NDA 018511/S-031

APPROVAL LETTER

Jubilant Draximage Inc.
c/o Syneos Health LLC
Attention: Theresa Broomall
1030 Sync Street
Morrisville, NC 27560

Dear Ms. Broomall:

Please refer to your Supplemental New Drug Application (sNDA) dated June 5, 2020, received June 12, 2020, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for DRAXIMAGE DTPA (kit for the preparation of Technetium Tc 99m pentetate injection).

We acknowledge receipt of your amendment dated April 22, 2022, which constituted a complete response to our October 1, 2020, action letter.

This Prior Approval supplemental new drug application provides for the addition of an alternate manufacturing site (b) (4) (b) (4) for its product DRAXIMAGE DTPA, Kit for DRAXIMAGE DTPA (kit for the preparation of Technetium Tc 99m pentetate injection).

APPROVAL & LABELING

We have completed our review of this supplemental application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling.

CARTON AND CONTAINER LABELS

Submit final printed carton and container labels that are identical to enclosed carton and container labels, as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format – Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications*. For administrative purposes, designate this submission "**Product Correspondence – Final Printed Carton and Container Labels for approved NDA 018511/S-031.**" Approval of this submission by FDA is not required before the labeling is used.

We remind you that you must comply with reporting requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Grecia C. Edwards, Regulatory Business Process Manager, at (240) 402 - 1773.

Sincerely,

{See appended electronic signature page}

Ramesh Raghavachari, PhD
Branch Chief, B1
Division of Post-Marketing Activities I
Office of Lifecycle Drug Products
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Enclosure:
Carton and Container Labeling

Ramesh Raghavachari

Digitally signed by Ramesh Raghavachari
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