



**West-ward**  
PHARMACEUTICAL CORP.

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December 20, 2006

Division of Dockets Management (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane  
Room 1061  
Rockville, MD 20852  
Attn.: Beth Duvall-Miller

**Re: DOCKET NO. 2006N-0468**

**Training Program for Regulatory Project Managers; Information Available to Industry**

Dear Ms. Duvall-Miller:

Reference is made to the Federal Register Notice, Volume 71, No. 228 dated November 28, 2006 regarding the FDA's announcement of the continuation of the Regulatory Project Management Site Tours and Regulatory Interaction Program (the Site Tours Program). At this time West-ward Pharmaceutical Corp. is interested in hosting a site tour at any one of our facilities. The US facility is located at 200/435/465 Industrial Way West, Eatontown, NJ 07724, USA. At this site we manufacture and package solid oral dosage form generic and branded products. Additionally, the Quality Control and Quality Assurance Departments are on this campus to release product into commercial distribution. The Regulatory Affairs Department has been filing electronic submissions for the past year.

West-ward Pharmaceutical Corp. is owned by Hikma Pharmaceuticals of Amman, Jordan. At the site in Jordan is a cephalosporin plant, a bulk chemical plant as well as a solid oral dosage form/powder for suspension manufacturing and packaging plant. In addition, there is a Contract Research Organization (IPRC) which conducts clinical trials for bioequivalence studies. All sites have received FDA approval status within the past 2 years.

A sister company, Hikma Farmaceutica is located in Sintra, Portugal. This site is in the completion stage of a brand new "state of the art" injectable sterile facility. Currently the facility manufactures liquid and powder fills for injection for sale in the United States and Europe. This site has also received satisfactory FDA approval within the last 2 years.

2006N-0468

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Please contact the undersigned directly at 732-720-2868 if West-ward is selected to participate in this Training Program. We would be more than happy to forward a detailed agenda when the specific site for the tour is decided.

Sincerely,

A handwritten signature in black ink, appearing to read 'Elizabeth A. Marro', with a long horizontal flourish extending to the right.

Elizabeth A. Marro

Senior Director, Regulatory Affairs and Quality Assurance

Cc: M. Raya-Executive V.P., Operations