17-B, Mahal Industrial Estate, Mahakali Caves Road, Andheri (E), Mumbai - 400 093. INDIA.

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CIN: L73100GJ2006PLC047837 Website: www.sunpharma.in

SPARC/Sec/SE/2016-17/035



22nd December 2016

To

The National Stock Exchange of India Ltd.

Exchange Plaza, 5th Floor, Plot No. C/1, G Block, Bandra Kurla Complex, Bandra (East), Mumbai – 400 051. BSE Limited P J Towers, Dalal street, Mumbai - 400001

Ref: Scrip Code: NSE: SPARC; BSE: 532872

Sub: Update on XELPROS<sup>TM</sup> (Latanoprost Ophthalmic Emulsion) NDA"

Dear Sir/ Madam,

This is to inform you that, the Company has received a Complete Response Letter (CRL) from the USFDA for the New Drug Application (NDA) for Xelpros<sup>TM</sup>, Latanoprost BAK-free eyedrops.

The CRL references the recent inspection of the Sun Pharmaceutical Industries Ltd.'s Halol manufacturing site by USFDA and indicates that satisfactory resolution of the deficiencies identified during the inspection is required before the final approval of Xelpros<sup>TM</sup>. There are no requirements of any additional data from USFDA in the CRL.

SPARC had out-licensed Xelpros<sup>TM</sup> to a subsidiary of Sun Pharmaceutical Industries Ltd. in June 2015.

This is for your information and public dissemination.

Yours faithfully,

For Sun Pharma Advanced Research Company Limited

**Debashis Dey** 

Company Secretary