comment period until June 13, 1997, for the proposed collection of certain information by the agency under the Paperwork Reduction Act of 1995 (the PRA).

DATES: Submit written comments on the collection of information for studies A and B by June 13, 1997.

ADDRESSES: Submit written comments on the collection of information for studies A and B to the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Desk Officer for FDA. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, rm. 16B–19, Rockville, MD 20857, 301–827–1472.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of May 23, 1997 (62 FR 28482), FDA published a notice soliciting comments on a data collection effort consisting of four consumer surveys regarding preferences for, and comprehension of information contained in different formats and methods for communication in over-the-counter (OTC) drug labels. For two of these studies (studies A and B), the agency has requested emergency processing of the proposed collection by OMB. To give interested persons additional time to submit comments on the proposed data collection for the two studies the agency is reopening the comment period until June 13, 1997.

Dated: June 2, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–14804 Filed 6–5–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97D–0191]

Medical Devices; Guidance for Industry; Premarket Notification (510(k)) Guidance Document for Contact Lens Care Products; Revised; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a revised guidance entitled, ''Guidance for Industry; Premarket Notification (510(k)) Guidance Document for Contact Lens Care Products.'' The revised guidance sets forth the types of tests the Center for Devices and Radiological Health (CDRH), FDA, believes are necessary to provide reasonable assurance of the safety and effectiveness of contact lens care products. The revised guidance accompanies a final rule, which appears elsewhere in this issue of the **Federal Register**, reclassifying rigid gas permeable contact lens solution; soft (hydrophilic) contact lens solution; and contact lens heat disinfecting units from class III (premarket approval) to class II (special controls).

DATES: Written comments may be submitted at any time.

ADDRESSES: Submit written requests for single copies of the revised guidance entitled, ''Guidance for Industry Premarket Notification (510(k)) Guidance Document for Contact Lens Care Products'' (shelf number 674) 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, 301–443–6597 (outside MD 1–800–638–2041). Send two self-addressed adhesive labels to assist that office in processing your requests. Submit written comments on the revised guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Requests and comments should be identified with the docket number found in brackets in the heading of this document. Comments may be submitted at any time and will be used to determine whether to revise the guidance further.

FOR FURTHER INFORMATION CONTACT: James F. Saviola, Center for Devices and Radiological Health (HFZ–460), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1744.

SUPPLEMENTARY INFORMATION:

I. The Statutory Requirements

The Safe Medical Devices Act (the SMDA) (Pub. L. 101–629), which amended the medical device provisions of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321 *et. seq.*), contains specific provisions on transitional devices (i.e., those devices regulated as new drugs before the Medical Device Amendments of 1976 (Pub. L. 94–295) became law) (see section 520(l) of the act (21 U.S.C. 360j(l)). In 1976, Congress classified into class III all transitional devices (i.e., those devices previously regulated as drugs). The legislative history of the SMDA reflects congressional concern that many transitional devices were being overregulated in class III (H. Rept. 808, 101st Cong., 2d sess. 26–27 (1990); S. Rept. 513, 101st Cong., 2d sess. 26–27 (1990)). Congress amended section 520(l) of the act to direct FDA to collect certain safety and effectiveness information from the manufacturers of transitional devices that still remain in class III to determine whether the devices should be reclassified into class II (special controls) or class I (general controls).

Under section 520(l)(5)(B) of the act, FDA was to publish regulations by December 1, 1992, either leaving the transitional class III devices in class III or revising their classification down to class I or class II. However, as permitted by section 520(l)(5)(C) of the act, in the **Federal Register** of November 30, 1992 (57 FR 56586), the agency published a notice extending the period for issuing such regulations until December 1, 1993. Due to limited resources, FDA was unable to publish the regulations before the December 1, 1993, deadline. In the **Federal Register** of April 1, 1996 (61 FR 14277), FDA published a proposed rule to reclassify from class III (premarket approval) to class II (special controls) the rigid gas permeable contact lens solution; the soft (hydrophilic) contact lens solution; and the contact lens heat disinfecting unit. FDA also announced the availability of a premarket notification (510(k)) draft guidance document for contact lens care products (61 FR 14330, April 1, 1996). Interested persons were invited to comment on the guidance document by May 31, 1996.

Elsewhere in this issue of the **Federal Register**, FDA is issuing a final rule reclassifying from class III (premarket approval) to class II (special controls) all transitional contact lens care products. In conjunction with the final rule, FDA is announcing the availability of the revised guidance for premarket notification for the reclassified contact lens care products entitled, ''Guidance for Industry; Premarket Notification (510(k)) for Contact Lens Care Products.''

II. The Revised Guidance

The revised guidance sets forth the types of testing that FDA believes will provide reasonable assurance of the continued safety and effectiveness of transitional contact lens care products. It also provides comprehensive

directions for manufacturers of contact lens care products to follow in submitting a 510(k) premarket notification submission demonstrating substantial equivalence of their device to a legally marketed contact lens care product (predicate device). Information on the battery of preclinical testing that may demonstrate substantial equivalence is included in the guidance. If the results of preclinical testing demonstrate that the device will have new characteristics, clinical performance data may be needed to establish substantial equivalence. If clinical performance data are needed, the guidance document suggests methodologies (e.g., size and scope of the study) to be included in the investigational protocol.

Other elements of the guidance include: (1) General information on the regulations and requirements for labeling contact lens care products; (2) information about 510(k) submission requirements relating to modifying a marketed contact lens care product; and (3) guidance for submitting a 510(k) notification for contact lens cases and contact lens accessories (i.e., mechanical cleaning aids and accessory cleaning pads).

In the event that clinical trials are necessary, FDA emphasizes that manufacturers are required to conduct the trials in accordance with the investigational device exemption regulations in 21 CFR part 812. At this time, FDA considers clinical studies of most contact lens care products to be nonsignificant risk investigations. For nonsignificant risk investigations, approval of an institutional review board (IRB) is necessary before initiating a clinical study, and an investigational plan and informed consent document must be presented to an IRB for review and approval. Prior FDA approval is not required.

However, FDA considers some clinical studies of solutions that contain new active ingredients for ophthalmic use and that are intended for use directly in the eye to be significant risk investigations that would require both IRB and FDA review and approvals. Examples of significant risk investigations requiring FDA and IRB review and approval include investigations of solutions intended for repeated use directly in the eye that contain new types of ingredients that have no history of ophthalmic use, that may require different testing than the preclinical tests in the guidance, that may contain ingredients that can perfuse through the cornea, or that may involve overlapping concerns with other FDA Centers, such as products or studies incorporating a biologic or a pharmaceutical compound. Sponsors proposing to conduct such studies should contact James F. Saviola (address above) concerning the risk status of the proposed investigation prior to implementing their studies.

Comments received from the public on the draft guidance were summarized at the July 26, 1996, meeting of the Ophthalmic Devices Panel of the Medical Devices Advisory Committee.

III. Summary and Analysis of Comments and FDA's Response

Separate comments were received from four individuals and a single set of comments from industry via the Contact Lens Institute. Comments were generally categorized as editorial, clarification, and substantive. The guidance document has been revised to address most of the editorial, providing clarification and substantive comments.

Comments pertaining to policy and clinical information are summarized as follows:

1. One comment suggested that FDA change the wording in the guidance which states that clinical studies of contact lens care products are nonsignificant risk investigations. The current wording in the guidance states that this is the case unless the device contains new active ingredients for ophthalmic use and is intended to be used directly in the eye.

FDA agrees in part with this comment. However, investigations of some in-eye products are significant risk investigations (e.g., investigations of solutions intended for repeated use directly in the eye that contain new types of ingredients that have no history of ophthalmic use, that may require different testing than the preclinical tests in the guidance, that may contain ingredients that can perfuse through the cornea, or that may involve overlapping concerns with other FDA Centers, such as products or studies incorporating a biologic or a pharmaceutical compound). The guidance has been revised to clarify when a contact lens care product investigation is considered significant risk and to recommend that sponsors contact FDA for guidance concerning risk status of such proposed investigations prior to beginning clinical studies.

2. One comment stated that discard dates alone will not necessarily reduce the risk of eye infections caused by contamination during use and suggested that the statement in the General Manufacturing section stating that, whenever possible, manufacturers should consider the use of discard dates after opening, be revised to be more consistent with 21 CFR 800.10(b).

FDA agrees that the guidance should reflect the regulation and has revised the guidance accordingly. However, FDA believes that discard dates would help to minimize contamination of lens care products and that responsible manufacturers should work in this direction.

3. A few comments were received pertaining to recommendations for clinical trials (e.g., size and scope, study design, and testing matrix). One comment stated that the studies are too short and may not uncover complications such as different levels of patient hypersensitivity. That comment stated that clinical studies for all new lens care formulations should be, at a minimum, 3 months in length with at least 100 patients. Also, for products that are substantially the same as one already on the market with the same indication, clinical studies would still be necessary.

FDA has designed the guidance to include preclinical testing as the primary evidence for establishing substantial equivalence, with supplemental clinical testing as additional confirmatory information. The clinical recommendations include minimum patient numbers. Sample sizes are similar to those used in the daily wear contact lens guidance. FDA has revised the guidance to clarify that a 30 patient/1-month study is appropriate in certain matrices for products with active ingredients within marketed concentrations, as well as for higher or lower concentrations. Under study design, FDA has clarified the statement that a crossover design with an in vitro analysis is an example of a method that may be used for clearer effectiveness studies, rather than stating that it may be the best method to use. The guidance has been revised to include suggestions for sponsors choosing to include data from a patient population greater than the minimum size recommended.

In Appendix B for protocol considerations, FDA has revised the visit schedule to delete the 2-week visit for trials conducted longer than 1 month, provided for the use of other suitable well-defined grading scales (e.g., International Standards Organization Scale), and revised the investigator-patient ratio section to provide additional guidance for the number of patients per study site.

4. One comment suggested that the title of the ''Adverse Reaction Section'' be changed to ''Serious Adverse Reaction.'' Another comment suggested that the discontinued eye summary

table be deleted. FDA disagrees with both of these comments. The first comment invites subjectivity of reporting adverse events. Discontinuation information could provide important safety or efficacy information and should be reported.

Comments pertaining to preclinical information are summarized as follows:

Concerning microbiology, most comments submitted for clarification or minor changes in test methods have been included in the revised guidance. Many of these comments addressed preparation of the microbial challenge used to conduct the test. Substantive comments on the disinfection efficacy tests, which are the stand alone and regimen tests, addressed the panel of test organisms, the methodology, and the performance criteria.

Concerning test organisms, one comment recommended that FDA add to the current panel of microorganisms used for evaluating antimicrobial efficacy.

This comment was rejected. FDA believes the current panel is adequate for determining the substantial equivalence of newly marketed products. Manufacturers may choose to test products against additional microorganisms during product evaluation; however, FDA's current policy is that labeling claims may not highlight product efficacy against individual microorganisms.

Concerning methodology, comments addressed the need to include organic load and biofilm in the test procedures.

FDA's position remains unchanged regarding the inclusion of organic load to establish the substantial equivalence of disinfecting solutions. FDA did not incorporate two separate comments on organic load (i.e., one that suggested inclusion of a mild organic load in the stand alone test procedure and one that recommended elimination of organic load in the regimen test). Stand alone disinfecting products are labeled with cleaning instructions to remove organic load. For lens care regimens with milder disinfecting agents, it is necessary to include removal of simulated lens deposits during cleaning and rinsing steps.

FDA rejected a comment to evaluate biofilm in the lens case. The issue of biofilm formation can be adequately addressed through labeling recommendations for daily cleaning and frequent lens case replacement.

Concerns were raised on the currently recommended performance regimen criteria of less than three colony forming units to determine substantial equivalence of disinfecting regimens.

FDA agrees that manufacturers should have alternative performance criteria due to limited experience with the revised regimen test procedure. Therefore, the guidance has been revised to include an option based on directly comparing regimen test results for the device with those obtained for a predicate device.

FDA revised the guidance to include the experimental error (+/-0.5 log) in the performance criteria requiring stasis on yeast and mold counts.

Based on the comments received concerning the bacteriostasis test, the following revisions have been made in the guidance:

1. A correction to eliminate a microbial rechallenge in the bacteriostasis test.

2. Including bacteriostasis testing outside of the actual product container.

FDA has incorporated most suggested clarifications for chemistry and manufacturing. Revisions include the following for chemistry:

1. A solution compatibility test has been included in all product test matrices.

2. A wetting angle test is recommended for all conditioning solutions in the test matrix.

3. The following example has been added as a modification not requiring a 510(k): Nonsignificant manufacturing changes made in accordance with 21 CFR 807.81 that meet good manufacturing practice requirements.

Comments on the protocol for establishing shelf-life concerned microbiology and chemistry testing.

1. FDA rejected the suggestion that sponsors should submit and/or reference data from identically packaged contact lens care products to support shelf-life sterility since a product formulation may affect microbial growth during storage.

2. FDA has added the statement that manufacturing changes to smaller bottle sizes from identical materials, using an approved shelf-life protocol, is an example of a change not requiring a 510(k).

3. FDA has deleted the recommendation for disinfection efficacy testing at the end of the recommended shelf life.

4. FDA has included container inversion as one example for maximally testing the container/closure system as clarification, and not as a specific recommendation.

5. FDA has reevaluated the recommendation for accelerated testing for establishing shelf life beyond 2 years and the recommendation for 6 months ambient temperature data prior to marketing. The recommendation that any shelf-life request beyond 2 years should be based on real time data has been eliminated. The guidance recommends that companies provide their shelf-life protocol in their 510(k) and certify that they will have shelf-life data sufficient to support their labeled expiration date prior to marketing their device.

Toxicology comments received on the product specific test matrices include:

1. Replacing the current 3-day acute ocular irritation test with a 5-day test.

2. Adding an additional battery of toxicology tests for the higher than marketed concentrations.

3. Including cytotoxicology and an ocular irritation toxicology screening test for active ingredients within marketed concentrations and for lower than marketed concentrations.

FDA's response to these comments are as follows:

1. The suggested 3-day acute ocular irritation test currently in the guidance is based on historical evidence that if adverse events occur, they will generally manifest themselves during the 3-day time period. If a sponsor prefers the 5-day test, this is acceptable.

2. While the additional battery of tests for the higher than marketed concentrations may be appropriate in some cases depending on the ingredients, they are not generally appropriate for all product specific matrices.

3. FDA agrees that toxicology screening is appropriate and the guidance has been revised accordingly.

Several comments were received concerning labeling. Many of these suggested editorial changes which have been incorporated in the revised guidance. The following four labeling comments were rejected:

1. FDA has not deleted the warning, ''To Avoid Contaminating Your Solution, Do Not Transfer to Other Bottles or Containers.'' This warning was recommended by the Ophthalmic Devices Panel as one means of helping to minimize contamination. FDA believes that, at a minimum, this warning should be on larger-sized bottles.

2. Company phone numbers to which adverse reactions should be reported is still included as a means of encouraging device reporting back to the manufacturer.

3. Boxed warnings were included in the ''Write-it-Right'' labeling example to provide an example of labeling developed according to specific principles. These warnings remain in the guidance because they are examples and not specific recommendations.

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.

[FR Doc. 97–14750 Filed 6–5–97; 8:45 am]

BILLING CODE 4160–01–F

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.

[FR Doc. 97–14759 Filed 6–5–97; 8:45 am]

BILLING CODE 4120–03–M

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