



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
Rockville, MD 20857

SENT VIA TELEFAX

Dear ANDA Applicant:

The Food and Drug Administration (FDA) has established Docket No. 2007N-0389 (<http://www.fda.gov/ohrms/dockets/default.htm>) for comments regarding 180-day generic drug exclusivity for granisetron hydrochloride injection. Anyone wishing to comment on this subject should submit their comments to the FDA's Dockets Management Branch and reference the docket number cited above within 14 calendar days from the date of this letter.

The submission will be on public display in the Dockets Management Branch, Room 1061, Mail Stop HFA-305, 5630 Fishers Lane, Rockville, MD 20852.

If you have any questions, please call Cecelia Parise, Regulatory Policy Advisor to the Director, Office of Generic Drugs, at 240-276-9310.

Sincerely,

Gary J. Buehler  
Director  
Office of Generic Drugs  
Center for Drug Evaluation and Research

2007N-0389

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/s/

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Robert L. West  
10/11/2007 03:10:43 PM  
for Gary Buehler