

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02D-0103]

DMB

Display Date 3-28-02

Publication Date 3-29-02

Certifier D. Hawkins

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 This draft guidance is being issued for public comment only and will not be implemented until a final CPG is announced in the **Federal Register**.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 [*insert date 90 days after date of publication in the Federal Register*].

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.

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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

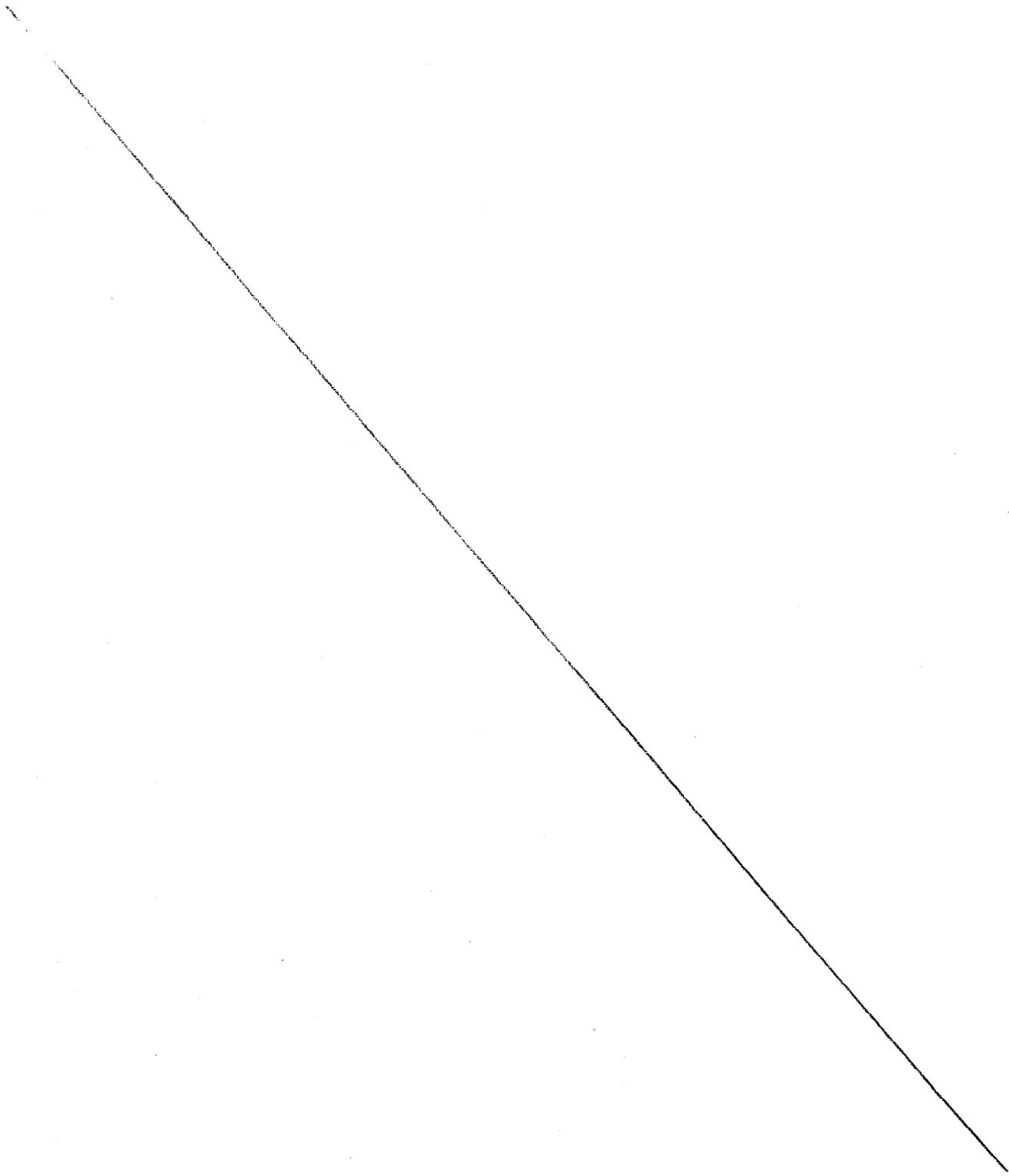
Copies of the draft CPG and current CPG may be downloaded to a personal computer with access to the Internet. The Office of Regulatory Affairs' home page includes these documents and may be accessed at <http://www.fda.gov/ora>. The referenced documents will be available on the Compliance References page.

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 *[insert date 90 days after date of publication in the Federal Register]*. 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: 03/21/02
March 21, 2002.



Dennis E. Baker,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 02-????? Filed ??-??-02; 8:45 am]

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