



Date: MAY 24 2007

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: Docket Number 2007D-0089
Response to FDA Call for Comments
Draft Guidance for Industry and Review Staff on Target Product Profile—A Strategic
Development Process Tool

Dear Sir or Madam:

Reference is made to the March 30, 2007, Federal Register notice announcing the request for comments on Draft Guidance for Industry and Review Staff on Target Product Profile—A Strategic Development Process Tool.

AstraZeneca has reviewed this draft guidance and our comments are attached.

Please direct any questions or requests for additional information to me or, in my absence, to Robert Orzolek, Senior Director, at 302-886-4550.

Sincerely,

A handwritten signature in black ink, appearing to read 'Cathie Schumaker'.

Cathie Schumaker, Executive Director
FDA Liaison Office
Regulatory Affairs
Telephone: 301-770-4479
Fax: 301-770-8714

CS
Enclosure



General Comments

- Overall, this is a clear and useful guidance, with obvious advantages to the approach proposed. This tool has the potential to better focus pharmacological development, resulting in faster decisions, higher quality work and lower costs of development.
- Given the resource constraints that impact formal meetings, it would be useful to discuss, in more detail, alternative mechanisms by which information may be exchanged to fully develop TPP documents and maximize their benefits.

Draft Guidance for Industry and Review Staff on Target Product Profile—A Strategic Development Process Tool		
Section	Page/ Line Number	Comment or proposed replacement text
		It is possible that during early development, a discussion may be held to discuss several related compounds. Would each of these require a separate TPP or would a generic be acceptable? Please provide a discussion in the guidance.
III.C.	3/92-93	<p>This section talks about “eliminating the need for a sponsor’s introduction to the history of the drug development program.” It seems unlikely that the need for a summary will be completely eliminated, but the TPP will certainly assist with streamlining the discussion of the history.</p> <p>Suggested wording: A well-organized TPP can save meeting time for discussion of issues by eliminating the need for a detailed summary of all prior agreements. The TPP provides a format for presenting the specific issues and agreements in a structured manner which will allow the sponsor’s introduction to be a short, simple overview of the meetings and correspondence to date.”</p>
III.C.	3/108	Please provide a discussion as to why having the TPP as part of the proprietary IND file is considered an advantage of a TPP.
III.C.	3/116 & 4/136	Although the TPP template provides a summary of drug labeling concepts, using the terminology “TPP summary” may be confusing and prompt some sponsors to provide a summary of the TPP. We recommend that the word “summary” be removed and reference only made to the TPP which is done throughout most of the document.
IV.A.	6/227 & 229	Replace the word “template” with TPP for consistency.
Appendix B		The guidance discusses the use of TPP to aid in constructive dialogue for promotional claims and/or presentations for use in product promotional materials. An example specific to promotional claims and/or presentations for use in promotional materials would be extremely helpful.