Japan Society of Pharmaceutical Machinery
and Engineering (JSPME)

October 31, 2003

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

Re: Docket No. 03D-0382, CDER 1997112

Dear Sir/Madam:

We, Japan Society of Pharmaceutical Machinery and Engineering (JSPME) are pleased to submit you our offers and comments concerning "Draft Guidance for Industry on Sterile Drug Products Produced by Aseptic Processing" (Docket No. 03D-0382, CDER 1997112). We hope that you will consider our comments, and this guidance will be a very fruitful guidance for PAT. This document prepared by using Microsoft® Word 2002 is also sent to FDA(coryj@cder.fda.gov) by e-mail today.

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

Contacts;
Katsuhide Terada, Ph. D.
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For your references, we, Japan Society of Pharmaceutical Machinery and Engineering (JSPME) are nonprofit industry group which is operated mainly in Japan with approx. 810 members, and we were established Oct. 1990 in order to seek the ideal pharmaceutical production through the research, development and discussion based on both theoretical and practical concept in cooperating with industry, government and academia.

Sincerely,

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Comments

Japan Society of Pharmaceutical Machinery and Engineering

[I] Outline

1. FDA's view of the harmonization with the related guidance in EU or Japan should be addressed in this guidance.
2. The modification from the concept paper released on 27 September, 2002 should be described in this guidance.
3. It will be useful for us to know about FDA's prospect for this guidance.

[II] Comments for each sections

1. More and concrete description about H_2O_2 should be added into "APPENDIX 1: ASEPTIC PROCESSING ISOLATORS".
2. Criteria for assessing state by Mediafill test described in Line 932 -944 are too strict so that less strict criteria are requested.