

4. FDA has revised the labeling examples to make product-specific warnings more direct.

FDA will continue to evaluate and amend the guidance in the future if changes are necessary to assure the continued safety and effectiveness of contact lens care products.

IV. Significance of a Guidance

In the past, guidances have generally been issued under § 10.90(b) (21 CFR 10.90(b)), which provides for the use of guidances to state procedures or standards of general applicability that are not legal requirements, but that are acceptable to FDA. The agency is now in the process of revising § 10.90(b). Therefore, this guidance is not being issued under the authority of § 10.90(b). This guidance document represents the agency's current thinking on the tests the agency believes necessary to provide reasonable assurance of the safety and effectiveness of transitional contact lens care products. 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, regulations, or both.

V. Requests for Comments

Interested persons may, at any time, submit to the Dockets Management Branch and to the contact person (addresses above) comments on the revised guidance. Two copies of any comments should 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 revised guidance and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. Comments received will be considered in future revisions of the guidance.

FDA/CDRH maintains an entry on the World Wide Web (WWW) for easy access to information including text, graphics, and files that may be downloaded to a PC with access to the Web. Updated on a regular basis, the CDRH home page includes the "Guidance for Industry; Premarket Notification (510(k)) for Contact Lens Care Products," 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 Industry Premarket Notification (510(k)) Guidance Document for Contact Lens Care Products" will be available on the Ophthalmic Guidance Document page at: <http://www.fda.gov/cdrh/ode/ed.op.html>. A text-only version of the CDRH Web site is also available from a computer or VT-100 compatible terminal by dialing 1-800-222-0185 (terminal settings are 8/1/N). Once the modem answers, press Enter several times and then select menu choice 1: FDA Bulletin Board Service. From there follow instructions for logging in, and at BBS Topics Page, arrow down to the FDA home page (do not select the first CDRH entry). Then select Medical Devices and Radiological Health for general information, or arrow down for specific topics.

Dated: May 28, 1997.

Joseph A. Levitt,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA-R-183]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, has submitted to the Office of Management and Budget (OMB) the following proposal for the collection of information. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection Request: Extension of currently approved collection; *title of Information Collection:* Voluntary Customer Surveys to Implement Executive Order 12862

within HCFA; *Form No.:* HCFA-R-183; *Use:* These voluntary customer surveys will be used to implement E.O 12862 to ascertain customer satisfaction with HCFA programs in terms of service quality. Surveys will involve individuals that are in direct or indirect beneficiaries of HCFA service and/or assistance, not partners. *Frequency:* Annually; *Affected Public:* Individuals or households; *Number of Respondents:* 1; *Total Annual Responses:* 1; *Total Annual Hours:* 1.

To obtain copies of the supporting statement for the proposed paperwork collections referenced above, access HCFA's WEB SITE ADDRESS at <http://www.hcfa.gov/regs/prdact95.htm>, or to obtain the supporting statement and any related forms, E-mail your request, including your address and phone number, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786-1326. Written comments and recommendations for the proposed information collections must be mailed within 30 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: OMB Human Resources and Housing Branch, Attention: Allison Eydt, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: May 29, 1997.

Edwin J. Glatzel,

Director, Management Analysis and Planning Staff, Office of Financial and Human Resources, Health Care Financing Administration.

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HEALTH AND HUMAN SERVICES

National Institutes 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 National Cancer Institute Special Emphasis Panel (SEP) meeting:

Name of SEP: Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial Expansion for Minority Enrollment.

Date: July 9, 1997.

Time: 8:30 a.m. to 5:30 p.m.

Place: Executive Plaza North, Conference Room E, 6130 Executive Boulevard, Rockville, MD 20852.

Contact Person: Wilma Woods, Ph.D., Scientific Review Administrator, National Cancer Institute, NIH, Executive Plaza North, Room 609, 6130