With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Assessment of the Effects of Antimicrobial Drug Residues from Food of Animal Origin on the Human Intestinal Flora

Description: Sponsors of new animal drugs must meet certain statutory requirements for new animal drug approval under section 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b). Among other things, the sponsor must demonstrate that the use of the drug is safe. Thus, when CVM reviews new animal drug applications for drugs that will be used in food-producing animals, it must determine whether residues of the drug that may remain in human food derived from those animals would be harmful to humans. One possible harmful effect of residues of antimicrobial drugs that CVM considers in this determination is the possible effect of residues on human intestinal flora.

This draft guidance document describes the recommended pathway approach for assessing such effects. An assessment of the safety of antimicrobial drug residues in food is a major issue that should be addressed by the sponsor of a new animal drug. For residues determined to have no antimicrobial activity against representatives of the human intestinal flora, an ADI should be calculated based on traditional toxicology studies. The burden hours required are reported and approved under OMB Control No. 0910–0032. However, the draft guidance recommends that additional information be provided for certain drugs. This additional information should be provided if an assessment of microbiological safety determines that a new animal drug produces residues in foods that are microbiologically active in the human colon. The likely respondents to this collection of information are sponsors of antimicrobial new animal drugs that will be used in food-producing animals.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Guidance	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Assessments (including studies) of safety of antimicrobial drug residues that are microbiologically active in the human colon	5	1	5	14,110	70,550

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The estimates in table 1 of this document resulted from discussions with sponsors of new animal drugs. The estimated burden includes studies, analysis of data, and writing the assessment. The number of respondents provided is based on current experience, however, the number may change in the future.

III. Comments

This draft guidance document is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Dockets Management Branch (address above) written or electronic comments regarding this draft guidance document. Submit written or electronic comments by March 27, 2002 to ensure adequate consideration by the VICH Microbial Safety Task Force and in the development of the final guidance. Two copies of any comments are to be submitted, 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. A copy of the draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Submit written comments concerning the information collection requirements to the Dockets Management Branch by March 27, 2002. A copy of the document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

Electronic comments may be submitted electronically on the Internet at http://www.fda.gov/dockets/ecomments. Once on this Internet site, select [Insert Docket Number for this publication] ''Assessment of the Effects of Antimicrobial Drug Residues from Food of Animal Origin on the Human Intestinal Flora'' and follow the directions. Copies of the draft guidance entitled ''Assessment of the Effects of Antimicrobial Drug Residues from Food of Animal Origin on the Human Intestinal Flora'' may be obtained on the Internet from the CVM home page at http://www.fda.gov/cvm.

Dated: December 18, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–31713 Filed 12–26–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Proposed Collection; Comment Request

AGENCY: Indian Health Service, HHS.

ACTION: Request for public comment: 60-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, to provide a 60-day advance opportunity for public comment on proposed information collection projects, the Indian Health Service (IHS) is publishing for comments a summary of a proposed information collection to be submitted to the Office of Management and Budget (OMB) for review.

Proposed Collection: Title: Hoz'ho'nii: An Intervention to Increase Breast and Cervical Cancer Screening Among Navajo Women. Type of Information Collection Request: New. Form Number: None. Need and Use of the Information Collection: The information is needed to evaluate a culturally appropriate education 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 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.

The table below provides the estimated burden response for this information collection:

ESTIMATED BURDEN RESPONSE TABLE

Data collection instrument	Estimated number of respondents	Responses per respondent	Average burden hour per response*	Total annual burden hrs
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
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: (1) Whether the information collection activity is necessary to carry out an agency function; (b) whether the agency processes the information collected in a useful and timely fashion; (c) the accuracy of public burden estimate (the estimated amount of time needed for individual respondents to provide the requested information); (d) whether the 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.

Send Comments and Requests For Further Information: Send your written comments, requests for more information on the proposed collection, or requests to obtain a copy of the data collection instrument(s) and instructions to: Mr. Lance Hodahkwen, Sr., M.P.H., IHS Reports Clearance Officer, 12300 Twinbrook Parkway, Suite 450, Rockville, MD 20852.1601, call non-toll free (301) 443–5938, send via facsimile to (301) 443–1522, or send your E-mail requests, comments, and return address to: lhodahkw@hqe.ihs.gov.

Comment Due Date: Your comments regarding this information collection are best assured of having their full effect if received within 60-days of the date of this publication.

Dated: December 14, 2001.

Michael H. Trujillo,

Assistant Surgeon General, Director, Indian Health Service.

[FR Doc. 01–31712 Filed 12–26–01; 8:45 am]

BILLING CODE 4160–16–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the National Cancer Institute Director's Consumer Liaison Group.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

Name of Committee: National Cancer Institute Director's Consumer Liaison Group.

Date: January 22, 2001.

Time: 2 p.m. to 4 p.m.

Agenda: To follow up on the Survivorship Forums and receive reports from Working Groups.

Place: National Cancer Institute, 6116 Executive Boulevard, Suite 300C, Room 3068 A, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Elaine Lee, Executive Secretary, Office of Liaison Activities, National Institutes of Health, National Cancer Institute, 6116 Executive Boulevard, Suite 300 C, Bethesda, MD 20892, 301/594–3194.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's home page: *deainfo.nci.nih.gov/advisory/dclg/delg.htm,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: December 14, 2001.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 01–31704 Filed 12–26–01; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice