

June 22, 2019

To,
Dy. General Manager
Department of Corporate Services,
BSE Ltd.,
P. J. Towers, Dalal Street,
Fort, Mumbai – 400 001.

To,
The Manager – Listing,
The National Stock Exchange of India Ltd.,
Plot No. C/1, G Block,
Bandra Kurla Complex,
Bandra (E), Mumbai – 400 051.

Ref: Scrip Code: 532296

Ref: Scrip Name: GLENMARK

Sub: FDA Issues Complete Response Letter for Ryaltris™ (olopatadine hydrochloride [665 mcg] and mometasone furoate [25 mcg])

Dear Sir,

We would like to inform you that the U.S. Food and Drug Administration (FDA) has issued a Complete Response Letter (CRL) regarding the New Drug Application for Ryaltris™ (olopatadine hydrochloride [665 mcg] and mometasone furoate [25 mcg]), Nasal Spray. The CRL cites deficiencies in the Drug Master File (DMF) pertaining to one of the active pharmaceutical ingredients (APIs) and in the manufacturing facilities.

The CRL does not specify any deficiencies with the clinical data supporting the New Drug Application for Ryaltris. We feel confident that we should be able to resolve these issues within the next 6 to 9 months. Glenmark Pharmaceuticals will continue to pursue regulatory approval for Ryaltris and work closely with the FDA to determine the appropriate next steps.

This is for your information and record please.

Thanking you,

Yours faithfully,
For Glenmark Pharmaceuticals Limited

Harish Kuber
Company Secretary & Compliance Officer

Glenmark Pharmaceuticals Ltd.

Glenmark House, B D Sawant Marg, Andheri (E), Mumbai 400 099

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