

rubber latex allergens through the medical glove powder. With the present shift in the medical glove market from powdered medical gloves to powder-free, the potential for a rapid increase in the demand for powder-free or nonpowdered gloves could result in products with poor barrier integrity and/or unacceptable shelf-life. Processes to remove glove powder such as chlorination have an adverse effect on various mechanical and physical glove properties, which may affect shelf-life.

Expiration dating is not currently required for patient examination or surgeon's gloves. However, FDA has just published a proposed regulation to require expiration dating for all medical gloves (64 FR 41709, July 30, 1999). Currently, if manufacturers voluntarily label their glove with an expiration date, they are expected to have real-time data to support the shelf-life labeling claim. If real-time data are not available, then a provisional shelf-life labeling claim, not to exceed a period of 2 years, may be established based on accelerated aging test data. This guidance provides recommended test methodology and protocols for both real-time and accelerated aging that the manufacturers may utilize to support an expiration date labeling claim. Additionally, manufacturers of medical gloves may utilize this guidance document to design process controls, as described in the quality system regulation, for controlling manufacturing processes, such as chlorination, to minimize adverse effects on glove barrier properties.

II. Significance of Guidance

This guidance document represents the agency's current thinking on conducting stability testing to support an expiration date labeling claim for medical gloves. 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 the "Guidance for Conducting Stability Testing to Support an Expiration Date Labeling Claim for Medical Gloves" 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 (1355) 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. The Center for Devices and Radiological Health (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 "Guidance for Conducting Stability Testing to Support an Expiration Date Labeling Claim for Medical Gloves," 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>. "Guidance for Conducting Stability Testing to Support an Expiration Date Labeling Claim for Medical Gloves" will be available at <http://www.fda.gov/cdrh>.

IV. Comments

Interested persons may, on or before February 14, 2000, submit to the Dockets Management Branch (address above) written comments regarding this draft guidance. 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 may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 28, 1999.

Linda S. Kahan,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N-0486]

Physician and Patient Labeling for Progestational Drug Products; Warnings and Contraindications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is revoking its previously issued guidance texts for physician and patient labeling for progestational drug products that were published in the **Federal Register** of January 12, 1989 (54 FR 1243). A notice announcing FDA's intention to revoke these guidance texts was published in the **Federal Register** on April 13, 1999 (64 FR 18035). FDA received no comments on this notice. The guidance texts, which supplied physician and patient labeling for progestational drug products as a class, are no longer needed for the reasons discussed in the proposed rule on progestational drug products published in the **Federal Register** on April 13, 1999 (64 FR 17985). For additional information, see the final rule on progestational drug products that appears elsewhere in this issue of the **Federal Register**.

EFFECTIVE DATE: November 16, 2000.

FOR FURTHER INFORMATION CONTACT:

Diane V. Moore, Center for Drug Evaluation and Research (HFD-580), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4260.

Dated: November 4, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 99-29855 Filed 11-15-99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institute of Health

National Cancer Institute; Notice of Closed meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C.,