in patients 12 years of age and over. On May 7, 2004, from 11 a.m. to 12 noon, each separate committee meeting will be open to the public, unless public participation does not last that long. From 12 noon to 3:30 p.m., each separate committee meeting will be closed to permit discussion and review of trade secret and/or confidential information.

Procedure: Interested persons may present data, information or views orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by April 23, 2004. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. on May 6, 2004. On May 7, 2004, oral presentations from the public will be scheduled for each separate committee between approximately 11 a.m. and 12 noon. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before April 23, 2004, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentations.

Closed Committee Deliberations: On May 7, 2004, from 12 noon to 3:30 p.m., the committee meetings will be closed to permit discussion and review of trade secret and/or confidential information (5 U.S.C. 552b (c)(4)).

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: April 15, 2004.

William K. Hubbard,

Associate Commissioner for Policy and Planning.

[FR Doc. 04–9070 Filed 4–21–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004–N–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.

[FR Doc. 04–9147 Filed 4–21–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Proposed Information Collection: Request for Public Comment: 30-Day Notice

AGENCY: Indian Health Service, HHS.

ACTION: Request for public comment: 30-day proposed collection; Hoz'ho'nii: An Intervention to Increase Breast and Cervical Cancer Screening Among Navajo Women.

SUMMARY: In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed information collection projects, the Indian Health Service (IHS) has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. This proposed information collection project was previously published in the **Federal Register** (66 FR 66912) on February 9, 2004 and allowed 60 days for public comment. No public comment was received in response to the notice. The purpose of this notice is to allow 30 days for public comment to be submitted directly to OMB.

Proposed Collection

Title: Hoz'ho'nii: An Intervention to Increase Breast and Cervical Cancer Screening Among Navajo Women.

Type of Information Collection Request: Previously Approved Collection.

Form Number: None.

Need and Use of the Information Collection: The information is needed to evaluate a culturally appropriate educational outreach program designed to increase breast and cervical cancer screening among Navajo women ages 20 and older. The purpose is to identify barriers that may prevent Navajo women from participating in breast and cervical cancer screening by comparing changes in knowledge, attitudes, and behaviors of three study groups; educational outreach only, education outreach plus chapter-based clinic, and a control group. Results will be used to assess the impact of the educational outreach program, improve breast and cervical cancer screening, and to guide the IHS and Tribal health programs in the delivery of culturally appropriate intervention to reduce mortality rates from breast and cervical cancer among Navajo women.

Affected Public: Individuals.

Type of Respondents: Individuals.

Table below provides the estimated burden response for this information collection:

ESTIMATED BURDEN RESPONSE TABLE

Data collection instrument	Estimated No. of respondents	Responses per respondent	Average burden hour per response*	Total annual burden hours
KAB Pretest	450	1	0.42 hr (25 minutes)	188.0
KAB Post test	450	1	0.42 hr (25 minutes)	188.0
Interviews	30	1	0.25 hr (15 minutes)	8.0