NDA 206185/S-009

SUPPLEMENT APPROVAL

Sun Pharma Global FZE
Attention: Jeffrey Yuan, Ph.D.
Vice President, Global Regulatory Affairs
2 Independence Way
Princeton, NJ 08540

Dear Dr. Yuan:

Please refer to your supplemental new drug application (sNDA) dated and received June 23, 2020, and your amendments, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for XELPROS (latanoprost ophthalmic emulsion). This Prior Approval supplemental new drug application provides for updates to the Use in Specific Populations section of the prescribing information to comply with the requirements of the Pregnancy and Lactation Labeling Rule.

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.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at FDA.gov.[1] Content of labeling must be identical to the enclosed labeling (text for the Prescribing Information), with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

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*.[2]

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

The SPL will be accessible from publicly available labeling repositories.

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 Derek Alberding, Regulatory Health Project Manager, at (240) 402-0963.

Sincerely,

{See appended electronic signature page}

Wiley A. Chambers, M.D.
Director
Division of Ophthalmology
Office of Specialty Medicine
Center for Drug Evaluation and Research

ENCLOSURE:

- Content of Labeling
    - Prescribing Information

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/

WILEY A CHAMBERS
12/21/2020 10:00:18 AM