

PHARMACIA

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August 2, 2002

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

**Re: Docket No. 02D-0231; ICH Draft Guidance on Stability
Data Package for Registration in Climatic Zones III and IV**

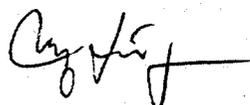
Dear Sir/Madam,

Thank you for this opportunity to review the draft guidance on the *Stability Data Package for Registration in Climatic Zones III and IV*. We would like to offer the following comments.

1. We welcome and support the change to 30°C/65%RH to represent both the intermediate condition for zones I and II and the long-term storage condition for zones III and IV.
2. There is no guidance for the transition of ongoing studies stored at either 30°/60%RH or 30°/70%RH to the new conditions. We recommend that the guideline address acceptable approaches to the transition. We propose that an acceptable transition approach would be to move all 30°/60%RH and 30°/70%RH studies to the 30°/65%RH condition. Studies that started at 30°/60%RH would be reported as such with a footnote to describe when the change occurred (essentially they would finish the study under worst case conditions). Studies that started at 30°/70%RH would be reported as 30°/65%RH with a footnote to describe when the change to 30°/65%RH occurred.
3. We appreciate this initiative to harmonize storage conditions with WHO. That being said, we note with concern that during April 2002 Brazil issued a guidance enforcing a long-term condition of 30°C/70%RH. The latter reflects the Resolution on Medication Stability as harmonized for the MERCOSUR countries. MERCOSUR, and other regions, need to endorse this change to make it truly useful.

Should any clarification of our input be required, please don't hesitate to contact Jenny Peters either by phone (269)-833-8141 or by email (jenny.l.peters@pharmacia.com). Sincerely,

Pharmacia Corporation


Ulf Hillgren PhD
Pharmaceutical Expert
Global Pharmaceutical Sciences


Jenny Peters RPh
Director
Global Regulatory Affairs

02D-0231

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109084292

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TO

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