

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
24-Month Father Interview	635	1	1.0	635
Father-Child Videotaping Protocol	168	1	0.3	50
Estimated Total Annual Burden				685

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained by writing to The Administration for Children and Families, Office of Information Services, Division of Information Resource Management, 370 L'Enfant Promenade, S.W., Washington, DC 20047, Attn.: ACF Reports Clearance Officer. All requests should be identified by title.

Comments are invited on: (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the

burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: June 2, 1997.

Bob Sargis,

Acting Reports Clearance Officer.

[FR Doc. 97-14778 Filed 6-5-97; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Voluntary Surveys of Program Partners to Implement Executive Order 12862 in the Administration for Children and Families.

OMB No.: 0980-0266.

Description: Under the provisions of the Federal Paperwork Reduction Act of 1995 (Pub. L. 104-13), the Administration for Children and Families (ACF) is requesting clearance for instruments to implement Executive Order 12862 within the ACF. The purpose of the data collection is to obtain customer satisfaction information from those entities who are funded to be our partners in the delivery of services to the American public. ACF partners are those entities that receive funding to deliver services or assistance from ACF programs. Examples of partners are States and local governments, territories, service providers, Indian Tribes and tribal organizations, grantees, researchers, or other intermediaries serving target populations identified by and funded directly or indirectly by ACF. The surveys will obtain information about how well ACF is meeting the needs of our partners in operating the ACF programs.

Respondents: State, Local, Tribal Govt. or Not-for-Profit.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
State Governments	51	10	1	510
Head Start grantees & Delegates	200	1	.5	100
Other Discretionary Grant Programs	200	10	.5	1,000
Indian Tribes & tribal organizations	25	10	.5	50

Estimated Total Annual Burden Hours: 1,660.

Additional Information: Copies of the proposed collection may be obtained by writing to The Administration for Children and Families, Office of Information Services, Division of Information Resource Management Services, 370 L'Enfant Promenade, SW., Washington, D.C. 20447, Attn: ACF Reports Clearance Officer.

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of

having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, 725 17th Street, N.W., Washington, D.C. 20503, Attn: Ms. Wendy Taylor.

Dated: May 29, 1997.

Bob Sargis,

Acting Reports Clearance Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N-0201]

Agency Information Collection Activities: Proposed Collection; Comment Request; Reopening of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is reopening the

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.

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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