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December 8, 2006

Via Facsimile, (301) 827-6870, and Email

Division of Dockets Management
Food and Drug Administration (HFA-305)
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: Notice of Participation for December 18, 2006 Hearing on Electronic Submission of Regulatory Information; Docket No. 2006N-0464

Dear Sir or Madam:

By this letter, we are requesting 20 minutes of time to present comments at FDA's meeting on Electronic Submission of Regulatory Information, scheduled to be held on December 18, 2006. Docket No. 2006N-0464. 71 Federal Register 67356 (November 21, 2006).

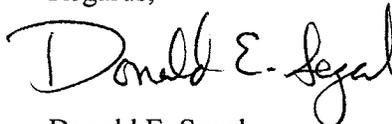
The presenter will be one of the undersigned. We will submit our comments to Dockets on the day of the hearing. Our expectation is to address the issues in Section IV.A. of notice, particularly items 1, 3, and 4.

Our contact information is below:

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We look forward to hearing from you regarding the scheduling of our presentation.

Regards,



Donald E. Segal
Marc J. Scheineson

cc: Lyle Jaffe (lyle.jaffe@fda.hhs.gov)
Paula S. McKeever (paula.mckeever@fda.hhs.gov)