engaged in the reprocessing of SUD's. 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.

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 ''Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals'' via your fax machine, call the CDRH Facts-On-Demand system at 800–899–0381 or 301–827–0111 from a touchtone telephone. At the first voice prompt press 1 to access DSMA Facts, at the second voice prompt press 2, and then enter the document number (1168) followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the 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 ''Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals,'' 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. ''Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals'' is also available at http://www.fda.gov/cdrh/comp/guidance/1168.pdf.

IV. Comments

Interested persons may, at any time, submit written comments regarding this guidance to the Dockets Management Branch (address above). Such comments will be considered when determining whether to amend the current 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 guidance document and received comments are available for public examination 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. 00–20462 Filed 8–11–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D–1383]

Draft Guidance for Industry on Surveillance and Detention Without Physical Examination of Condoms; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA)is announcing the availability of a draft guidance for industry entitled ''Guidance for Industry, Surveillance and Detention Without Physical Examination of Condoms.'' Many foreign manufacturers and shippers of condoms have consistently failed to provide condoms of adequate quality for distribution in the United States, which presents a potentially serious hazard to health for users. The draft guidance is intended to help industry understand FDA's policy to monitor continuously recidivist firms under our import program. This policy is neither final nor is it in effect at this time.

DATES: Submit written comments on the draft guidance by November 13, 2000.

ADDRESSES: Submit written requests for single copies on a 3.5″ diskette of the draft guidance entitled ''Guidance for Industry, Surveillance and Detention Without Physical Examination of Condoms'' to the Division of Small Manufacturers Assistance (HFZ–220), Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301–443–8818. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the draft guidance.

Submit written comments concerning this draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the docket number found in the brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: John J. Farnham, Center for Devices and Radiological Health (HFZ–332), Food and Drug Administration, 2094 Gaither Rd., Rockville, MD 20850, 301–594–4616.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Surveillance and Detention Without Physical Examination of Condoms.'' This draft guidance is intended to provide guidance to FDA staff and industry about a recidivist policy for firms that repeatedly attempt to import condoms that violate quality requirements. FDA's experience with sampling, examination, and testing of condoms raises concerns about the barrier properties of some condoms exported to the United States. Our analyses of condoms exported to the United States show a significant variation in the quality of the condoms exported by various manufacturers/shippers. We repeatedly place the same manufacturers/shippers on import detention due to leaks and defects in their condoms. These firms then need to provide us with private laboratory analyses for a number of shipments in order to demonstrate that the quality of the condoms and the firm's manufacturing operations comply with FDA standards. Once the firms provide such evidence, we remove them from import alert. However, many of these same manufacturers/shippers have repeated violative analyses and return to import alert status. This cyclical problem of violations requires continuous auditing and monitoring of recidivist firms to prevent the entry of defective condoms into the United States.

In an attempt to ensure that condoms exported to the United States are in compliance with FDA standards, we revised Import Alert #85–02, ''Surveillance (100% Sampling) and Detention Without Physical Examination of Condoms,'' referred to as the ''Recidivist Policy.'' This initiative was a joint effort between the agency's Center for Devices and Radiological Health's Office of Compliance, the Office of Regulatory Affairs' Division of Import Operations

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.

[FR Doc. 00–20465 Filed 8–11–00; 8:45 am]

BILLING CODE 4160–15–P

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**