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

**Re: Docket No. 2004D-0041
Draft Guidance for Industry on Providing
Regulatory Submissions in Electronic Format –
Content of Labeling**

Dear Sir or Madam:

Reference is made to the Draft Guidance for Industry on Providing Regulatory Submissions in Electronic Format – Content of Labeling. Procter & Gamble Pharmaceuticals appreciates the opportunity to respond to the Agency's request for comments on this important guidance.

Assuming that an HL 7 standard recommendation and final FDA guidance for implementing Structured Product Labeling in Extensible Markup Language (XML) become available in the next several months, the ability of the healthcare industry to properly implement these changes by the end of 2004 is doubtful. We believe that the process may take as much as a year. This projection incorporates appropriate timing for interactions with vendors to evaluate software, internal test version trials, harmonization with existing submission tools, validation testing, training, and conversion of existing label files. It should also be pointed out that there will likely be a limited number of vendors capable of providing these services for literally hundreds of companies.

Therefore, we recommend that the goal of the guidance (II. Background, B. New Technology for Processing Labeling and Labeling Changes, page 3, Lines 103-104) be revised to reflect a 12 month transition period from issuance rather than a specific calendar date.

If you have any questions or need additional information about this submission, please do not hesitate to contact me.

Sincerely,

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