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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of Pharmaceutical Machinery and Engineering (JSPME) are pleased to submit you our offers and comments concerning "Draft Guidance for Industry on Investigational New Drugs; Approaches to Complying with Current Good Manufacturing Practice During Phase 1" (Docket No. 2005D-0286).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

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

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Comments on Guidance for Industry INDs – Approaches to Complying with CGMP During Phase 1(Docket No. 2005D-0286)

The Japan Society of Pharmaceutical Machinery and Engineering (JSPME)

JSPME believes that this draft guidance is very important and useful for developing an investigational drug product used during a Phase 1 study, and much appreciate FDA's effort to develop this guidance document. We offer the following comments on the draft guidance for your consideration.

1. General:

In the stage of Phase 1 development, API is often produced on a small scale as a drug product is so. Therefore, this guidance should be also applied to the API used in the manufacture of an investigational drug product for a Phase 1 study. (Related section: III Scope, line 112 – 117)

2. General:

Five different terms, "investigational new drug", "investigational new product", "investigational product", "final investigational product", "IND product" are used to represent a drug product manufactured for a Phase 1 trial. We recommend that a single term should be used to represent one entity.

3. General:

Three different terms, "Phase 1 clinical trial", "Phase 1 study", "Phase 1 development", are used in the draft guidance. We recommend that a single term should be used to represent one entity.

4. Section III SCOPE (Line 100):

Suggest that this guidance should be applied to a medical device such as a drug-eluting stent.

5. Section III SCOPE (Line 116-117):

Suggest that the sentence "may want to consider the recommendations described in this guidance" should be modified, for example, as "can utilize the recommendations described in this guidance". (Related comment: Comment No.1)

6. Section IV STATUTORY AND REGULATORY REQUIREMENTS (Line 145-147):

The guidance states that "In certain circumstances, the Agency may choose to conduct an inspection". However, the inspection conducted based on this guidance may have a different basis with that an inspection conducted under CGMP has. Therefore, details for operations for this inspection should be described elsewhere in this guidance or any reference documents should be added into "REFERENCE" section.

7. Section V RECOMMENDATIONS FOR COMPLYING WITH THE STATUTE (Line 212):

Suggest adding reference documents regarding to "risk assessment" into "REFERENCES" section.

8. Section V RECOMMENDATIONS FOR COMPLYING WITH THE STATUTE (Line 250):

Suggest deleting the term "periodic" from "the additional, periodic review" because the manufacture of a drug product used in a Phase 1 study is completed in relatively a short-time period and only a few batches are produced.

9. Section V RECOMMENDATIONS FOR COMPLYING WITH THE STATUTE (Line 281-282):

At the timing of accepting components that will be used for an investigational product, any batch number for the investigational product may not be determined yet. Therefore, suggest deleting the term "investigational product batch number" from the sentence.

10. Section V RECOMMENDATIONS FOR COMPLYING WITH THE STATUTE (Line 294-296):

The sentence, "If documentation for a component is incomplete, testing for the incomplete attribute of the component is recommended." may not be clear enough to present the intention of this guidance. Suggest, for example, the following sentence: If characterization of a component attribute is insufficient, testing for the incomplete attribute of the component is recommended.

11. Section V RECOMMENDATIONS FOR COMPLYING WITH THE STATUTE (Line 310-311):

The guidance states that "A record of changes in procedures and processes used for

subsequent batches along with the rationale for any changes". However, specific criteria that determine any data is acceptable as "rationale" are not given in this document. For example, it is not clear whether a validation study is strictly required or not even at the change of the supplier of solvent used in the investigational product. Manufacturing conditions are often changed or improved at the stage of Phase 1 development. Therefore, suggest giving certain criteria or decision points essential in forming "rationale" in this document or adding any reference documents into "REFERENCE" section.

12. Section V RECOMMENDATIONS FOR COMPLYING WITH THE STATUTE (Line 342)

Suggest using the term "date of the last administration" instead of "study termination".

13. Section V RECOMMENDATIONS FOR COMPLYING WITH THE STATUTE (Line 377-380)

Suggest using the term "the drug product" instead of "the drug" in this sentence.