



**JAPAN SOCIETY of PHARMACEUTICAL
MACHINERY and ENGINEERING**

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March 20, 2006

**Dockets Management Branch (HFA-305)
Food and Drug Administration (FDA)
5630 Fishers Lane, rm. 1061
Rockville, MD 20852
U.S.A.**

Re: Docket No. 2005D-0286

Dear Sir/Madam:

We, the Japan Society of Pharmaceutical Machinery and Engineering (JSPME) are pleased to submit you our offers and comments concerning "Draft Guidance for Industry on Investigational New Drugs; Approaches to Complying with Current Good Manufacturing Practice During Phase 1" (Docket No. 2005D-0286). We hope that you will consider our comments, and this guidance will be a very fruitful guidance for supporting the manufacture of investigational new drug.

We would be much obliged if you give us FDA review of our comments by letter or e-mail.

Sincerely,

Katsuhide Terada, Ph.D.

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PS: The letter and comments sheet will be sent you by DHL.