



Purdue Pharma L.P.

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August 16, 2002

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

Reference: Docket No. 02D-0231: *International Conference on Harmonisation: Stability Data Package for Registration in Climatic Zones III and IV*

Dear Sir or Madam:

On behalf of Purdue Pharma L. P., we have reviewed International Conference on Harmonisation: Draft Guidance on Q1F: *Stability Data Package for Registration in Climatic Zones III and IV*, and appreciate the opportunity to provide the attached comments.

Sincerely,
Suzett L. Perry

Sr. Regulatory CMC Associate
Regulatory Affairs

02D-0231

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Purdue Pharma L.P. Comments

1	Will the implementation of this guidance affect registered/pending products, or will it apply only to the registration of new products? Example: If a product is pending approval in climatic zones III and IV, and has a sufficient amount of stability data at 30 °C/60 % RH, will the existing data still support the registration with a reduction of expiry?
2	Replacing the current 30 °C/60% RH with the proposed 30 °C/65% RH seems like a logical approach; however, in some instances, a 5% increase in humidity might negatively impact the stability of the drug. The only recourse, according to the guidance, is to reduce the retest period or expiry. If the product is not intended for Zones III or IV, the proposed back-up condition may not offer enough flexibility.
3	There is no back-up condition for Zones III and IV, which means in many cases we will have a shorter expiry, or, as the guidance suggests, have to introduce more protective packaging.
4	Will these guidelines be globally accepted? For example, health authorities in Australia and Hong Kong require stability data at 30 °C/75% RH.
5	Please refer to comments submitted by PhRMA (Pharmaceutical Research and Manufacturers of America) to the FDA on July 30, 2002. We also agree with their following suggestion: "Delete the third paragraph in this section (2.3) and replace with the following: 'Where special transportation and storage conditions are identified that are outside the storage conditions specified in this guidance, additional study data supporting such conditions may need to be made available.'"

From: JUDITH B. SANTOS (203)588-8045
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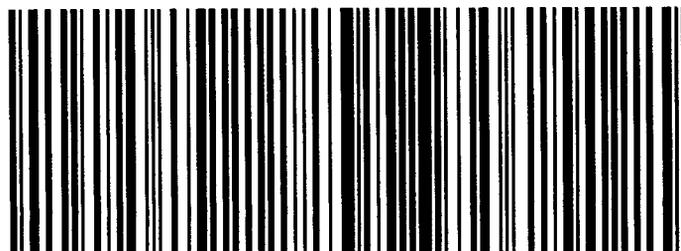
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