ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attention: Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Mark L. Pincus, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, rm. 16B–19, Rockville, MD 20857, 301–827–1471.

SUPPLEMENTARY INFORMATION: In compliance with section 3507 of the PRA (44 U.S.C. 3507), FDA has submitted the following proposed collection of information to OMB for review and clearance:

Title: Electronic Records; Electronic Signatures—21 CFR Part 11

Description: FDA regulations in part 11 (21 CFR part 11) provide criteria for acceptance of electronic records, electronic signatures, and handwritten signatures executed to electronic records in place of paper records. The regulations will become effective on August 20, 1997. Under these regulations, records and reports may be submitted to FDA electronically, provided the agency has stated its ability to accept the records electronically in an agency-established public docket and that the other requirements of part 11 are met.

The recordkeeping provisions in part 11 (§§ 11.10, 11.30, 11.50, and 11.300) require standard operating procedures to assure appropriate use of, and precautions for, systems using electronic records and signatures. The reporting provision (§ 11.100) requires persons to certify in writing to FDA that they will regard electronic signatures used in their systems as the legally binding equivalent of traditional handwritten signatures.

Description of Respondents: Businesses and other for-profit organizations, State or local governments, Federal agencies, and nonprofit institutions.

Most of the burden created by the information collection provisions of this final rule will be a one-time burden associated with the creation of standard operating procedures, validation, and certification. The agency anticipates that the use of electronic media will result in a substantial net reduction in the paperwork burden associated with maintaining FDA-required records.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL RECORDKEEPING BURDEN

21 CFR Section	Frequency per Recordkeeper	Hours per Recordkeeper	Total Hours
11.10	50	40	2,000
11.30	50	40	2,000
11.50	50	40	2,000
11.300	50	40	2,000
Total Recordkeeping Burden Hours			8,000

There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2.—ESTIMATED ANNUAL REPORTING BURDEN

21 CFR Section	No. of Respondents	Annual Frequency per Response	Hours per Response
11.100	1,000	1	1,000
Total Reporting Burden Hours			1,000

There are no capital costs or operating and maintenance costs associated with this information collection.

Dated: June 16, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–16178 Filed 6–19–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97F–0170]

Toyo-Morton, Ltd.; Filing of Food Additive Petition; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of April 30, 1997 (62 FR 23467). The document announced that Toyo-Morton, Ltd., filed a petition proposing that the food additive regulations be amended to provide for the safe use of polyester-epoxy-urethane adhesive for use as a nonfood contact layer of laminated articles intended for use in contact with food. The document published with an incorrect docket number. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: LaJuana D. Caldwell, Office of Policy (HF–27), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–2994.

In FR Doc. 97–11078, appearing on page 23467 in the **Federal Register** of Wednesday, April 30, 1997, the following correction is made:

1. On page 23467, in the third column, Docket No. ''97C–0171'' is corrected to read ''97F–0170''.

Dated: June 9, 1997.

Alan M. Rulis,

Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.

[FR Doc. 97–16236 Filed 6–19–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Ophthalmic Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA regulatory issues.

Date and Time: The meeting will be held on July 10 and 11, 1997, 8 a.m. to 5 p.m.

Location: Gaithersburg Hilton, Salons A, B, and C of the Ballroom, 620 Perry Pkwy., Gaithersburg, MD.

Contact Person: Sara M. Thornton, Center for Devices and Radiological Health (HFZ–460), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD, 20850, 301–594–2053, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12396, or the world wide web at http://www.fda.gov. Please call the Information Line for up-to-date information on this meeting.

Agenda: On July 10, 1997, there will be a presentation of the basic concepts of FDA's Product Development Protocol Process with specific focus on the implementation of the process within the Division of Ophthalmic Devices. The committee will discuss issues relating to a premarket approval application (PMA) for a monofocal intraocular lens and a PMA for a multifocal intraocular lens for primary implantation for the visual correction of aphakia. On July 11, 1997, the committee will discuss issues relating to a PMA for an excimer laser for the correction of myopia using laser in-situ keratomileusis (LASIK).

Procedure: Interested persons may present data, information, or views, orally, or in writing, on issues pending before the committee. Written submissions may be made to the contact person by July 1, 1997. Oral presentations from the public will be scheduled between approximately 8 a.m. and 9 a.m. on July 10 and 11, 1997. Time allotted for each presentation may be limited. Those desiring to make formal presentations should notify the contact person before July 1, 1997, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

FDA regrets that it was unable to publish this notice 15 days prior to the July 10 and 11, 1997, Ophthalmic Devices Panel of the Medical Devices Advisory Committee meeting. Because the agency believes there is some urgency to bring these issues to public discussion and qualified members of the Ophthalmic Devices Panel of the Medical Devices Advisory Committee were available at this time, the Commissioner concluded that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.

Dated: June 12, 1997.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 97–16235 Filed 6–19–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

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

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget, in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office on (301) 443–1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

Assessment of HIV Counseling and Testing (C&T) Services for Women of Childbearing Age in Bureau of Primary Health Care (BPHC) Programs—

New—The Health Resources and Services Administration (HRSA), Bureau of Primary Health Care (BPHC) is planning to conduct a survey-based study of its primary care programs to examine various implementation issues related to the design and delivery of HIV counseling and testing (HIV C&T) services to women of childbearing age. The survey population will be a probability sample of the BPHC-funded grantees, designed to permit analysis by type of BPHC funding received.

The mail survey instrument will be designed to explore various HIV C&T implementation issues and relevant research questions, including: (a) Extent to which HIV C&T services are available (provided directly by programs or through referrals), (b) attributes of the BPHC programs that offer HIV C&T services to women of childbearing age; (c) characteristics of HIV C&T services, provided by BPHC programs; (d) programmatic and population-specific barriers to delivery of HIV C&T services; (e) lessons and best practices for replication; (f) recommendations for technical assistance to facilitate timely, effective implementation. The resulting analysis and report will present program-based lessons and recommendations for assisting and improving capacity of various BPHC programs to design and implement HIV C&T services for women of childbearing age, and thus assist in promoting community-based HIV C&T services for women, especially pregnant women. Response burden is as follows:

Type of respondent	Number of respondents	Responses/ respondent	Hours per response	Total burden hours
Grantees providing HIV C&T Services	141	2	2	282
Grantees not providing HIV C&T Services	69	1	1	69
Total	210	.....	.....	351

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to: Virginia Huth, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, D.C. 20503.

Dated: June 12, 1997.

James J. Corrigan,

Acting Associate Administrator for Management and Program Support.

[FR Doc. 97–16237 Filed 6–19–97; 8:45 am]

BILLING CODE 4160–15–P