



Office of
General Counsel

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August 6, 2004

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

FDA Docket No. 2004N-0181, OC 2004106. Critical Path Initiative

Dear Sir or Madam:

As a leader in the discovery, development, manufacture and marketing of medical products, the Johnson & Johnson family of companies is committed to improving health and well being through innovative products and services. We share the Agency's goal of bringing safer and more effective medical products to the market as rapidly as possible. We agree that improvements in the applied sciences needed for medical product development have not kept pace with advances in the basic sciences. A new product development toolkit is urgently needed to improve predictability and efficiency along the Critical Path. We appreciate the Agency's efforts to take the lead on this initiative, and are pleased to have the opportunity to comment on the FDA's report of March 16, 2004, entitled **Innovation/Stagnation-- Challenge and Opportunity on the Critical Path to New Medical Products.**

The following comments are submitted on behalf of the Johnson & Johnson family of companies.

We agree that the current medical product development processes are inefficient and could benefit from new predictive tools. We also believe similar efforts to revolutionize the product development requirements and approval processes made by Health Authorities are required. This critical alignment between improving the product "development" process and the product "approval" process should be addressed in this initiative. However, additional incentive, support and empowerment are needed from the Agency to accredit the use of new predictive tools in product development and approval. We support advances in science, tools, and methodology. However, as the advances are identified, the Agency needs to then perform an equally thorough

evaluation of those current requirements, identify those that no longer add value, and eliminate them.

The research and development collaborations to validate the new tools, and then to generate the standards for their use will be challenging. Industry, health authorities, and the scientific community at large must work together to reset product approval standards.

Lastly, global initiatives such as the International Conference on Harmonisation and the Global Harmonisation Task Force have been successful. As progress is made with this Critical Path Initiative, it will be important that the FDA be mindful of ideas worldwide and adopt new ways to harmonize in the future. The outcomes of this effort could require changes to current guidelines.

In closing, we appreciate the opportunity to comment on the FDA report on **Innovation/Stagnation**. We agree that FDA is uniquely positioned to help identify the challenges to development, and we look forward to working with the Agency and scientific community at large to develop solutions. This submission to the FDA docket includes our initial comments on this initiative, and we look forward to communicating additional ideas to the Agency in the future.

Sincerely,

Kathy J. Schroeher
Associate General Counsel

Attachment (1)