Dated: June 30, 2003.

Thomas A. Bartenfeld,

Acting Associate Director for Policy, Planning and Evaluation, Centers for Disease Control and Prevention.

[FR Doc. 03–17013 Filed 7–3–03; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–03–85]

Proposed Data Collections Submitted for Public Comment and Recommendations

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 Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call the CDC Reports Clearance Officer on (404) 498–1210.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper 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. Send comments to Anne O'Connor, CDC Assistant Reports Clearance Officer, 1600 Clifton Road, MS–D24, Atlanta, GA 30333. Written comments should be received within 60 days of this notice.

Proposed Project: 2003 Tribal Adult Tobacco Survey (ATS)—New—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

The purpose of this project is to test and pilot a culturally appropriate Adult Tobacco Survey questionnaire for American Indians and Alaska Natives. This questionnaire will expand data and existing knowledge of tobacco use among American Indians and Alaska Natives in order to benefit tobacco use and prevention surveillance at a tribal, state, and/or regional level. The questions will help to narrow existing gaps in knowledge of tobacco use among different tribes and inform development of tribal-specific interventions.

Current smoking prevalence among American Indians and Alaska Natives (36.0 percent) is highest compared to all other racial/ethnic groups (2000 NHIS). While national and regional data exist for American Indians and Alaska Natives, tribal level data is extremely limited. Currently, there are over 500 sovereign tribal nations in the U.S. In order to better understand tobacco use among American Indians and Alaska Natives, CDC is conducting a survey project that includes:

(1) Developing a culturally appropriate Adult Tobacco Survey questionnaire for tribes.

(2) Piloting the final instrument in approximately 30 tribes represented by six of seven Tribal Support Centers (TSCs).

In an effort to better understand the effects of smoking in American Indian and Alaska Native populations, the Support Centers for Tobacco Programs (SCTP) will utilize a culturally appropriate questionnaire for pilot implementation in six different tribal centers. The centers are located in Alaska, California, Oklahoma, Michigan, along with two tribal centers located in the upper Midwest and Northwest. In total, the SCTPs will collect approximately 2,400–2,800 completed surveys (the number varying by Center respective to the size of each tribe, 18 years of age and older), which will be representative of distinct tribal communities conducting the survey. The SCTP will be responsible for obtaining the completed surveys. Trained individuals from each of the respective communities and/or support centers will conduct interviews. Most interviews will be conducted face-to-face, with a small proportion conducted by telephone. There is no cost to respondents.

Respondents	No. of respondents	No. of responses/ respondent	Avg. burden/response (in hrs.)	Total burden (in hrs.)
Pilot Survey: Tribal members 18 years of age and older	2,800	1	45/60	2,100
Total				2,100

Dated: June 30, 2003.

Thomas A. Bartenfeld,

Acting Associate Director for Policy, Planning and Evaluation, Centers for Disease Control and Prevention.

[FR Doc. 03–17014 Filed 7–3–03; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel: Public Health Laboratory Biomonitoring Implementation Program, Program Announcement #03034

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following meeting:

Name: Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Public Health Laboratory Biomonitoring Implementation Program, Program Announcement #03034.

Times and Dates: 8:30 a.m.–9:15 a.m., July 28, 2003 (Open), 9:15 a.m.–4:30 p.m., July 28, 2003 (Closed).

Place: J.W. Marriott, 3300 Lenox Road, NE., Atlanta, GA 30326, Telephone 404.262.3344.

Status: Portions of the meeting will be closed to the public in accordance with provisions set forth in Section 552b(c) (4) and (6), Title 5 U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Public Law 92–463.

Matters To Be Discussed: The meeting will include the review, discussion, and

evaluation of applications received in response to Program Announcement #03034.

For Further Information Contact: Drue Barrett, Ph.D., Deputy Associate Director for Science, National Center for Environmental Health, CDC, 4770 Buford Highway, MS–F29, Atlanta, GA 30341, Telephone 770.488.7653.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the CDC and the Agency for Toxic Substances and Disease Registry.

Dated: June 26, 2003.

John C. Burckhardt,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 03–17017 Filed 7–3–03; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D–0209]

Guidance for Industry and FDA Staff on Class II Special Controls Guidance Document; Breath Nitric Oxide Test System; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ''Class II Special Controls Guidance Document: Breath Nitric Oxide Test System.'' This guidance describes a means by which the breath nitric oxide test system may comply with the requirement of special controls for class II devices. Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule to classify the breath nitric oxide test system into class II (special controls). This guidance is effective immediately as the special control for the breath nitric oxide test system, but it remains subject to comment in accordance with the agency's good guidance practices (GGPs).

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies on a 3.5″ diskette of the guidance document entitled ''Class II Special Controls Guidance Document: Breath Nitric Oxide Test System'' to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443–8818.

Submit written comments concerning this guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Jean Cooper, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301–594–1243.

SUPPLEMENTARY INFORMATION:

I. Background

Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule classifying the breath nitric oxide test system into class II (special controls) under section 513(f)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c(f)(2)). This guidance document will serve as the special control for the breath nitric oxide test system device. Section 513(f)(2) of the act provides that any person who submits a premarket notification under section 510(k) of the act (21 U.S.C. 360(k)) for a device that has not previously been classified may, within 30 days after receiving an order classifying the device in class III under section 513(f)(1) of the act, request FDA to classify the device under the criteria set forth in section 513(a)(1) of the act. FDA shall, within 60 days of receiving such a request, classify the device by written order. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the **Federal Register** announcing such classification. Because of the timeframes established by section 513(f)(2) of the act, FDA has determined, under § 10.115(g)(2) (21 CFR 10.115(g)(2)), that it is not feasible to allow for public participation before issuing this guidance as a final guidance document. Therefore, FDA is issuing this guidance document as a level 1 guidance document that is immediately in effect. FDA will consider any comments that are received in response to this notice to determine whether to amend the guidance document.

II. Significance of Guidance

This guidance is being issued consistent with FDA's GGPs regulation (§ 10.115). The guidance represents the agency's current thinking on the breath nitric oxide test system. 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 and regulations.

III. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 USC 3501–3520). The collections of information addressed in the guidance document have been approved by OMB in accordance with the PRA under the regulations governing premarket notification submissions (21 CFR part 807, subpart E, OMB control number 0910–0120). The labeling provisions addressed in the guidance have been approved by OMB under the PRA under OMB control number 0910–0485.

IV. Comments

Interested persons may, at any time, submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the guidance document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

V. Electronic Access

To receive ''Class II Special Controls Guidance Document: Breath Nitric Oxide Test System'' by fax, call the CDRH Facts-On-Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt, press 1 to order a document. Enter the document number (1211) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a paper copy of the guidance may also do so by using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a