



ALKEM LABORATORIES LTD.

Regd. Office : " ALKEM HOUSE", Senapati Bapat Marg,
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Email : contact@alkem.com Website : www.alkemlabs.com
CIN :- L00305MH1973PLC174201



23rd December, 2016

The Corporate Relationship Department BSE Limited Phiroze Jeejeebhoy Towers, Dalal Street, Mumbai 400 001. <i>Scrip Code: 539523</i>	National Stock Exchange of India Limited Exchange Plaza, Bandra Kurla Complex, Bandra East , Mumbai 400 051. <i>Scrip Symbol: ALKEM</i>
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Dear Sirs

Sub: Closure of US FDA Inspection at Alkem's Daman Facility.

In furtherance to the intimation captioned "Update on US FDA Inspection at Alkem's Daman Facility" dated 29th September, 2016, this is to inform you that the US FDA has issued an Establishment Inspection Report (EIR) for its Daman formulation facility which was inspected in September 2016. The inspection has now been closed by the US FDA.

In response to the Form 483 issued by the US FDA, the Company had submitted a detailed corrective and preventive action (CAPA) plan to the regulator within the stipulated timelines. The US FDA has reviewed the CAPA and has found them acceptable.

A copy of Press Release is enclosed herewith for your information. Kindly take the same on record.

Sincerely,
For Alkem Laboratories Limited


Manish Narang
President - Legal, Company Secretary & Compliance Officer





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Alkem receives EIR from the US FDA for its Daman formulation facility

Mumbai, December 23, 2016: Alkem Labs Ltd (Alkem) would like to inform that the US FDA has issued an Establishment Inspection Report (EIR) for its Daman formulation facility which was inspected in September 2016. The inspection has now been closed by the US FDA.

The US FDA had inspected the Daman formulation facility from 20th to 29th September 2016 and had issued Form 483 with thirteen (13) observations. Post this, the Company had submitted a detailed corrective and preventive action (CAPA) plan to the regulator within the stipulated timelines. The US FDA has reviewed the CAPA and has found them acceptable.

About Alkem Laboratories Ltd.

Established in 1973 and headquartered in Mumbai, Alkem (NSE: ALKEM, BSE: 539523, Bloomberg: ALKEM.IN, Reuters: ALKE.NS) is a leading Indian pharmaceutical company with global operations, engaged in the development, manufacture and sale of pharmaceutical and nutraceutical products. The Company produces branded generics, generic drugs, active pharmaceutical ingredients (APIs) and nutraceuticals, which it markets in India and International markets. With a portfolio of more than 700 brands in India, Alkem is ranked the fifth largest pharmaceutical company in India in terms of domestic sales (Source: IMS SSA MAT March 2016). The Company also has presence in more than 50 international markets, with the United States being its key focus market.

For more information on Alkem Laboratories Ltd., please visit www.alkemlabs.com

For further information or queries please contact

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