additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product Astelin® Nasal Spray (azelastine hydrochloride). Astelin® Nasal Spray is indicated for the treatment of the symptoms of seasonal allergic rhinitis such as rhinorrhea, sneezing, and nasal pruritus in adults and children 12 years and older. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Astelin® Nasal Spray (U.S. Patent No. 5,164,194) from Astra Medica AG, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated February 18, 1997, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of Astelin® Nasal Spray represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for Astelin® Nasal Spray is 2,797 days. Of this time, 749 days occurred during the testing phase of the regulatory review period, while 2,048 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) became effective*: March 8, 1989. The applicant claims February 6, 1989, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was March 8, 1989, which was 30 days after FDA receipt of the IND on February 6, 1989.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the Federal Food, Drug, and Cosmetic Act*: March 26, 1991. FDA has verified the applicant's claim that the new drug application (NDA) for Astelin® Nasal Spray (NDA 20–114) was initially submitted on March 26, 1991.

3. *The date the application was approved*: November 1, 1996. FDA has verified the applicant's claim that NDA 20–114 was approved on November 1, 1996.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 349 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before June 3, 1997 submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before October 1, 1997 for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 27, 1997.

Allen B. Duncan,

Acting Associate Commissioner for Health Affairs.

[FR Doc. 97–8626 Filed 4–3–97; 8:45 am]

BILLING CODE 4160–01–F

National Institutes of Health

Pretesting of Office of Cancer Communications Messages; Proposed Collection; Comment Request

Summary: In compliance with the requirements 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 Cancer Institute (NCI), 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: Pretesting of Office of Cancer Communications Messages.

Type of Information Collection Request: EXTENSION (OMB # 0925–0046, expires 8/31/97).

Need and Use of Information Collection: In order to carry out NCI's legislative mandate to educate and disseminate information about cancer prevention, detection diagnosis, and treatment to a wide variety of audiences and organizations (e.g. cancer patients, their families, the general public, health providers, the media, voluntary groups, scientific and medical organizations), the Office of Cancer Communications (OCC) needs to pretest its communications strategies, concepts, and messages while they are under development. The primary purpose of this pretesting, or formative evaluation, is to ensure that the messages, communications materials, and information services created by OCC have the greatest capacity of being received, understood, and accepted by their target audiences. By utilizing appropriate qualitative and quantitative methodologies, OCC is able to (1) Understand characteristics of the intended target audience—their attitudes, beliefs and behaviors—and use this information in the development of effective communications tools; (2) produce or refine messages that have the greatest potential to influence target audience attitudes and behavior in a positive manner; and (3) expend limited program resources dollars wisely and effectively. *Frequency of Response:* On occasion. *Affected public:* Individuals or households; Businesses or other for

profit; Not-for-profit institutions; Federal Government; State, Local or Tribal Government. *Type of Respondents:* Adult cancer patients; members of the public; health care professionals; organizational representatives. The annual reporting burden is as follows: *Estimated Number of Respondents:* 13,780; *Estimated Number of Responses per Respondent:* 1; *Average Burden Hours Per Response;* 1458; and *Estimated Total Annual Burden Hours Requested:* 2,010. There are no Capital Costs, Operating Costs and/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 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 their 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 Ellen Eisner, Communications Research Manager, Health Promotion Branch, OCC, NCI, NIH, Building 31, Room 10A03, 9000 Rockville Pike, Bethesda, MD 20892, or call non-toll-free number (301) 496–6667 or E-mail your request, including your address to EisnerE@occ.nci.nih.gov.

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received by June 3, 1997.

Dated: March 27, 1997.

Nancie L. Bliss,

Project Clearance Liaison, NCI.

[FR Doc. 97–8595 Filed 4–3–97; 8:45 am]

BILLING CODE 4140–01–M

A Comprehensive Alcohol Education Program for Pre-Adolescents Using Interactive Multimedia; Submission for OMB Review; Comment Request

SUMMARY: Under the provisions of Section 3506 © (2) (A) of the Paperwork Reduction Act of 1995, the National Institute on Alcohol Abuse and Alcoholism (NIAAA), National Institutes of Health (NIH) 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 was previously in the **Federal Register** on March 22, 1996, and allowed 60 days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The NIH may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after September 28, 1997, unless it displays a currently valid OMB control number.

PROPOSED COLLECTION: *Title:* A Comprehensive Alcohol Education Program for Pre-Adolescents Using Interactive Multimedia. *Type of Information Collection request:* NEW. *Need and Use of Information Collection:* The information proposed for collection will be used by the NIAAA to determine the efficacy of interactive multimedia for delaying the onset of drinking among 7th and 8th grade males and females. Interactive multimedia enables the combination of the elements of television and movies that engage and motivate the target populations with computer-based interaction, simulations, and games to (1) increase information about the negative consequences of teen drinking and (2) teach practical skills for avoiding and refusing alcohol. Subject participation will involve (1) focus groups, during development of the multimedia program, and (2) post-development behavioral trials.

Frequency of Response: On Occasion.

Affected Public: Pre-adolescents.

Type of Respondents: Minor Students (Grades 7th and 8th).

Estimated Number of Respondents: 308.

Estimated Number of Responses per Respondent: 1.

Average Burden Hours per Response: .281.

And Estimated Total Annual Burden Hours Requested: 89.2.

There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

The annual burden estimates are as follows:

Type and number of respondents	Responses per respondent	Total responses	Hours	Total hours
Focus Group Subjects 40	1	40	0.5	20
Trial Subjects 268	4	1072	0.5	536

Total Number of Respondents: 308.

Total Number of Responses: 1112.

Total Hours: 556.

REQUEST FOR COMMENTS: Comments are invited on: (a) whether the proposed collection is necessary, including whether the information has practical use; (b) ways to enhance the clarity, quality, and use of the information to be collected;© the accuracy of the agency estimate of burden of the proposed collection; and (d) ways to minimize the collection burden of the respondents. Send written comments to Dr. Kendall Bryant, Prevention Research Branch, Division of Clinical and Prevention Research (DCPR), NIAAA, NIH, Willco Building, Room 505, 6000 Executive Boulevard, MSC 7003, Bethesda, Maryland 20892–7003.

DIRECT COMMENTS TO OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time should be directed to the Office of Management and Budget, Office of Regulatory Affairs, New Executive Office Building, Room 10235, Washington, DC 20503, Attention: Desk Officer for NIH.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans, contact Dr. Kendall Bryant, Prevention Research Branch, Division of Clinical and Prevention Research (DCPR), NIAAA, NIH, Willco Building, Room 505, 6000 Executive Boulevard, MSC 7003, Bethesda, Maryland 20892–7003, or call non-toll-free number (301) 443–8820.

COMMENTS DUE DATE: Comments regarding this information collection are