

May 25, 2007

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

**Re: Docket No. 2007D-0089 Draft Guidance for Industry and Review Staff on
Target Product Profile - A Strategic Development Process Tool**

Dear Sir or Madam,

On behalf of Johnson & Johnson Family of Companies, I am writing to comment on the Food and Drug Administration's (FDA) DRAFT Guidance for Industry and Review Staff, *Target Product Profile - A Strategic Development Process Tool*.

Johnson & Johnson is the world's most comprehensive and broadly based manufacturer of health care products, as well as a provider of related services, for the consumer, pharmaceutical and medical devices and diagnostics markets. Johnson & Johnson has more than 200 operating companies in 54 countries around the world employing approximately 110,600 employees and selling products in more than 175 countries. The fundamental objective of Johnson & Johnson is to provide scientifically sound, high quality products and services to help heal, cure disease and improve the quality of life.

Johnson & Johnson supports the use of a Target Product Profile (TPP) to facilitate communication between FDA review staff and the sponsor during drug development. Johnson & Johnson welcomes the DRAFT Guidance for Industry and Review Staff, *Target Product Profile - A Strategic Development Process Tool* and appreciates the opportunity to comment on this draft guidance. We have provided both general and specific comments below.

General Comments

Johnson & Johnson supports the draft guidance and believes it meets its aim of informing sponsors and FDA review staff of the availability and potential usefulness of a TPP. The concept, key elements and potential usefulness of a TPP are clearly explained in the guidance document.

Specific Comments

Line 168 A. Labeling Concepts

We suggest allowing for the inclusion of a *Highlights* section, especially in the later stage of label development when draft wording for the Full Prescribing Information is available.

Line 234 Proposed Promotional Claims

The guidance indicates that there is an opportunity for proposed promotional claims to be included in the TPP. Presumably, this would be reviewed by CDER Division of Drug Marketing, Advertising and Communication (DDMAC) staff at the FDA. The guidance document should outline the process by which DDMAC review should be requested by the sponsor.

Line 444 6 Adverse Reactions

We suggest including the selection criteria that are used to determine Adverse Drug Reactions (ADRs).

Proposed wording under *Annotations*:

“Summary information regarding completed or planned studies to support the target: protocol #, serial #, submission date, selection criteria that are used to determine the ADRs.”

Line 540 14 Clinical Studies

We suggest including the efficacy parameters intended to be described in the label.

Proposed wording under *Target*:

“Provide a description of studies that support the statements about efficacy or safety benefits. Consider including a description of supporting tables or graphs. Consider including the efficacy parameters intended to be described in the label.”

In summary, Johnson & Johnson supports the use of a TPP to facilitate communication between FDA review staff and the sponsor during drug development and believes the concept, key elements and potential usefulness of a TPP are clearly explained in the draft guidance document.

Sincerely,



Bruce Boselli MD,
Vice President, Global Labeling,
Johnson & Johnson Pharmaceutical Research & Development.