2) application for Kit for the Preparation of Technetium Tc 99m Mertiatide which will rely on this NDA as RLD?

FDA Response:

Assuming that a scientific bridge can be established between your product and the listed drug, we agree in principle that reliance on FDA's findings of safety and effectiveness for Technescan MAG3 in NDA 019882 could provide sufficient support for your marketing application. Note that determination of the adequacy of the evidence to support approval of your NDA will be made during review.

For information on data required to establish the scientific bridge, please refer to FDA's response to Question 3.

Question 3:

Does the FDA agree that a request for waiver of evidence of *in vivo* bioavailability or bioequivalence based on the FDA 21CFR 320.22 applies for JDI's 505(b)(2) proposed application for Kit for the Preparation of Technetium Tc 99m Mertiatide which will rely on NDA 019882 (Technescan MAG3™ from CURIUM US LLC) as the RLD?

FDA Response:

No, we do not agree. As the proposed drug product is not compositionally proportional (Q1/Q2) to the LD, waiver of bioavailability studies for the proposed product cannot be established under 21CFR 320.22(b)(1).

However, based on the limited data and information provided in the briefing document, bridging of the proposed drug product and LD could potentially be established per 21 CFR 320.24(b)(6), provided the comparative data are adequate to support the scientific bridge. To establish bridging of your proposed drug product to the LD, we recommend that you submit a formal request with a justification and supporting data demonstrating that the differences in the inactive ingredients between the proposed and listed products do not contribute to differences in their *in vivo* performance. Additionally, provide in a side-by-side comparison table the physicochemical characteristics of the proposed product and the LD, including the relevant physical-chemical properties to justify that the proposed formulation will not alter the *in vivo* performance of the drug product. Include justification for any differences in the formulation's composition, pH, osmolality, dosage, mode of administration, drug concentration, administered volume, etc., relative to the LD.

Please note, the adequacy of the data to establish the scientific bridge is a review issue that will be determined during the NDA review.

If you have any questions, call Modupe Fagbami, Regulatory Project Manager, at 301-796-1348.

Sincerely,

{See appended electronic signature page}

Libero Marzella, M.D., Ph.D.
Director
Division of Imaging and Radiation Medicine
Office of Specialty Medicine
Office of New Drugs
Center for Drug Evaluation and Research

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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