

of the applicable statutes and regulations.

II. Comments

Interested persons may, at any time, submit written or electronic comments to the Dockets Management Branch (see **ADDRESSES**) regarding this guidance document. Two copies of any comments are to be submitted, except individuals may submit one copy. Comments should be identified with the docket number found in brackets in the heading of this document. A copy of the 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.

III. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/cber/guidelines.htm> or <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: March 13, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02-7581 Filed 3-28-02; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02D-0103]

Draft Revised Compliance Policy Guide; Male Condom Defects; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft revised compliance policy guide (CPG) entitled "Male Condom Defects (CPG 7124.21)." This draft CPG provides guidance concerning FDA's water leak testing and air burst testing of male condoms. This draft guidance is being issued for public comment only and will not be implemented until a final CPG is announced in the **Federal Register**.

DATES: Submit written or electronic comments on the draft by June 27, 2002.

ADDRESSES: Submit written requests for single copies on a 3.5" diskette of the draft CPG, current CPG, and Laboratory Information Bulletin (LIB) No. 4176 to the Division of Small Manufacturers, International and Consumer Assistance (DSMICA), Center for Devices and

Radiological Health (CDRH) (HFZ-220), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850 (301-443-6597 or outside MD 1-800-638-2041). 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 on the draft CPG to the Dockets Management Branch (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 these documents.

FOR FURTHER INFORMATION CONTACT: John J. Farnham, Center for Devices and Radiological Health, Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301-594-4618, ext. 117.

SUPPLEMENTARY INFORMATION:

I. Background

The draft CPG entitled "Male Condom Defects (CGP 7124.21)" is revising CPG 7124.21 that is currently entitled "Condoms; Defects—Criteria for Direct Reference Seizure." The title of this CPG was changed in the draft document; however, the CPG number remains the same.

The purpose of this draft CPG is to provide guidance to FDA personnel concerning FDA's water leak testing of both latex and synthetic male condoms as well as air burst testing of latex male condoms.

In accordance with section 514(c) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360d(c)), as amended by the FDA Modernization Act of 1997, the agency now recognizes some voluntary industrial standards for purposes of meeting the act's requirements. For latex male condoms, FDA has recognized, in part, two standards: (1) American Society for Testing and Materials' Standard Specification for Rubber Contraceptives (Male Condoms)—ASTM D3492-97 and (2) International Organization for Standardization's Rubber Condoms Standard—ISO 4074-1.

Several important changes were included in this draft revised CPG to conform to these two standards. For water leak testing, the acceptable quality level was lowered from 0.4 to 0.25 in conformance with the two referenced standards. Regulatory guidance and sampling plans were included for FDA's air burst testing for the first time. FDA is concerned about the ability of latex condoms to resist breakage and has implemented air burst testing as a

measure of elasticity and strength. A "lot" definition for FDA sampling and more specific guidance on sampling and analyses were also added to the revised draft CPG.

II. Significance of Guidance

This draft guidance document represents the agency's current thinking on male condom defect regulatory guidance and test and sampling methods. 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. In accordance with FDA's good guidance practices (21 CFR 10.115), this draft CPG is considered level 1 guidance. This draft guidance document is being issued for public comment only and is not in effect at this time. Only after a notice of availability is published in the **Federal Register** for the final CPG will the agency implement the revised policy.

III. Electronic Access

Copies of the draft CPG and current CPG may be downloaded to a personal computer with access to the Internet. The Office of Regulatory Affairs' home page includes these documents and may be accessed at <http://www.fda.gov/ora>. The referenced documents will be available on the Compliance References page.

Facsimiles of the draft CPG, current CPG, and LIB 4176 are available from DSMICA. To receive the referenced documents on your FAX machine, call the CDRH Facts-On-Demand (FOD) system at 1-800-899-0381 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 numbers 39 (current CPG), 1399 (draft CPG) and 1400 (LIB 4176) followed by the pound sign (#). Follow the remaining voice prompts to complete the request.

IV. Comments

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments on this draft CPG by June 27, 2002. 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 agency will review all comments, but in issuing a final CPG, need not specifically address each comment. If appropriate, the agency will make changes to the CPG in response to comments. Copies of the draft CPG,

current CPG, LIB 4176, and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 21, 2002.

Dennis E. Baker,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 02-7582 Filed 3-28-02; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Committee; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act, (Pub. L. 92-463), announcement is made of the following National Advisory Committee scheduled to meet during the month of April 2002.

Name: Advisory Committee on Interdisciplinary, Community-Based Linkages.

Date and Time: April 29, 2002; 8:00 a.m.—5:00 p.m., April 30, 2002; 8:00 a.m.—4:00 p.m.

Place: The Doubletree Hotel, 1750 Rockville Pike, Rockville, Maryland 20852.

The meeting is open to the public.

Agenda items will include, but not be limited to: Welcome; plenary discussion of interdisciplinary demonstration projects and promotion of interdisciplinary teams; workforce issues linked to regional and local need; collaboration with institutions that train minority and immigrant health care professionals in rural and inner city areas; presentations by speakers representing: the Bureau of Health Professions (BHP), Health Resources and Services Administration; Committee members; the Division of State, Community and Public Health, BHP; and BHP staff supporting Committee activities. Meeting content will be based on the Committee's charge under section 756 of the Public Health Service Act, to include discussion and outline of the 2002 Committee report and scheduling of topics for the next Committee meeting in June 2002.

Public comment will be permitted before lunch and at the end of the Committee meeting on April 30, 2002. Oral presentations will be limited to 5 minutes per public speaker. Persons interested in providing an oral presentation should submit a written request, with a copy of their presentation to: Mrs. Tempie R. Desai, Principal Staff Liaison, Division of State, Community and Public Health, Bureau of Health Professions, Health Resources and Services Administration, Room 9-105, 5600 Fishers Lane, Rockville, Maryland 20857, Telephone (301) 443-0132.

Requests should contain the name, address, telephone number, and any business or professional affiliation of the person desiring to make an oral presentation. Groups having similar interests are requested to combine their comments and present them

through a single representative. The Division of State, Community and Public Health will notify each presenter by mail or telephone of their assigned presentation time.

Persons who do not file an advance request for a presentation, but wish to make an oral statement may register to do so at the Doubletree Hotel, Rockville, Maryland, on April 29, 2002. These persons will be allocated time as the Committee meeting agenda permits.

Anyone requiring information regarding the Committee should contact Mrs. Desai, Division of State, Community and Public Health, Bureau of Health Professions, Health Resources and Services Administration, Room 9-105, 5600 Fishers Lane, Rockville, Maryland 20857, Telephone (301) 443-0132.

Proposed agenda items are subject to change as priorities dictate.

Dated: March 25, 2002.

Jane M. Harrison,

Director, Division of Policy Review and Coordination.

[FR Doc. 02-7584 Filed 3-28-02; 8:45 am]

BILLING CODE 4165-15-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Council; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), announcement is made of the following National Advisory body scheduled to meet during the month of May 2002:

Name: National Advisory Council on Migrant Health.

Date and Time: May 1, 2002; 9 a.m. to 5 p.m.; May 2, 2002; 9 a.m. to 5 p.m.

Place: Hyatt Regency Indianapolis, 1 South Capitol Avenue, Indianapolis, Indiana. Phone: (317)632-1234; Fax (317)616-6299.

The meeting is open to the public.

Agenda: The agenda includes an overview of general Council business activities and priorities. Topics to be addressed will include dissemination of the Migrant Health Issues Monograph Series and finalizing the 2002 Recommendations and background statements. In addition, the Council will be discussing workforce needs in the expansion of migrant health centers. Finally, the Council will attend the National Association of Community Health Centers' 2002 National Farmworker Health Conference, which is also being held in Indianapolis at this time.

Agenda items are subject to change as priorities indicate.

Contact: Anyone requiring information regarding the subject

Council should contact Margaret Davis, staff support to the National Advisory Council on Migrant Health, Migrant Health Program, Bureau of Primary Health Care, Health Resources and Services Administration, 4350 East-West Highway, Bethesda, Maryland 20814, Telephone (301) 594-0291.

Dated: March 25, 2002.

Jane M. Harrison,

Director, Division of Policy Review and Coordination.

[FR Doc. 02-7585 Filed 3-28-02; 8:45 am]

BILLING CODE 4165-15-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Reimbursement Rates for Calendar Year 2002

AGENCY: Indian Health Service, HHS.

ACTION: Notice.

SUMMARY: Notice is given that the Director of Indian Health Service (IHS), under the authority of sections 321(a) and 322(b) of the Public Health Service Act (42 U.S.C. 248(a) and 249(b)) and section 601 of the Indian Health Care Improvement Act (25 U.S.C. 1601), has approved the following rates for inpatient and outpatient medical care provided by IHS facilities for Calendar Year 2002 for Medicare and Medicaid Beneficiaries and Beneficiaries of other Federal Agencies. Since the inpatient rates set forth below do not include physician services, IHS facilities may also be entitled to bill State Medicaid programs for physician services to the extent that those services meet applicable requirements under an approved State Medicaid plan.

	Calendar year 2002
<i>Inpatient Hospital Per Diem Rate (Excludes Physician Services)</i>	
Lower 48 States	\$1,507
Alaska	1,967
<i>Outpatient Per Visit Rate (Excluding Medicare)</i>	
Lower 48 States	\$197
Alaska	374
<i>Outpatient Per Visit Rate (Medicare)</i>	
Lower 48 States	\$160
Alaska	364
<i>Medicare Part B Inpatient Ancillary Per Diem Rate</i>	
Lower 48 States	\$287