



NDA 208051/S-003

SUPPLEMENT APPROVAL

Puma Biotechnology Inc.
Attention: Jesse Ho, PharmD
Associate Director, Regulatory Affairs
10880 Wilshire Blvd. Suite 2150
Los Angeles, CA 90024-4800

Dear Dr. Ho:

Please refer to your Supplemental New Drug Application (sNDA) dated and received October 23, 2018, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Nerlynx (neratinib) Tablets, 40 mg.

This “Changes Being Effected” supplemental new drug application provides for the addition of a tamper-resistant, adhesive “SAMPLE – NOT FOR SALE” sticker to the carton label of the 126-count bottle professional sample.

APPROVAL & LABELING

We have completed our review of this supplemental application. 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, 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 208051/S-003.**” 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 (21 CFR 314.80 and 314.81).

If you have any questions, call Adijat Abass-Fasuyi, Regulatory Business Process Manager, at (301) 796 - 3609.

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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