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 Please describe the product development issue, the nature of the evaluation tool that is out-of-date or absent, how this problem hinders product development, and how a solution would improve the product development process.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

ESTIMATED BURDEN RESPONSE TABLE—Continued

Data collection instrument	Estimated No. of respondents	Responses per respondent	Average burden hour per response*	Total annual burden hours
Total	930	1		384.0

* For ease of understanding, burden hours are also provided in actual minutes.

There are no Capital Costs, Operating Costs and/or Maintenance Costs to report for this information collection.

Request for Comments: Your written comments and/or suggestions are invited on one or more of the following points: (a) Whether the information collection activity is necessary to carry out an agency function; (b) whether the IHS processes the information collected in a useful and timely fashion; (c) the accuracy of the public burden estimate (the estimated amount of time needed for individual respondents to provide the requested information); (d) whether methodology and assumptions used to determine the estimate are logical; (e) ways to enhance the quality, utility, and clarity of the information being collected; and (f) ways to minimize the public burden through the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Direct Comments to OMB: Send your written comments and suggestions regarding the proposed information collection contained in this notice, especially regarding the estimated public burden and associated response time, to: Office of Management and Budget, Office of Regulatory Affairs, New Executive Office Building, Room 10235, Washington, DC 20503, Attention: Desk Officer for IHS.

To request more information on the proposed collection or to obtain a copy of the data collection plan(s) and/or instruction(s), contact: Ms. Christina Ingersoll, IHS Reports Clearance Officer, 12300 Twinbrook Parkway, Suite 450, Rockville, MD 20852.1601, or call non-toll free (301) 443–5938, or send via facsimile to (301) 443–2613, or send your E-mail requests, comments, and return address to: *cingerso@hqe.ihs.gov.*

Comment Due Date: Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

Dated: April 2, 2004.

Eugenia Tyner-Dawson,

Acting Deputy Director, Indian Health Service.

[FR Doc. 04–9155 Filed 4–21–04; 8:45 am]

BILLING CODE 4160–16–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer on (301) 443–7978.

Comments are invited on: (a) Whether the proposed collections of information are necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Participant Feedback on Training Under the Cooperative Agreement for Mental Health Care Provider Education in HIV/AIDS Program IV

(OMB No. 0930–0195; Extension, no change)—The Substance Abuse and Mental Health Services Administration's (SAMHSA) Center for Mental Health Services (CMHS) intends to continue to conduct a multi-site assessment for the Mental Health Care Provider Education in HIV/AIDS Program IV. The education programs funded under this cooperative agreement are designed to disseminate knowledge of the psychological and neuropsychiatric sequelae of HIV/AIDS to both traditional (*e.g.,* psychiatrists, psychologists, nurses, primary care physicians, medical students, and social workers) and non-traditional (*e.g.*, clergy, and alternative health care workers) first-line providers of mental health services, in particular to providers in minority communities.

The multi-site assessment is designed to assess the effectiveness of particular training curricula, document the integrity of training delivery formats, and assess the effectiveness of the various training delivery formats. Analyses will assist CMHS in documenting the numbers and types of traditional and non-traditional mental health providers accessing training; the content, nature and types of training participants receive; and the extent to which trainees experience knowledge, skill and attitude gains/changes as a result of training attendance. The multi-site data collection design uses a two-tiered data collection and analytic strategy to collect information on (1) the organization and delivery of training, and (2) the impact of training on participants' knowledge, skills and abilities.

Information about the organization and delivery of training will be collected from trainers and staff who are funded by these cooperative agreements/contracts, hence there is no respondent burden. All training participants will be asked to complete a brief feedback form at the end of the training session. CMHS anticipates funding 10 education sites for the Mental Health Care Provider Education in HIV/AIDS Program. The annual burden estimates for this activity are shown below: