



ABBOTT LABORATORIES

Corporate Regulatory and Quality Science

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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Ref: Docket No. 02D-0231, CDER 200239. International Conference on Harmonization; Stability Data Package for Registration in Climatic Zones III and IV.

Abbott Laboratories is very pleased to have the opportunity to provide comments on the "Stability Data Package For Registration in Climatic Zones III and IV" ICH draft guidance, published in the Federal Register on June 14, 2002.

We commend the Agency on the international harmonization efforts and for providing guidance to industry on Stability Data Package requirements. We appreciate the ICH Q1F guidance, however, its future implementation raises some concerns.

We would like the Agency to clarify whether stability studies currently being performed at temperature and humidity conditions of 30°C/60%RH or 30°C/70%RH will support the requirements for conditions for Zones IV for new applications. In addition, we recommend that the guideline clearly states that stability conditions for existing products need not to be changed and can continue as committed to. The guideline should, also, state that the new conditions should only be applicable to new registrations or to significant changes in product formulations that will require new stability study commitments.

Taking into consideration our recommendations above, we strongly recommend that the parent guideline (Q1Ar) for the intermediate storage condition for Zones I&II be harmonized with the Zone III&IV conditions as stated in the ICH Q1F, but that this guideline be applicable to only new future applications, and a new guideline be developed for marketed or existing products.

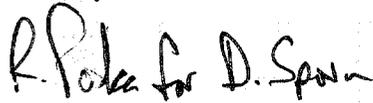
02D-0231

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Docket No. 02D-0231

We thank the Agency for their 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 Sporn,
Divisional Vice President
Corporate Regulatory Affairs

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