



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

July 18, 2003

PhRMA
Attn: Dr. Alice Till
1100 Fifteenth St. NW
Washington DC 20005

Dear Dr. Till:

This is in response to your letter to Docket # 02D-0526 requesting an extension of the comment period for the draft guidance for industry *Drug Product: Chemistry, Manufacturing, and Controls Information*. FDA declines to grant your request for an extension of the comment period. We agree the guidance is of great importance, broad scope, and slightly longer than the typical chemistry guidance. We considered this when deciding to allow a 6-month comment period for the drug product guidance instead of our typical 3 or 4-month comment period for chemistry guidances. Comments can be submitted on guidance documents at any time. We will consider all comments on this guidance that are submitted in a timely fashion, even if it is after the closing of the official comment period. We encourage you to submit your comments as soon as possible.

If you have any questions relating to this letter you can contact me at 301-594-5633.

Sincerely yours,

A handwritten signature in cursive script, reading "Nancy B. Sager".

Nancy B. Sager
Associate Director
Office of Pharmaceutical Science
Center for Drug Evaluation and Research

c.c.
Public Docket # 02D-0526
Dr. Upinder Atwal