



NDA 203697/S-003

SUPPLEMENT APPROVAL

PLx Pharma Inc.
Attention: Estela Von Chong, MBIOT, RAC
Senior Director of Regulatory & Clinical Affairs
82885 El Rio Street, Suite 130
Houston, TX 77054

Dear Ms. Von Chong:

Please refer to your supplemental new drug application (sNDA) dated and received January 26, 2018, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for aspirin capsules, 325 mg (PL2200).

This “Prior Approval” supplemental new drug application provides for a proprietary name change from Aspertec to Vazalore and changes to the carton and container labeling to incorporate the new proprietary name.

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

LABELING

Submit final printed labeling (FPL), as soon as they are available, but no more than 30 days after they are printed. The FPL must be in the “Drug Facts” format (21 CFR 201.66), where applicable, and identical to the labeling listed in the table below.

Submitted Labeling	Date Submitted
7-ct immediate container (blister), Vazalore	March 28, 2018
7-ct outer carton, Vazalore	March 28, 2018
28-ct outer carton, Vazalore	March 28, 2018
30-ct immediate container (bottle), Vazalore	March 28, 2018
30-ct outer carton, Vazalore	March 28, 2018
120-ct immediate container (bottle), Vazalore	March 28, 2018
120-ct outer carton, Vazalore	March 28, 2018

The final printed labeling should be submitted electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (May 2015, Revision 3)*. For administrative purposes, designate this submission “**Final Printed Labeling for approved NDA 203697/S-003.**” Approval of this submission by FDA is not required before the labeling is used.

DRUG REGISTRATION AND LISTING

All drug establishment registration and drug listing information is to be submitted to FDA electronically, via the FDA automated system for processing structured product labeling (SPL) files (eLIST). At the time that you submit your final printed labeling (FPL), the content of labeling (Drug Facts) should be submitted in SPL format as described at <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>. Information on submitting SPL files using eLIST may be found in the guidance for industry titled “SPL Standard for Content of Labeling Technical Qs and As” at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>. In addition, representative container or carton labeling, whichever includes Drug Facts, (where differences exist only in the quantity of contents statement) should be submitted as a JPG file.

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 Tinya Sensie, Regulatory Project Manager, at (240) 402-4230.

Sincerely,

{See appended electronic signature page}

Theresa M. Michele, MD
Director
Division of Nonprescription Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

ENCLOSURE(S):
Carton and Container Labeling

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/

THERESA M MICHELE
07/25/2018