Screening Kits.'' On September 25, 1997, FDA held an open public meeting of the Clinical Chemistry and Clinical Toxicology Panel (the Panel), an FDA advisory committee, in order to discuss and receive comments on the September 1997 guidance. Based upon comments and recommendations received at this meeting from the Panel, the public, and manufacturers, FDA has revised the September 1997 guidance.

II. Significance of Guidance

This draft guidance represents the agency's current thinking on drugs of abuse home screening kits. 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 applicable statute, regulations, or both. This guidance is not final nor is it in effect at this time. This draft guidance replaces the September 17, 1997, guidance.

The agency has adopted good guidance practices (GGP's), which set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (62 FR 8961, February 27, 1997). This guidance document is issued as a Level 1 guidance consistent with GGP's.

III. Electronic Access

In order to receive ''Guidance for Premarket Submissions for Kits for Screening Drugs of Abuse to Be Used By the Consumer'' via your fax machine, call the CDRH Facts-On-Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. At the first voice prompt press 1 to access DSMA Facts, at second voice prompt press 2, and then enter the document number 2209 followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the draft guidance may also do so using the World Wide Web (WWW). CDRH maintains an entry on the WWW for easy access to information including text, graphics, and files that may be downloaded to a personal computer with access to the WWW. Updated on a regular basis, the CDRH home page includes ''Guidance for Premarket Submissions for Kits for Screening Drugs of Abuse to Be Used By the Consumer,'' device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, mammography matters, and other device-oriented information. The CDRH home page may be accessed at ''http://www.fda.gov/cdrh''.

IV. Comments

Interested persons may, on or before March 30, 1999, submit to the Dockets Management Branch (address above) written comments regarding this draft 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. The draft guidance and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: December 15, 1998.

D.B. Burlington,

Director, Center for Devices and Radiological Health.

[FR Doc. 98–34346 Filed 12–29–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Child Health and Human Development; Proposed Collection; Comment Request; Young Drivers Intervention Study

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

PROPOSED COLLECTION:

Title: Young Drivers Intervention Study.

Type of Information Collection Request: New.

Need and Use of Information Collection: The purposes of this study are (1) to determine the impact of parental actions to monitor and control their adolescents' driving behavior on adolescent driving behavior and motor vehicle crashes, and (2) to test the efficacy of educational persuasive communications in promoting parental restriction of their adolescent's risky driving behavior. The specific questions addressed in this study include: (1) Are parents' perceptions about dangers associated with adolescent driving associated with parental involvement in their adolescent's driving experiences? (2) Is a parent-teen driving agreement an effective way of increasing parental involvement and reducing adolescent risky driving? (3) Does increased parental involvement reduce risky driving behaviors and decrease traffic tickets and crashes among adolescents?

A sample of adolescents applying for their learner's permit and one of their parents will be recruited through department of motor vehicles offices and driver's education courses in two states. In each state, 1600 parent-adolescent dyads will be recruited and interviewed four times over the course of the 2-year prospective observational study. During the initial interview, consent, demographic information, and contact information will be obtained. Within two weeks, parents and their adolescents will be interviewed over the telephone. Parents will be asked about their expectations and parenting practices regarding their adolescents' driving behaviors. Adolescents will be asked about their driving practices, their parents' rules and restrictions regarding driving, and other psychosocial variables. These same variables will be assessed again during telephone interviews with both parents and adolescents at six, twelve, and eighteen months intervals. The driving records for each adolescent will be obtained from the state motor vehicle administration and examined at the end of the 24-month period.

Parent-teen dyads will be randomly assigned to the basic information comparison condition or the special-intervention treatment condition. Parents in the comparison condition will receive standard information about the move toward graduated licensing in their state and the high risk related to adolescent driving. Parents in the special intervention will receive personalized educational material in the mail, including a parent-teen driving agreement and an educational videotape. During the 24 month period of the study, dyads will be contacted three more times: (1) when adolescents apply for their provisional/full license, (2) 6 months after provisional/full licensure, and (3) 12 months after provisional/full licensure. At each time, parents and adolescents will be interviewed over the telephone regarding parenting practices related to involvement in and restriction of adolescents' driving experience, and adolescents' driving behaviors.

Frequency of Response: data will be collected 4 times over a two-year period; two times each year for two years.

AFFECTED PUBLIC: PARENTS AND THEIR TEENAGE CHILDREN

Type of respondents	Estimated number of respondents	Estimated number of responses per respondent	Average burden hours per response	Estimated total annual burden hours requested
Parents	3,200	2	0.5	3,200
Adolescents	3,200	2	0.5	3,200

The annualized cost to respondents is estimated at $64000 (based on $10 per hour). There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

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 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 CONTACT:

To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Dr. Bruce Simons-Morton, Chief, Prevention Research Branch, Division of Epidemiology, Statistics, and Prevention Research, National Institute of Child Health and Human Development, Building 6100, 7B05, 9000 Rockville Pike, Bethesda, Maryland, 20892–7510, or call non-toll free number (301) 496–5674 or E-mail your request, including your address to <bm79K@nih.gov>.

COMMENTS DUE DATE: 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 17, 1998.

Ben Fulton,

Executive Officer, NICHD.

[FR Doc. 98–34528 Filed 12–29–98; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, DHHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by agencies of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

ADDRESSES: Licensing information and copies of the U.S. patent applications listed below may be obtained by contacting Susan S. Rucker, J.D., Patent and licensing Specialist, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone 301/496–7057 ext. 245; fax: 301/402–0220; e-mail: sr156v@nih.gov. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

cDNA Encoding A Gene, BOG (B5T Over-Expressed Gene), And Its Protein Product

SS Thorgeirsson, JT Woitach, M Zhang (NCI) Serial Nos. 60/079,567 filed 27 Mar 98 and 60/075,922 filed 25 Feb 98.

These applications describe a newly identified gene, termed BOG (B5t Over-Expressed Gene), and its protein product. Rat, murine and human homologs of the gene are described. Human BOG has been mapped to chromosome 20 and murine BOG to chromosome 2.

The applications describe the binding of the BOG gene product with the gene product pRb, of the well-known tumor suppressor gene RB (retinoblastoma susceptibility gene). The complex formed between Rb and BOG typically does not contain E2F–1 *in vivo.* This binding property suggests that cells which are transformed/transfected with cDNA or other functional nucleotide sequences which encode the BOG gene product will be useful as tools for studying cell cycle control and oncogenesis.

Studies using rat liver epithelial cell (RLE) lines which are resistant to the growth inhibitory effects of TGF-β1 and primary liver tumors have been shown to over-express BOG. In addition, when normal RLE continuously over-express BOG the cells become transformed and the transformed cells are able to form hepatolblastoma-like tumors when transplanted into nude mice. BOG antisense nucleotides can be used to restore sensitivity to TGF-β in cells which over-express BOG. Therefore, biologics derived from BOG may be useful as diagnostics or therapeutics.

Thymosin α1 Promotes Tissue Repair, Angiogenesis and Cell Migration

KM Malinda, HD Kleinman (NIDCR), RK Maheshwari, and A Goldstein, Serial Nos. 09/186,476 filed 04 Nov 98, 60/069,590 filed 12 Dec 97, and 60/065,032 filed 10 Nov 97.

These applications describe the use of the compound thymosin α1 as an agent for promoting wound healing. Thymosin α1 is a small, 28 mer, peptide which can be made by chemical synthesis or recombinantly. Studies using a punch model for wounds in rats have shown that providing thymosin α1 either intraperitoneally or topically accelerates wound healing. In addition, thmosin α1 has been shown to promote endothelial and keratinoctye cell migration *in vivo* and to promote angiogenesis *in vivo.*

This work has been published in *J. Immunol.* 160(2); 1001–6 (Jan 15, 1998).

Double-Stranded RNA Dependent Protein Kinase Derived Peptides To Promote Proliferation of Cells and Tissues in a Controlled Manner

DP Bottaro (NCI), R Petryshyn (EM), Serial No. PCT/US97/14350 filed 29 Jul 97 and 60/023,307 filed 30 Jul 97

These applications describe a number of peptides having a minimum size of eight (8) amino acids which act as