

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N-0181]

Critical Path Initiative; Establishment of Docket

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is establishing a public docket to obtain input on activities that could reduce existing hurdles in medical product design and development. As described in a recently released Report, “Innovation/Stagnation: Challenge and Opportunity on the Critical Path to New Medical Products,” there is an urgent need to modernize the product development toolkit, to make the development process more predictable and less costly. FDA is seeking input in identifying and prioritizing the most pressing medical product development problems, and the areas that provide the greatest opportunities for rapid improvement and public health benefits. To this end, we are establishing this open docket to obtain input from industry, patients, academics investors, and all interested parties.

DATES: Submit written or electronic comments through July 30, 2004.

ADDRESSES: Submit written comments concerning this document to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

FOR FURTHER INFORMATION CONTACT: Lisa Rovin, Office of the Commissioner (HFP-1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857-0001, 301-827-1443.

SUPPLEMENTARY INFORMATION:

I. Background

On March 16, 2004, FDA released a report, “Innovation/Stagnation: Challenge and Opportunity on the Critical Path to New Medical Products.” (The full report is available at <http://www.fda.gov/oc/initiatives/criticalpath/whitepaper.pdf>.) The report notes the recent slowdown in new medical products submitted for approval to FDA, and describes ways in which the product development process, the “critical path,” could be modernized to make product development more predictable and less costly. According to Acting FDA Commissioner Lester Crawford, “A new focus on updating the tools currently used to assess the safety and efficacy of new medical products will very likely bring tremendous public health benefits.”

Recent investments in basic medical research and translational research are intended to promote scientific discoveries and move some of them into medical testing. At that point, however, a potential medical product’s journey from concept to commercialization is far from complete. To produce a commercial medical product, developers must successfully negotiate a “critical path” to ascertain whether the potential drug, device, or biologic is effective and sufficiently safe for use, and how it can be safely and reliably manufactured. Each of the three dimensions of the critical path—assessment of safety testing, proof of efficacy, and industrialization—presents its own set of scientific and technologic challenges, often unrelated to the science behind the mechanism of action of the product.

- The ethics of human testing required that there be a reasonable assurance of safety before people are exposed in clinical trials. The tools used to predict preclinical safety (e.g., animal toxicology) are time consuming and cumbersome. In some cases, particularly for assessment of products based on recent innovative science, entirely new tools must be developed. There is an urgent need for new biomarkers for evaluating safety during human trials.

- Demonstrating the medical effectiveness of a product is one of the most difficult challenges in product development. Even identifying the best way to assess whether a product is effective (what symptoms or physiologic indicators should be followed, and for how long) can present significant unknowns.

- Product development companies must figure out how to manufacture large amounts of the product reliably. Turning a laboratory prototype into a mass-produced medical product requires solutions to problems in physical design, characterization, manufacturing scaleup and quality control. These problems can be rate-limiting for new technologies, which are frequently more complex than traditional products.

Because of its unique vantage point, FDA can work with outside experts in companies and the academic community to coordinate, develop, and/or disseminate solutions to critical path problems, to improve the efficiency of product development industrywide.

The first step is to identify and prioritize the most pressing medical product development problems, and the areas that provide the greatest opportunities for rapid improvement and public health benefits. It is critical that we enlist all relevant stakeholders in this effort. Such a national “Critical Path Opportunities List” is intended to bring concrete focus to tasks (whether

best undertaken by industry, academia, FDA, by others, or jointly) that can modernize the critical path.

For additional information, you may visit FDA's critical path home page at www.fda.gov/oc/initiatives/criticalpath.

II. Request for Comments

We are seeking input on identification of the most pressing scientific and/or technical hurdles causing major delays and other problems in the drug, device, and/or biologic development process, as well as proposed approaches to their solution. For each critical path hurdle, we are particularly interested in receiving the following information. Please note that all material submitted to this docket will be publicly available.

1. Hurdle Identification. Please describe the product development issue, the nature of the evaluation tool that is out-of-date or absent, how this problem hinders product development, and how a solution would improve the product development process. Please be as specific as possible.

2. Please rank each hurdle identified in Question 1, above, in priority order according to which hurdles create the most severe product development problems. That is, which problems present the greatest opportunity for improving product development processes? Our goal is to identify those aspects of product development that would most benefit from new evaluation tools.

3. For each problem identified, please indicate the type of drug, biologic, or device to which the hurdle applies.

4. For each problem identified, if a solution would facilitate the development of drugs, biologics, and/or devices for a particular disease or categories of disease, please indicate which diseases would be affected?

5. Nature of the Solution. For each problem identified, please describe the evaluation tool that would solve the problem and the work necessary to create and implement the tool/solution. For example, would a solution come from scientific research to develop a new assay or validate a new endpoint? If the solution involves biomedical research, please specify the necessary research project or program. Would a tool be developed through data mining or computer modeling? Would the right tool be a new FDA guidance or industry standard? If work on a solution is underway, what steps remain? Are there other innovative solutions that could be explored?

6. For each solution identified, please indicate which could be accomplished quickly, in less than 24 months, and which require a long-term approach?

7. For each problem identified, what role should FDA play and what role should be played by others? Should FDA play a convening role, bringing the relevant parties together to discuss an approach or solution? If so, who else should participate? Should FDA coordinate scientific research, the results of which would be publicly available? We are seeking input on ways to target FDA scientific and collaborative activities to help industry bring more safe and effective medical products to us for review.

8. What factors should guide FDA in setting priorities among the hurdles and solutions identified?

III. Submission of Comments

Interested persons may submit written or electronic comments to the Division of Dockets Management (see **ADDRESSES**). Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one copy. Comments are to be identified with the

docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday. You can also view received comments on the Internet at <http://www.fda.gov/ohrms/dockets/dockets/dockets.htm>.

Dated: April 16, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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