NDA 203697/S-004

SUPPLEMENT APPROVAL

PLx Pharma Inc.
Attention: Leonard M. Baum
Regulatory Consultant for PLx Pharma
9 Fishers Lane
Sparta, NJ 07871

Dear Mr. Baum:

We refer to your supplemental new drug application (sNDA) dated and received June 11, 2019, and your amendments, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Vazalore (aspirin) capsule, 325 mg.

This Prior Approval supplemental new drug application provides for a new 6-count blister card, 6- and 30-count blister carton labeling, labeling revisions to existing 30-count bottle labeling, new secondary container design scheme, and additional labeling statements to the principal display panel and Drug Facts labeling.

APPROVAL & LABELING

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 enclosed agreed-upon labeling.

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 identical to the enclosed labeling described in the table below and must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

Submitted Labeling for Approval	Dates Submitted
30-count Immediate Container (Bottle)	November 27, 2019
30-count Outer Carton (Bottle)	November 27, 2019
6-count Immediate Container Blister Card	June 11, 2019
6-count Outer Carton (1 x 6-ct Blister Card)	November 27, 2019
30-count Outer Carton (5 x 6-ct Blister Card)	November 27, 2019

The FPL should be submitted 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*.[1] For administrative purposes, designate this submission "**Final Printed Labeling for approved NDA 203697/S-004**." 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 FDA.gov.[2] Information on submitting SPL files using eLIST may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As*. 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 LT Sally Doan, Regulatory Project Manager, at (301) 796-8025.

Sincerely,

{See appended electronic signature page}

Karen Murry Mahoney, MD, FACE
Deputy Director
Division of Nonprescription Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

ENCLOSURE(S):

- Carton and Container Labeling

[1] We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

[2] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm

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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/

KAREN M MAHONEY
12/11/2019 11:45:39 PM