

December 13, 2007

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Attention: Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane, Room 1061
phone 301-827-6860
fax 301-827-6870

To Whom It May Concern:

We are in the process of finalizing comments to submit to the following draft Guidance documents (with docket numbers):

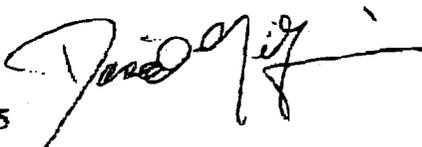
2007D-0367, *Antibacterial Drug Products: Use of Noninferiority Studies to Support Approval*, deadline for comments 12/14/07

2007D-0386, *Guidance for Industry on Postmarketing Adverse Event Reporting for Nonprescription Human Drug Products Marketed Without an Approved Application*, deadline for comments 12/14/07

We anticipate submitting our comments to these dockets no later than January 18, 2008. We would like FDA to extend the comment period for these two dockets to allow us this additional time to complete our comments. If you have any response to our request, please contact me using the contact information below.

Thank you very much for consideration of this request.

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