

Alice E. Till, Ph.D.
VICE PRESIDENT
SCIENCE POLICY AND TECHNICAL AFFAIRS



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July 30, 2002

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

Re: International Conference on Harmonisation; Stability Data Package for Registration in Climatic Zones III and IV [Docket No. 02D-0231, 67 *Federal Register*, 40951, June 14, 2002]

Dear Sir/Madam:

The Pharmaceutical Research and Manufacturers of America (PhRMA) represents the country's leading research-based pharmaceutical and biotechnology companies, which are devoted to inventing medicines that allow patients to lead longer, happier and more productive lives. Investing more than \$30 billion in 2001 in discovering and developing new medicines, PhRMA companies are leading the way in the search for cures.

PhRMA, therefore, appreciates the opportunity to provide the attached comments on the Stability Data Package for Registration in Climatic Zones III and IV.

We hope that you will give careful consideration to the attached comments as you work to finalize the guidance. Please contact me if there are any questions.

Sincerely,

Alice E. Till, Ph.D.

CC Chi-wan Chen

Att.

02D-0231

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Pharmaceutical Research and Manufacturers of America

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PhRMA Stability Expert Team Comments on Q1F Step 3 02Feb2002

General Comments:

**An implementation phase-in period of one-year is recommended. This will allow companies to move to 30C/65% RH.
The document needs to clearly state throughout the guidance that this is for registration of new drug substance and products.**

Section	Paragraph #	Sentence #	Comments
2.3	3		Delete the third paragraph in this section 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."

RMA



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