



NDA 017588/S-046

APPROVAL LETTER

Corden Pharma Latina S.p.A.
c/o Clinipace Inc.
Attention: Adeana Dorsey
Director, Regulatory and Strategic Development
1434 Spruce Street
Suite 100
Boulder, CO 80302

Dear Ms. Dorsey:

Please refer to your Supplemental New Drug Application (sNDA) dated and received December 11, 2019, and your amendment, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Gleostine (Iomustine) Capsules.

This “Changes Being Effected” supplemental new drug application provides for a change in labeling due to serialization

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 text.

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and immediate container labels that are identical to enclosed carton and immediate container labels and carton and immediate container labels submitted on March 25, 2020, 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 – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (May 2015, Revision 3). For administrative purposes, designate this submission “Product Correspondence – Final Printed Carton and Container Labels for approved **NDA 017588/S-046.**” Approval of this submission by FDA is not required before the labeling is used.

REPORTING REQUIREMENTS

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

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If you have any questions, call Jessica Springer, Regulatory Business Process Manager, at (240) 402 - 5926.

Sincerely,

{See appended electronic signature page}

Ramesh Raghavachari, Ph.D.
Chief, Branch I
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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