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December 5, 2006

TO

Division of Dockets Management (HFA-305)
Food and Drug Administration,
5630 Fishers Lane , Room # 1061
Rockville, MD 20857

Reference: *Docket No.2006N-0464, Electronic submission of regulatory information, and creating an Electronic Platform for enhanced Information Management; Public Hearing.*

The following Members would like to make an oral presentation during the December 18th hearing

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During the presentation we highlight the electronic submission : Issues for discussion as listed in section IV of the docket No.2006N-0464

1. We will discuss the electronic submission challenges specific to small companies where we will not have integrated management information systems.
2. Challenges faced with propriety data storage format in Discovery and development process.
3. Employee Cross Training costs for Information Technology and Business knowledge.
4. Geographically distributed system integration, Compliance requirement challenges to work with HL7 and other Domain area.

Thanking You,

Sincerely

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