Register of December 13, 1994 (59 FR 64240), FDA published a final rule that encouraged manufacturers to provide more information in the labeling on the use of a drug in the pediatric population. The rule recognized several methods of establishing substantial evidence to support pediatric labeling claims, including relying in certain cases on studies carried out in adults. Under the final rule, products may be labeled for pediatric use based on adequate and well-controlled studies in adults together with other information supporting pediatric use (e.g., pharmacokinetic data, safety data, pharmacodynamic data). In the **Federal Register** of August 15, 1997 (62 FR 43899), FDA published a proposed rule that would require new drugs and biological products to be labeled for use in the pediatric population. The enactment of the Food and Drug Modernization Act of 1997 (Pub. L. 105–111) (Modernization Act) on November 21, 1997, further addressed this need by providing incentives to sponsors for conducting pediatric studies (21 U.S.C. 355a). This draft guidance addresses general considerations for conducting PK studies in the pediatric population.

This draft level 1 guidance is being issued consistent with FDA's good guidance practices (62 FR 8961, February 27, 1997). It represents the agency's current thinking on pediatric pharmacokinetic studies. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

Interested persons may submit written comments on the draft guidance to the Dockets Management Branch (address above). 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. The draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 19, 1998.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 98–31691 Filed 11–27–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; Evaluation of National Youth Anti-Drug Media Campaign

SUMMARY: In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Institutes on Drug Abuse of the National Institutes of Health will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget for review and approval.

PROPOSED COLLECTION: *Title:* Evaluation of National Youth Anti-Drug Media Campaign. *Type of Information Collection Request:* New. *Need and use of Information Collection:* The White House Office of National Drug Control Policy has transferred funds to NIDA to conduct an independent, scientifically designed and implemented evaluation of the National Youth Anti-Drug Media Campaign, the first prevention campaign to use paid advertising to discourage youth from drug use. The study will assess the outcomes and impact of the national campaign in reducing illegal drug use among children and adolescents.

For this study, two different surveys will be conducted: (1) the National Survey of Parents and Youth, a cross-sectional household survey; and (2) a Longitudinal Study of Parents and Youth in four communities with an ethnographic component. All data will be collected using a combination of computer-assisted personal interviews (CAPI) and audio computer-assisted self-interviews (ACASI). The findings will form the basis of semiannual and annual reports on campaign progress. These reports will provide assistance in improving the national campaign, and will help to establish a rich data base of information about the process involved in changing attitudes and behaviors by the mass media.

Frequency of Response: The National Survey of Parents and Youth will be carried out in 8 waves over a four-year period. Each data collection wave will last 6 months. The Longitudinal Study will be carried out annually over four years. *Affected Public:* Individuals and households. *Type of Respondents:* Children and parents. The annual reporting burden is as follows:

TABLE 1: RESPONDENT AND BURDEN ESTIMATE

Type of respondents	Estimated number of respondents	Estimated number of responses of per respondent	Average burden hours per response	Estimated total burden hours requested	Estimated annualized burden (over 3 years)
National Survey of Youth and Parents					
Screener respondent	225,600	1	.07	15,792	5,264
Youth 9–11	6,600	1	.50	3,300	1,100
Adolescents 12–18	13,800	1	.75	10,350	3,450
Parents	20,700	1	.75	15,525	5,175
Longitudinal Study					
Screener respondent	38,000	1	.07	2,600	887
Youth 9–11	2,150	3	.58	3,741	1,247
Adolescents 12–14	2,150	3	.92	5,934	1,978
Parents	3,500	3	.92	9,660	3,220
Total	312,500		.21	66,962	22,321

There are no Capital Costs to report. There are no Operating or Maintenance Costs to report. Because of the sensitivity of collecting data from families in households involving children as young as 9 years old, and

the importance of minimizing costs for repetitive, return visits to obtain respondent cooperation, NIDA is considering the provision of a reasonable cost incentive to reimburse respondents for their time.

REQUEST FOR COMMENTS: Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency'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 those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

FOR FURTHER INFORMATION: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Susan David, Project Officer; Division of Epidemiology and Prevention Research, National Institutes on Drug Abuse, Room 9A54, 5600 Fishers Lane, Rockville, MD 20857; or call non-toll-free number (301) 443–6543; or fax to (301) 443–2636; or e-mail your request, including your address, to: Sd69t@nih.gov.

COMMENTS DUE DATE: Comments regarding this information collection are best assured of having their full effect if received by January 29, 1999.

Dated: November 19, 1998.

Laura Rosenthal,

Executive Officer, NIDA.

[FR Doc. 98–31728 Filed 11–27–98; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Data Collection; Comment Request; Survey of Colorectal Cancer Screening Practices in Health Care Organizations

SUMMARY: In compliance with the provisions of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comments on proposed data collection projects, the National Institutes of Health (NIH), National Cancer Institute (NCI) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget for review and approval.

PROPOSED COLLECTION: *Title:* Survey of Colorectal Cancer Screening Practices in Health Care Organizations. *Type of Information Collection Request:* New. *Need and Use of Information Collection:* This study will measure primary care and specialty physicians' knowledge, attitudes, and practice patterns related to colorectal cancer screening and diagnostic follow-up. This study also will assess guidelines, policies, and programs to provide or promote colorectal cancer screening within health plans. The purpose of this study is to obtain current, nationally representative data on the physician and health system factors that may influence the use of colorectal cancer screening and diagnostic follow-up for suspected colorectal cancer in community practice. Three questionnaires will be administered by mail, telephone, facsmile, or Internet using national samples of physicians and health plans. Study participants will select their preferred response mode. Study participants will be primary care and speciality physicians with active licenses to practice medicine in the U.S., and the medical directors of health plans listed by the American Association of Health Plans. Burden estimates are as follows:

Questionnaire	Estimated # respondents	# responses per respondent	Average burden hours per response	Estimated total annual burden hours
Primare care physician	1,810	1	0.250	452
Speciality physician	1,544	1	0.333	514
Health plan	453	1	0.333	*151*
Total:				1,117

REQUEST FOR COMMENTS: Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (a) whether the proposed collection of information is necessary for the 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.

FOR FURTHER INFORMATION CONTACT: Send comments to Carrie N. Klabunde, Ph.D., Epidemiologist, National Cancer Institute, EPN 313, 6130 Executive Boulevard, MSC 7344, Bethesda, Maryland 20892–7344, telephone 301–402–3362.

COMMENTS DUE DATE: Comments regarding this information collection are best assured of having their full effect if received by January 29, 1999.

Dated: November 19, 1998.

Reesa Nichols,

OMB Project Clearance Liaison.

[FR Doc. 98–31729 Filed 11–27–98; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Licensing Opportunity and/or Cooperative Research and Development Agreement (''CRADA'') Opportunity: Drug And Method For The Therapeutic Treatment of Lymphomas And Leukemias

AGENCY: National Institutes of Health, PHS, DHHS.

ACTION: Notice.

SUMMARY: The NIH is seeking Licensee(s) and/or a Cooperative Research and Development Agreement (''CRADA'') to further develop, evaluate, and commercialize a recombinant immunotoxin, termed RFB4(dsFv)–PE38