determine appropriate dosing of cough and cold ingredients in the pediatric population? How should these studies be designed and powered?

2. Should cough and cold products for the pediatric population continue to be available OTC, or should they be made available only by prescription?

3. If the pediatric indications and dosing for cough and cold products were no longer available OTC, would the public use the adult formulations of the OTC monograph products for children, and thus create a greater risk of misuse or overdose?

4. Do the answers to the previous questions depend on the age of the pediatric patients? If so, how should age be considered in making regulatory decisions for these products?

5. At the time the monograph was established, FDA routinely extrapolated safety and efficacy data from adults to children age 12 and over. Current PREA standards permit extrapolation of pediatric efficacy -- but not safety-- based upon sufficient adult data. Does it remain appropriate to recommend in the cough and cold monograph that children 12 and over should receive the same dose of medication as adults, without requiring any additional studies in children in this age group? What additional safety and/or efficacy studies should be required in this age group?

6. What is the most appropriate method for determining pediatric doses that could be used as an alternative to the quarter- and half-dose assumptions used in the monograph? Should products be dosed by age, by weight, or both?

7. There are monographs for topical and intranasal ingredients to treat the common cold. Should these monographs be considered in a similar fashion to the oral cough and cold products? Are the answers to the previous questions different for any subcategories of cough and cold medicines (e.g., topical or intranasal products)?

8. The CCABADP monograph allows for the combination of ingredients to treat colds and/or coughs. Should combination products be permitted for all pediatric age groups? Should data be provided to support each unique combination?

9. Can measurement errors in dosing be reduced using more standardized measuring devices or alternative dosage forms and, if so, what is the best way to effect this change?

III. Notice of Hearing Under 21 CFR Part 15

The Commissioner is announcing that the public hearing will be held in accordance with part 15 (21 CFR part 15). The hearing will be conducted by a presiding officer, accompanied by FDA senior management from the Office of the Commissioner and the Center for Drug Evaluation and Research.

Under § 15.30(f), the hearing is informal, and the rules of evidence do not apply. No participant may interrupt the presentation of another participant. Only the presiding officer and panel members may question any person during or at the conclusion of each presentation. Public hearings under part 15 are subject to FDA's policy and procedures for electronic media coverage of FDA's public administrative proceedings (part 10 (21 CFR part 10), subpart C)). Under § 10.205, representatives of the electronic media may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA's public administrative proceedings, including presentations by participants. The hearing will be transcribed as stipulated in § 15.30(b). To the extent that the conditions for the hearing, as described in this document, conflict with any provisions set out in part 15, this document acts as a waiver of those provisions as specified in 21 CFR 15.30(h).

IV. Comments

Regardless of attendance at the public hearing, 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 paper copy. Comments should be identified with the docket number found in brackets in the heading of this document. To ensure consideration, submit comments by (see **DATES**). Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA through FDMS only.

V. Transcripts

Please be advised that as soon as a transcript is available, it will be accessible at *http://www.regulations.gov*. It may be viewed at the Division of Dockets Management (see ADDRESSES). A transcript will also be available in either hard copy or on CD–ROM, after submission of a Freedom of Information request. Written requests are to be sent to Division of Freedom of Information (HFI–35), Office of Management Programs, Food and Drug Administration, 5600 Fishers Lane, rm. 6–30, Rockville, MD 20857. Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic notices of participation and comments for consideration.

Dated: August 20, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–19657 Filed 8–22–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Request for Public Comment: 60-Day Proposed Information Collection: Indian Health Service; HIV Knowledge/ Attitudes/Practice Customer Survey

AGENCY: Indian Health Service, HHS.

ACTION: Notice.

SUMMARY: In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 which requires 60 days for public comment on proposed information collection projects, the Indian Health Service (IHS) is publishing for comment a summary of a proposed information collection to be submitted to the Office of Management and Budget (OMB) for review.

Proposed Collection: Title: 0917–NEW, ''Indian Health Service HIV Knowledge/Attitudes/Practice Customer Survey.'' *Type of Information Collection Request:* This is a one time survey to deliver the mission of the IHS and Centers for Disease Control (CDC) national guidelines collection, 0917–NEW, ''Indian Health Service HIV Knowledge/Attitudes/Practice Customer Survey.'' *Form(s):* The Indian Health Service Customer Survey. *Need and Use of Information Collection:*

The IHS goal is to raise the health status of the American Indian and Alaska Native (AI/AN) people to the highest possible level by providing comprehensive health care and preventive health services. To support the IHS mission, the Division of Epidemiology and Disease Prevention (DEDP) and the Human Immunodeficiency Virus (HIV) Program collaborate to provide programmatic, technical, and financial assistance to

IHS Areas and Service Units for improving prevention, detection, and treatment of infectious and chronic disease, specifically in this case, HIV and Sexually Transmitted Disease (STD).

The ''HIV Knowledge/Attitudes/Practice Customer Survey'' (hereto referred to as Customer Survey), will provide the information needed to understand the most effective and appropriate methods to complete these goals. With the information collected from patients, we will be able to offer recommendations to Service Units on how to best scale up screening for sensitive topics such as HIV and STDs in AI/AN communities. Also, the information will give IHS the tools to assist our Service Units with implementation of current national recommendations by CDC. At the moment, we are encouraging uptake of current CDC national recommendations; however, without this information, we are unable to maximize effectiveness, dispel myths, and identify misinformation.

Voluntary customer surveys will be conducted through self-administered questionnaires, face-to-face interviews, and potentially electronic media. The information gathered will be used by DEDP and the HIV Program to identify how patients would prefer to be offered expanded testing in a way that is respectful, confidential, and effective. *Affected Public:* Individuals. *Type of Respondents:* IHS customers.

The table below provides: Types of data collection instruments, Estimated number of respondents, Number of responses per respondent, Average burden hour per response, and Total annual burden hour(s).

ESTIMATED BURDEN HOURS

Data collection instrument	Estimated number of respondents	Responses per respondent	Average burden hour per response	Total annual burden hours
Customer survey	1000	1	10/60	166
Total	1000			166

There are no Capital Costs, Operating Costs, and/or Maintenance Costs to report.

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 agency 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 the methodology and assumptions used to determine the estimates 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: Ms. Janet Ingersoll, Acting IHS Reports Clearance Officer, 801 Thompson Avenue, TMP 450, Rockville, MD 20852–1627; call non-toll free (301) 443–6177; send via facsimile to (301) 443–2316; or send your E-mail requests, comments, and return address to: *janet.ingersoll@ihs.gov*.

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

Dated: August 18, 2008.

Robert G. McSwain,

Director, Indian Health Service.

[FR Doc. E8–19479 Filed 8–22–08; 8:45 am]

BILLING CODE 4165–16–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Request for Public Comment: 60-Day Proposed Information Collection: Indian Health Service; Health Promotion/Disease Prevention Grantee Survey

AGENCY: Indian Health Service, HHS.

ACTION: Notice.

SUMMARY: In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 which requires 60 days for public comment on proposed information collection projects, the Indian Health Service (IHS) is publishing for comment a summary of a proposed information collection to be submitted to the Office of Management and Budget (OMB) for review.

Proposed Collection: Title: 0917–NEW, ''Indian Health Service Health Promotion/Disease Prevention Grantee Survey.'' *Type of Information Collection Request:* This is a one time survey to fulfill an OMB request for an independent external evaluation collection, 0917–NEW, ''Indian Health Service Health Promotion/Disease Prevention (HP/DP) Grantee Survey.'' *Form(s):* The Indian Health Service HP/DP Interview Survey. *Need and Use of Information Collection:* The IHS goal is to raise the health status of the American Indian and Alaska Native (AI/AN) people to the highest possible level by providing comprehensive health care and preventive health services. HP/DP is one of the three IHS Director's Initiatives to reduce health disparities among AI/AN populations through a coordinated and systematic approach to enhance health promotion and chronic disease prevention approaches at the local, regional, and national levels.

The HP/DP competitive grant was established in 2005 to encourage Tribal and urban Indian programs to fully engage their local schools, communities, health care providers, health centers, faith-based/spiritual communities, senior centers, youth programs, local governments, academia, non-profit organizations, and many other community sectors to work together to enhance and promote health and prevent chronic disease in their communities. Thirty-three Tribal/urban Indian organizations and programs were awarded competitive grants to expand and enhance health promotion and disease prevention to address health disparities among AI/AN populations.

To conduct a thorough evaluation of the grant program, 29 telephone and four face-to-face interviews will be conducted to collect information to complete a quantitative and qualitative evaluation of the HP/DP grant program. The teleconference interviews may include one staff member per site. Each of the Tribal/urban organization/