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

PhRMA

July 30, 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Re: Draft Guidance For Industry on Drug Product: Chemistry, Manufacturing, and Controls Information [Docket No. 02D-0526, 68 *Federal Register*, 4219, January 28, 2003]

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 and more productive lives. Investing more than $30 billion annually in discovering and developing new medicines, PhRMA companies are leading the way in the search for cures.

We welcome the opportunity to comment on the draft guidance on chemistry, manufacturing, and controls (CMC) information for drug products.

We appreciate FDA's efforts to provide draft guidances that are easy to understand and comment on. This lengthy guidance was, in general, clearly written and the inclusion of line numbers facilitated providing easily identified point of reference comments.

This guidance suggests useful recommendations for providing the FDA information to support applications for new drug products. However, we conclude that its usefulness can be enhanced through the suggestions and revisions detailed in the attachment.

These comments represent the collective view of the membership of PhRMA. We believe the following general observations emphasize major points where the usefulness of the guidance may be enhanced:

1. **The concepts of critical steps, critical in process controls and critical tests need clearer definition.**

   Because of the varied use and interpretation of the term "critical" throughout the industry, PhRMA recommends that the FDA solicit industry input and general agreement on the appropriate application of this term through a public workshop before including it in a guidance document.

2. **To demonstrate support of the ICH process, the guidance should be expanded to recognize materials that have compendial designations from non-USA ICH participants.**

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PhRMA recognizes that the Federal Food, Drug and Cosmetic Act only recognizes the USP/NF as official compendia. However, provisions should be made to minimize extra testing that is required in this draft guidance when using excipients that hold ICH participant compendia designation. This will help move our industry towards global consistency and the spirit of harmonization.

3. **Make allowances to accept vendor Certificates of Analysis (COA) for compendial excipients.**

   Because it is not always known at the time of submission which tests a sponsor will accept on COA, PhRMA does not see the value added by identifying the tests that the drug product manufacturer will routinely perform and the test results that will be accepted from the excipient manufacturer's COA.

Additional specific and detailed comments are provided in the attachment. We trust that you will give careful consideration to our attached comments as you finalize the guidance. Please contact me if you need further assistance or have any questions regarding these comments.

Sincerely,

Alice E. Till

Alice E. Till, Ph.D.

CC: N. Sager (FDA)

Attachment