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

PhRMA

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June 10, 2003

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

RE: Draft Guidance for Industry on Drug Product: Chemistry, Manufacturing, and Controls Information [Docket No. 02D-0526]; **Request for Extension of the Comment Period**

Dear Sir/Madam:

The Pharmaceutical Research and Manufacturers of America (PhRMA) requests an extension of the comment period for written comments on the draft Guidance for Industry, Drug Product: Chemistry, Manufacturing, and Controls Information. This guidance is very important to our member companies and our technical experts have been working diligently to provide comprehensive and meaningful comments to the agency to facilitate finalization of the guidance. However, because of the size and scope of the draft guidance and the number of comments being generated, we have found that the allotted time for comment is insufficient to enable us to provide the FDA a well-coordinated compilation of comments that truly reflects the views of the PhRMA membership.

It is not to the advantage of either the FDA or the industry to submit anything less than thoroughly thought out and broadly representative comments on such a critical document. To this end, PhRMA requests a 90-day extension of the comment period for the draft drug product guidance so that we can provide the best possible response to FDA on its content.

Thank you for your consideration of this request. I look forward to hearing from you soon.

Sincerely,

Alice E. Till

Alice E. Till, Ph.D.

Cc: Dr. Upinder Atwal, Dr. Nancy Sager

02D-0526 EXT 1

Pharmaceutical Research and Manufacturers of America

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