



The Leading Global Society for
Healthcare Technology Professionals

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December 17, 2001

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1060
Rockville, MD 20852

**Re: Docket No. 00D-1538, Draft Guidance for Industry; 21 CFR Part 11;
Electronic Records; Electronic Signatures, Validation**

ISPE, the International Society for Pharmaceutical Engineering, welcomes the opportunity to comment on the *Draft Guidance for Industry on Electronic Records; Electronic Signatures, Validation*.

We support FDA's intention to provide guidance on computer system validation. ISPE will not submit a detailed review of the draft guidance, but would like to suggest reference to "GAMP 3" should be updated to reference "GAMP 4". This is the latest edition of the GAMP Guide that was released December 3, 2001.

Sincerely,

Robert P. Best
President/CEO

00D-1538

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