IV. Comments

Interested persons may submit to Dockets Management Branch (address above) written or electronic comments regarding this draft guidance by September 24, 2001. Submit two copies of any comments, 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 The draft guidance document and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 13, 2001.

Linda S. Kahan,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 01–18480 Filed 7–24–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA–10024]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Health Care Financing Administration, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection Request: New collection; *Title of Information Collection:* Development of Survey Instrument for Special Populations; *Form No.:* HCFA–10024 (OMB# 0938–NEW); *Use:* Development of Survey Instrument for Special Populations; *Frequency:* Once; *Affected Public:* Individuals or households; *Number of Respondents:* 2,160; *Total Annual Responses:* 2,160; *Total Annual Hours:* 498.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access HCFA's Web Site address at http://www.hcfa.gov/regs/prdact95.htm, or E-mail your request, including your address, phone number, OMB number, and HCFA document identifier, to Paperwork@hca.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 30 days of this notice directly to the OMB desk officer: OMB Human Resources and Housing Branch, Attention: Alison Eydt, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: June 27, 2001.

John P. Burke III,

HCFA Reports Clearance Officer, HCFA Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards.

[FR Doc. 01–18553 Filed 7–24–01; 8:45 am]

BILLING CODE 4120–03–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget, in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35). To request a copy of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office on (301)–443–1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995: Proposed Project: U.S. Component of the 2001/2002 World Health Organization Study of Health Behavior in School Children (WHO–HBSC): New

The Office of Data and Information Management (ODIM), Maternal and Child Health Bureau (MCHB), Health Resources and Services Administration (HRSA), will participate on behalf of the United States in the 2001/2002 WHO Study of Health Behavior in School Children. The information proposed for collection will be used by MCHB, HRSA, and the National Institutes of Health (NIH) to increase understanding of adolescent health to improve the quality of health programs and services. This cross-national research study will collect survey data to study adolescent health status and behaviors in relation to their social and supportive environment. Types of data will include measures of physical activity, body size, nutrition, social inequality, diversity, injury, violence, and perceptions of peers, school, and family as a supportive environment.

The estimated response burden is as follows:

Survey	Number of respondents	Responses per respondent	Hours per response	Total burden hour
Students	17,172	1	.75	12,879
Administrator	755	1	.25	189
School Staff	744	1	.5	372
Survey	18,671	.....	.....	13,440

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to: John Morrall, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: July 18, 2001.

Jane M. Harrison,

Director, Division of Policy Review and Coordination.

[FR Doc. 01–18481 Filed 7–24–01; 8:45 am]

BILLING CODE 4165–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

National Toxicology Program (NTP); Request for Comments on Substances Nominated to the National Toxicology Program (NTP) for Toxicological Studies and on the Testing Recommendations Made by the NTP Interagency Committee for Chemical Evaluation and Coordination

SUMMARY: The National Toxicology Program (NTP) continuously solicits and accepts nominations for toxicological studies to be undertaken by the Program. Nominations of substances of potential human health concern are received from Federal agencies, the public, and other interested parties. These nominations undergo several levels of review before selections for testing are made and toxicological studies are designed and implemented. The NTP Interagency Committee for Chemical Evaluation and Coordination (ICCEC) serves as the first level of review for NTP nominations. At the 8 May 2001 ICCEC meeting, 13 new nominations were reviewed and testing recommendations were made. To inform the public and to obtain input for consideration when selecting chemicals for toxicological evaluation, the NTP routinely seeks public comment on the nominated substances and the ICCEC's testing recommendations. This announcement (1) provides brief background information regarding the substances nominated to NTP for study, (2) presents the ICCEC's testing recommendations from its 8 May 2001 meeting, (3) solicits public comment on the nominations and recommendations, and (4) requests the submission of additional relevant information for consideration by the NTP in its continued evaluation of these nominations.

Background

The NTP actively seeks to identify and select for study chemicals and other agents for which sufficient information is not available to adequately evaluate potential human health hazards. The NTP accomplishes this goal through a formal open chemical nomination and selection process. Substances selected for study generally fall into two broad overlapping categories: (1) Those substances of greatest concern for public or occupational health based on the extent of human exposure and/or suspicion of toxicity; and (2) substances for which toxicological data gaps exist and additional studies would aid in assessing potential human health risks, e.g. by facilitating cross-species extrapolation or evaluating dose-response relationships. Particular assistance is also sought for the nomination of studies that permit the testing of hypotheses to enhance the predictive ability of future NTP studies, address mechanisms of toxicity, or fill significant gaps in the knowledge of the toxicity of classes of chemicals. Substances may be studied for a variety of health-related effects, including but not limited to reproductive and developmental toxicity, genotoxicity, immunotoxicity, neurotoxicity, metabolism and disposition, and carcinogenicity. In evaluating and selecting nominated substances, the NTP also considers legislative mandates that require responsible private sector commercial organizations to evaluate their products for health and environmental effects. The possible human health consequences of anticipated or known human exposure, however, remain the over-riding factor in the NTP's decision to study a particular chemical or agent.

The review and selection of substances nominated for study is a multi-step process. A broad range of concerns are addressed during this process through the participation of representatives from Federal agencies, the NTP Board of Scientific Counselors—an external scientific advisory body, the NTP Executive Committee—the NTP Federal interagency policy body, and a public comment period. This process is described in further detail in a 2 March 2000 **Federal Register** announcement (Volume 65, Number 42, pages 11329–11331). This multi-step evaluative process provides the NTP direction and guidance to ensure that it's testing program addresses toxicological concerns relative to all areas of public health, and furthermore, that there is balance among the types of substances selected for study (e.g., industrial chemicals, consumer products, therapeutic agents, etc.). As such, it should be recognized that for any given committee review, the new testing nominations under consideration do not necessarily reflect the overall balance of substances historically or currently being evaluated by NTP in it's testing program. For further information on NTP studies (previous or in progress) visit the NTP web site at *http://ntp-server.niehs.nih.gov.*

Nominated Substances and Interagency Review

The ICCEC is composed of representatives from the Agency for Toxic Substances and Disease Registry, Consumer Product Safety Commission, Department of Defense, Environmental Protection Agency, Food and Drug Administration's National Center for Toxicological Research, National Cancer Institute, National Institute of Environmental Health Sciences, National Institute for Occupational Safety and Health, National Library of Medicine, and the Occupational Safety and Health Administration. The ICCEC meets once or twice annually to evaluate groups of new nominations and to make testing recommendations with respect to both specific types of studies and testing priorities. At its meeting on 8 May 2001, the ICCEC reviewed 13 new nominations for NTP studies. For eight of these nominations, one or more types of testing was recommended, and for three nominations, no testing was recommended at this time. A testing recommendation for two nominations was deferred pending receipt of (1) additional information or data from the nominator or other organizations on related studies completed, anticipated or in progress, or (2) additional information on production, human exposure, use patterns, or regulatory needs. The nominated substances with CAS numbers, nomination source, nomination rationale, specific study recommendations, and other information are given in the attached tables.

Request for Public Comment

Interested parties are invited to submit comments or supplementary information on the nominated substances and recommendations identified in the attached tables. The NTP would welcome receiving toxicology and carcinogenesis information from completed, ongoing, or planned studies, as well as information on current production levels, use patterns, human exposure, environmental occurrence, or public health concerns for any of the nominated substances. Comments or information should be sent to Dr. Scott Masten at the address given below through September 24, 2001. Persons responding to this request are asked to include their name, affiliation, mailing address, phone, fax, e-mail address and sponsoring organization (if any) with