

➤ **Comment: For the single dose toxicity tabular summaries:**

1. Would it be acceptable to include a detailed description of the study design in the footnotes of the summaries if there is nothing unique or particularly noteworthy about the study design?

2. Instead of summarizing 2 to 3 single-dose or nonpivotal repeat dose studies per page, would it be acceptable to present one study on each page? It seems to us that inclusion of a detailed description of the study design in the footnotes of the summaries would add value to the summaries and contribute to the reviewer's understanding of how the study was conducted, thus contributing to an expedited review of the data. We have prepared NDA tabular summaries for single dose and non-pivotal repeat dose studies in the past using the detailed description of study design in the footnotes and we have also presented one study per page as opposed to summarizing 2-3 studies per page and the applications have been accepted by the Regulatory Agencies.

You can contact us at:

- Name: Norma J. Browder, Ph.D.
- E-Mail: normab@mocr.oapi.com
- Phone: (301) 990-0030; Fax: (301) 721-7205

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OTSUKA AMERICA PHARMACEUTICAL, INC.

2440 Research Boulevard, Rockville, Maryland 20850
Telephone (301) 990-0030 Telefax (301) 990-0036

Fax Cover Page

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TO:

FROM:

Ms. Jeannie Butler
US Food and drug administration
Ref.: Comments on ICH Nonclinical Common Technical Document
301-827-6870

Dr. Oluwadare Martins Adeyemo
Asst. Director, Preclinical Drug Safety Evaluation
Tel: (301) 990-0030 Fax: (301) 721-7012
Adeyemo, Martins

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Subject

Comments: Nonclinical Section of the ICH Common Technical Document