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Dockets Management Branch (HFA-305)

Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Ref: **Docket No. 01D-0361 - "International Conference on Harmonization : Draft Guidance on ICH Q1D Bracketing and Matrixing Designs for Stability Testing of Drug Substances and Drug Products"**

To Whom it may Concern:

Abbott Laboratories is very pleased to have the opportunity to provide comments on the "International Conference on Harmonization : Draft Guidance on ICH Q1D Bracketing and Matrixing Designs for Stability Testing of Drug Substances and Drug Products" published on September 25, 2001 in the *Federal Register*.

We thank the Food and Drug Administration for your consideration of our comments. Should you have any questions, please contact Ivone Takenaka, PhD. at 847-935-9011 or by FAX at 847-938-3106.

Sincerely,


Douglas L. Sporn

01D-0361

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**COMMENTS ON
ICH Q1D Bracketing and Matrixing Designs for
Stability Testing of Drug Substances and Drug Products –
Draft Guidance**

Docket No. 01D-0361

Abbott commends the Agency and the International Conference of Harmonization committees on the efforts to provide industry guidelines for stability testing of drug substances and drug products.

The following are Abbott's comments on this draft guidance.

Section 2.4.4 – Lines 255 - 258.

In regards to the applicability of a matrix design, the draft guidance states:

- “In general, a matrix design is applicable if the supporting data indicate very small variability and excellent product stability. Where the supporting data exhibit moderate variability and moderate stability,... supportive data show large variability and poor product stability.”

Abbott believes the terms “small”, “moderate” and “large” variability should be clearly defined to include a set of criteria for each category.

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