and startups originating from the Dallas District area. The Small Business Program presents this workshop to help achieve objectives set forth in section 406 of the Food and Drug Administration Modernization Act of 1997 (21 U.S.C. 393), which include working closely with stakeholders and maximizing the availability and clarity of information to stakeholders and the public. This is consistent with the purposes of the Small Business Program, which are in part to respond to industry inquiries, develop educational materials, sponsor workshops and conferences to provide firms, particularly small businesses, with firsthand working knowledge of FDA's requirements and compliance policies. This workshop is also consistent with the Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104–121), as outreach activities by government agencies to small businesses.

The goal of the workshop is to present information that will enable manufacturers and regulated industry to better comply with labeling requirements, especially in light of growing concerns about food allergens. Information presented will be based on agency position as articulated through regulation, compliance policy guides, and information previously made available to the public. Topics to be discussed at the workshop include: (1) Mandatory label elements, (2) nutrition labeling, (3) claims, (4) allergen policy, and (5) labeling of special cases. FDA expects that participation in this workshop will provide regulated industry with greater understanding of the regulatory and policy perspectives on food labeling and allergen declaration.

Transcripts: Transcripts of the public workshop will not be available due to the format of this workshop. Workshop handouts may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, approximately 15 working days after the public workshop at a cost of 10 cents per page.

Dated: March 25, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–7583 Filed 3–28–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0314]

"Guidance for Industry: Providing Regulatory Submissions to CBER in Electronic Format—Investigational New Drug Applications (INDs);" Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a document entitled ''Guidance for Industry: Providing Regulatory Submissions to CBER in Electronic Format—Investigational New Drug Applications (INDs)'' dated March 2002. The document is intended to provide guidance to sponsors on the design, development, organization, and submission in electronic format of an IND to the Center for Biologics Evaluation and Research (CBER). This guidance finalizes the draft guidance that was announced in the **Federal Register** on June 1, 1998 (63 FR 29741).

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

ADDRESSES: Submit written requests for single copies of this guidance to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. The document may also be obtained by mail by calling the CBER Voice Information System at 1–800–835–4709 or 301–827–1800, or by fax by calling the FAX Information System at 1–888–CBER–FAX or 301–827–3844. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit written comments on the guidance document 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.

FOR FURTHER INFORMATION CONTACT: Nathaniel L. Geary, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a document entitled ''Guidance for Industry: Providing Regulatory Submissions to CBER in Electronic Format—Investigational New Drug Applications (INDs)'' dated March 2002. The agency has developed this guidance to assist sponsors on the design, development, organization, and submission in electronic format of INDs to CBER. The guidance announced in this notice finalizes the draft ''Guidance for Industry: Pilot Program for Electronic Investigational New Drug (eIND) Applications for Biological Products'' dated May 1998 (63 FR 29741, June 1, 1998).

This document reflects CBER's experience with the electronic IND pilot program and incorporates knowledge gained from development of the electronic marketing applications guidance document entitled ''Guidance for Industry: Providing Regulatory Submissions to the Center for Biologics Evaluation and Research (CBER) in Electronic Format—Biologics Marketing Applications [Biologics License Application (BLA), Product License Application (PLA)/Establishment License Application (ELA) and New Drug Applications (NDA)]'' November 12, 1999 (64 FR 61647), revised. The agency also incorporated suggestions and recommendations from sponsors in developing a table of contents driven navigational system. However, this guidance does not address the scientific, clinical, and regulatory requirements for preparing an IND submission. These requirements can be found in title 21 of the Code of Federal Regulations, part 312 (21 CFR part 312). Part 312 must be followed in the preparation of any IND.

FDA currently is working on electronic submissions in the Common Technical Document (CTD) format developed by the International Conference on Harmonization (ICH). As FDA develops guidance on electronic CTD submissions, CBER intends to harmonize this guidance with the CTD guidance. This guidance describes how sponsors may submit electronic INDs to CBER. Sponsors may continue to submit INDs in paper form.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). This guidance document represents the agency's current thinking on this topic. 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 requirement

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]

BILLING CODE 4160–01–S

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,