

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D-4487]

Medical Devices; Draft Guidance for Conducting Stability Testing to Support an Expiration Date Labeling Claim for Medical Gloves; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled "Guidance for Conducting Stability Testing to Support an Expiration Date Labeling Claim for Medical Gloves." This guidance is neither final nor is it in effect at this time. This guidance describes the information needed to support an expiration date labeling claim for powdered or powder-free, surgeon's or patient examination gloves. Expiration dating of medical gloves is voluntary at this time. FDA recommends that manufacturers, repackagers, or importers who add an expiration date labeling claim follow the enclosed recommended criteria and protocols for conducting testing described in this guidance.

DATES: Written comments concerning this draft guidance must be received by *(insert date 90 days after date of publication in the Federal Register)*.

ADDRESSES: See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the draft guidance. Submit written requests for single copies on a 3.5" diskette of the guidance document entitled, "Guidance for Conducting Stability Testing to Support an Expiration Date Labeling Claim for Medical Gloves" to the Division of Small Manufacturers Assistance (HFZ-220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301-443-8818. Written comments concerning this

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Certifier	SNReese

guidance must be submitted 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 brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Chiu S. Lin, Center for Devices and Radiological Health (HFZ-480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-443-8913.

SUPPLEMENTARY INFORMATION:

I. Background

It is estimated that millions of health care workers use medical gloves on a daily basis as a barrier against blood borne pathogens and microorganisms. The effective use of medical gloves as a barrier, however, is dependent upon the integrity of the glove material. Degradation of the glove material may occur when exposed to various types of manufacturing processes (e.g., chlorination) and/or environmental conditions.

In response to growing concerns regarding the use of natural rubber latex (NRL), the National Institute of Occupational Safety and Health recently issued a safety alert recommending the use of powder-free medical gloves as a means to reduce exposure to natural 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

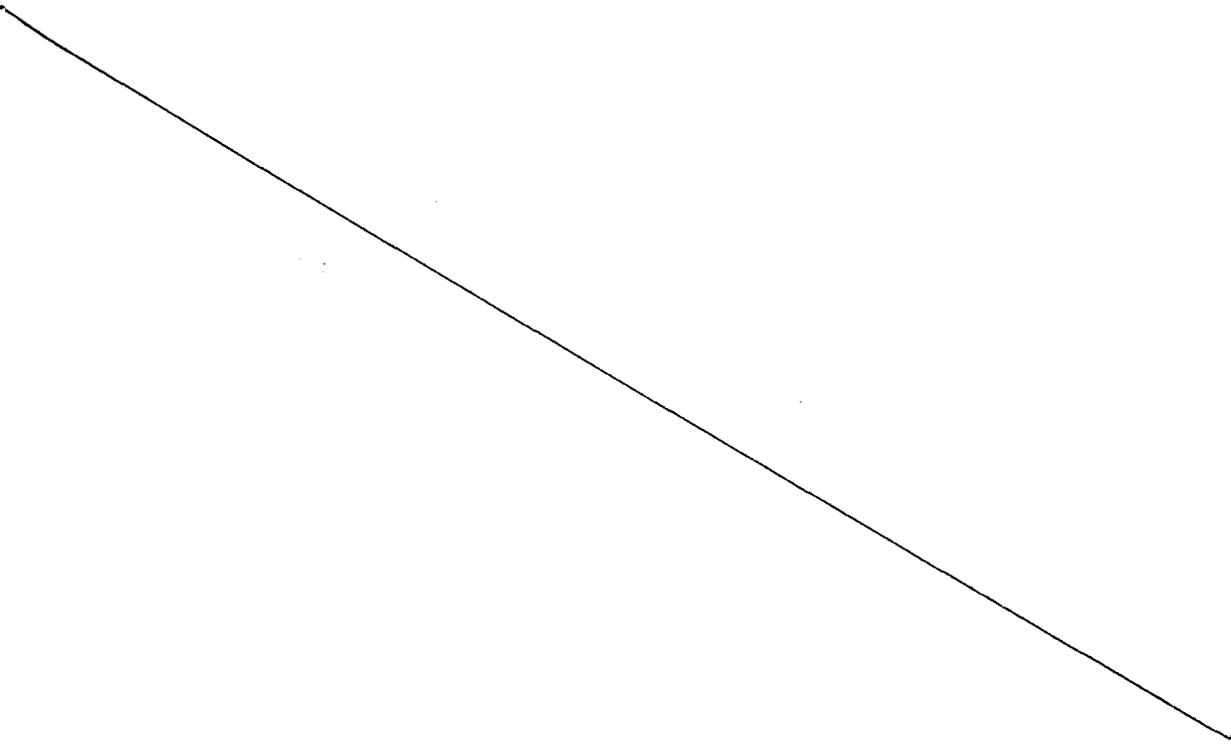
In order to receive the "Guidance for Conducting Stability Testing to Support an Expiration Date Labeling Claim for Medical Gloves" via your fax machine, call the CDRH Facts-On-Demand (FOD) system at 800-899-0381 or 301-827-0111 from a touch-tone telephone. At the first voice prompt press 1 to access 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>.

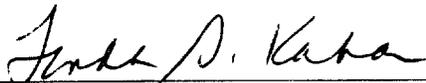
IV. Comments

Interested persons may, on or before (*insert date 90 days after date of publication in the Federal Register*), 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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