

and Policy, and the Office of Chief Counsel.

The Recidivist Policy defines three increasingly stringent compliance levels for firms who have shipped violative condoms to the United States. Levels 1 and 2 allow voluntary compliance opportunities, while Level 3 provides a mechanism to issue a warning letter for apparent violations of the Federal Food, Drug, and Cosmetic Act, including noncompliance with the quality systems regulation for good manufacturing practices. A finding of Level 3 noncompliance will automatically place any future shipments of condoms from the manufacturer/shipper on detention, without the need for FDA to perform an actual inspection at the foreign manufacturer, due to the continued failure of condoms to pass minimum FDA standards upon import.

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 This draft guidance is issued as a draft Level 1 guidance consistent with GGP's.

This draft guidance represents the agency's current thinking on the surveillance and detention without physical examination of condoms. 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.

## II. Electronic Access

In order to receive the draft guidance entitled "Surveillance and Detention Without Physical Examination of Condoms" via your fax machine, call the CDRH Facts-On-Demand (FOD) system at 800-899-0381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 1139 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Persons interested in obtaining a copy of the draft guidance may also do so using the Internet.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 access to the Internet. Updated on a regular basis, the CDRH home page includes various Level 1 guidance documents for comment, 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>. "Surveillance and Detention Without Physical Examination of Condoms" will be available at <http://www.fda.gov/cdrh/oc/condom1.pdf>.

## III. Comments

Interested persons may submit to Dockets Management Branch (address above) written comments regarding this draft guidance by November 13, 2000. 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: July 31, 2000.

**Linda S. Kahan,**

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

[FR Doc. 00-20463 Filed 8-11-00; 8:45 am]

**BILLING CODE 4160-01-F**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### White House Initiative on Asian Americans and Pacific Islanders, President's Advisory Commission; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92-463), announcement is made of the following National Advisory body scheduled to conduct a public meeting during the month August 2000.

*Name:* President's Advisory Commission on Asian Americans and Pacific Islanders (AAPIs)

*Date and Time:* August 21, 2000; 2:15 p.m.—3:15 p.m. PST

*Place:* International Community Health Services, 720 8th Avenue South, Suite 100, Seattle, WA 98104

The meeting is open to the public.

The President's Advisory Commission on AAPIs will conduct a public meeting on August 21, from 2:15 p.m. to 3:15 p.m. PST inclusive.

Agenda items will include, but will not be limited to: approval of June

Commission conference call meeting minutes; reports from subcommittees; administrative tasks; deadlines; and upcoming Town Hall and Commission meetings.

The purpose of the Commission is to advise the President on the issues facing Asian Americans and Pacific Islanders (AAPIs). The President's Advisory Commission on AAPIs will be seated through June 7, 2001.

Requests to address the Commission should be made in writing and should include the name, address, telephone number and business or professional affiliation of the interested party. Individuals or groups addressing similar issues are encouraged to combine comments and present through a single representative. The allocation of time for remarks may be adjusted to accommodate the level of expressed interest. Written requests should be faxed to (301) 443-0259.

Anyone who has interest in joining any portion of the meeting or who requires additional information about the Commission should contact: Mr. Tyson Nakashima, Office of the White House Initiative on AAPIs, Parklawn Building, Room 10-42, 5600 Fishers Lane, Rockville, MD, 20857, Telephone (301) 443-2492. Anyone who requires special assistance, such as sign language interpretation or other reasonable accommodations, should contact Mr. Nakashima no later than August 15, 2000.

Dated: August 4, 2000.

**Dolores R. Etherith,**

*Acting Director, Division of Policy Review and Coordination.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Submission for OMB Review; Comment Request; Alcoholism Prevalence and Gene/Environment Interactions in Native American Tribes (a 10 Tribe Study) OMB No. 0925-0449, Expiration 08/31/00

**SUMMARY:** Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institute on Alcohol Abuse and Alcoholism, the National Institutes of Health 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 published in the **Federal**

**Register** on April 3, 2000, page 17513 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.

5 CFR 1320.5 (General requirements) Reporting and Recordkeeping Requirements: Final Rule requires that the agency inform the potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number. This information is required to be stated in the 30-day **Federal Register** Notice.

**PROPOSED COLLECTION:** *Title:* Alcoholism Prevalence and Gene/Environment Interactions in Native American Tribes (a 10 Tribe Study). *Type of Information Collection Request:* Revision. *Need and Use of Information Collection:* The Ten Tribe Study is being conducted to collect psychiatric and personal data from tribes with different rates of alcoholism. This data will be analyzed to determine, if possible, why tribes with similar lifestyles have different rates of alcoholism and alcohol abuse. Specifically, the information gathered during this study will be used to: (1) Determine prevalence rates of alcoholism in 10 demographically sampled Native American tribes using structured or semi-structured interviews to rigorously diagnose alcoholism; (2) systematically diagnose conditions which are often comorbid with alcoholism including drug abuse, depression, and antisocial personality; (3) address crucial antecedents and consequences of alcoholism and environmental issues in alcohol vulnerability such as post-traumatic stress, violence, acculturation, and child abuse; and (4) investigate genetic vulnerability factors for tribal populations with high, moderate, and low alcoholism prevalence. This study has been ongoing for three years and is to be extended for three additional years. *Frequency of Response:* Once per respondent. *Affected Public:* Individuals. *Type of Respondents:* Adults. The annual reporting burden is as follows: *Estimated Number of Respondents:* 600; *Estimated Number of Responses per Respondent:* 1; *Average Burden Hours Per Response:* 3.75; and *Estimated Total Annual Burden Hours Requested:* 2,250. There are no Costs to Respondents to report. 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) Evaluate whether the extension of this collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agency's estimate of the burden of the extension of this collection of information, including the validity of the methodology and assumptions used; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) 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.

**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. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Ms. Ronni Nelson, Laboratory of Neurogenetics, Division of Intramural Clinical and Biological Research, NIAAA, NIH, 12420 Parklawn Drive, Suite 451, Rockville, Maryland 20852 or E-mail your request, including your address to: rn46h@nih.gov. Ms. Nelson can be contacted by telephone at 301-443-5781.

**COMMENTS DUE DATE:** Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

Dated: August 2, 2000.

**Stephen Long,**

*Executive Officer, NIAAA.*

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**BILLING CODE 4140-01-M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Cancer Institute; Notice of Closed Meeting; Correction

Notice is hereby given of a change in the meeting of the National Cancer Institute Initial Review Group,

Subcommittee E—Cancer Epidemiology, Prevention & Control, August 17–18, 2000, Georgetown Holiday Inn, 2101 Wisconsin Ave., NW., Washington, DC 20007, which was published in the **Federal Register** on July 19, 2000 (65 FR 44798).

The meeting will begin on Wednesday, August 16, 2000, at 7 p.m. due to a schedule change. The meeting is closed to the public.

Dated: August 2, 2000.

**LaVerne Y. Stringfield,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 00-20387 Filed 8-11-00; 8:45 am]

**BILLING CODE 4140-01-M**

## DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR-4563-N-12]

### Notice of Proposed Information Collection for Financial Standards for Housing Agency-Owned Insurance

**AGENCY:** Office of the Assistant Secretary for Public and Indian Housing, HUD.

**ACTION:** Notice.

**SUMMARY:** The proposed information collection requirement described below will be submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

**DATES:** *Comments Due Date:* October 13, 2000.

**ADDRESSES:** Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control number and should be sent to: Mildred M. Hamman, Reports Liaison Officer, Public and Indian Housing, Department of Housing and Urban Development, 451 7th Street, SW., Room 4238, Washington, DC 20410-5000.

**FOR FURTHER INFORMATION CONTACT:** Mildred M. Hamman, (202) 708-3642, extension 4128, for copies of the proposed forms and other available documents. (This is not a toll-free number).

**SUPPLEMENTARY INFORMATION:** The Department will submit the proposed information collection to OMB for review, as required by the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35, as amended).

This Notice is soliciting comments from members of the public and affected