Branch, Iowa, also known as the Aspelmeier Family; to retain control of Mediapolis Bancorporation, Mediapolis, Iowa, and thereby indirectly acquire Mediapolis Savings Bank.

4. Donald and Carol Schmidgall, Hartzell and Marian Schmidgall, Jon and Julie Schmidgall, Ronald and Jane Schmidgall, Mediapolis, Iowa, also known as the Schmidgall Family; to retain control of Mediapolis Bancorporation, Mediapolis, Iowa, and thereby indirectly acquire Mediapolis Savings Bank, Mediapolis, Iowa.

Board of Governors of the Federal Reserve System, November 14, 2003.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. 03–28940 Filed 11–19–03; 8:45 am]

BILLING CODE 6210–01–S

GENERAL SERVICES ADMINISTRATION

Office of Governmentwide Policy; Revision of the Standard Form 1103

AGENCY: Office of Governmentwide Policy, GSA.

ACTION: Notice.

SUMMARY: The General Services Administration, Office of Governmentwide Policy revised Standard Form 1103, U.S. Government Bill of Lading to reflect the new regulation on transportation payments and audits. This form is now used only for overseas and international shipments. All other shipments follow the procedures in 41 CFR 102–118.

SF 1103 (which new title is U.S. Government Bill of Lading—International and Domestic Overseas Shipments) is authorized for local reproduction. You can obtain the updated camera copy in two ways:

On the Internet. Address: *http://w3.gsa.gov//web/c/newform.nsf/MainMenu?OpenForm,* or;

From GSA, Forms Management, Attn.: Barbara Williams, (202) 501–0581.

FOR FURTHER INFORMATION CONTACT: Ms. Barbara Williams, General Services Administration, (202) 501–0581 for availability of the form and Ed Davis, General Services Administration (202) 208–7638 for any other information.

DATES: Effective November 20, 2003.

Dated: November 5, 2003.

Barbara M. Williams,

Deputy Standard and Optional Forms Management Officer, General Services Administration.

[FR Doc. 03–28939 Filed 11–19–03; 8:45 am]

BILLING CODE 6820–34–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D–0229]

Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance for Industry on Continuous Marketing Applications: Pilot 2—Scientific Feedback and Interactions During Development of Fast Track Products Under the Prescription Drug User Fee Act

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection contained in the guidance for industry on Continuous Marketing Applications: Pilot 2—Scientific Feedback and Interactions During Development of Fast Track Products Under the Prescription Drug User Fee Act of 1992 (PDUFA).

DATES: Submit written or electronic comments on the collection of information by January 20, 2004.

ADDRESSES: Submit electronic comments on the collection of information to: *http://www.fda.gov/dockets/ecomments.* Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Karen Nelson, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Guidance for Industry on Continuous Marketing Applications: Pilot 2—Scientific Feedback and Interactions During Development of Fast Track Products Under the Prescription Drug User Fee Act (OMB Control Number 0910–0518)

FDA is requesting OMB approval under the PRA (44 U.S.C. 3507) for the reporting and recordkeeping requirements contained in the guidance for industry entitled ''Continuous Marketing Applications: Pilot 2—Scientific Feedback and Interactions During Development of Fast Track Products Under Prescription Drug User Fee Act.'' This guidance discusses how the agency will implement a pilot program for frequent scientific feedback and interactions between FDA and applicants during the investigational phase of the development of certain Fast Track drug and biological products. Applicants are being asked to apply to participate in the pilot 2 program.

In conjunction with the June 2002 reauthorization of the PDUFA, FDA agreed to meet specific performance goals (PDUFA goals). The PDUFA goals include two pilot programs to explore the continuous marketing application

(CMA) concept. The CMA concept builds on the current practice of interaction between FDA and applicants during drug development and application review and proposes opportunities for improvement. Under the CMA pilot program, pilot 2, certain drug and biologic products that have been designated as Fast Track (i.e., products intended to treat a serious and/or life-threatening disease for which there is an unmet medical need) are eligible to participate in the program. Pilot 2 is an exploratory program that will allow FDA to evaluate the impact of frequent scientific feedback and interactions with applicants during the investigational new drug application (IND) phase. Under the pilot program, a maximum of one Fast Track product per review division in the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) will be selected to participate. This guidance provides information regarding the selection of participant applications for pilot 2, the formation of agreements between FDA and applicants on the IND communication process, and other procedural aspects of pilot 2. FDA will begin accepting applications for participation in pilot 2 on October 1, 2003.

The guidance describes one collection of information: Applicants who would like to participate in pilot 2 must submit an application (pilot 2 application) containing certain information outlined in the guidance. The purpose of the pilot 2 application is for the applicants to describe how their designated Fast Track product would benefit from enhanced communications between the FDA and the applicant during the product development process.

FDA's regulation at § 312.23 (21 CFR 312.23) states that information provided to the agency as part of an IND must be submitted in triplicate and with an appropriate cover form. Form FDA 1571 must accompany submissions under INDs. Both 21 CFR part 312 and FDA Form 1571 have a valid OMB control number (OMB control number 0910–0014), which expires January 31, 2006.

In the guidance document, CDER and CBER ask that a pilot 2 application be submitted as an amendment to the application for the underlying product under the requirements of § 312.23; therefore, pilot 2 applications should be submitted to the agency in triplicate with Form FDA 1571. The agency recommends that a pilot 2 application be submitted in this manner for two reasons: (1) To ensure that each pilot 2 application is kept in the administrative file with the entire underlying application, and (2) to ensure that pertinent information about the pilot 2 application is entered into the appropriate tracking data bases. Use of the information in the agency's tracking databases enables the agency to monitor progress on activities.

Under the guidance, the agency asks applicants to include the following information in the pilot 2 application:

- Cover letter prominently labeled ''Pilot 2 Application;''
- IND number;
- Date of Fast Track designation;
- Date of the end-of-phase 1 meeting, or equivalent meeting, and summary of the outcome;
- A timeline of milestones from the drug or biological product development program, including projected date of NDA/biologic license application submissions;
- Overview of the proposed product development program for a specified disease and indication(s), providing information about each of the review disciplines (e.g., chemistry/manufacturing/controls, pharmacology/toxicology, clinical, clinical pharmacology, and biopharmaceutics);
- Rationale for interest in participating in pilot 2, specifying the ways in which development of the subject drug or biological product would be improved by frequent scientific feedback and interactions with FDA and the potential for such communication to benefit public health by improving the efficiency of the product development program; and
- Draft agreement for proposed feedback and interactions with FDA.

This information will be used by the agency to determine which Fast Track products are eligible for participation in pilot 2. Participation in this pilot program will be voluntary.

Based on the number of approvals for Fast Track designations and data collected from the review divisions and offices within CDER and CBER, FDA estimates that in fiscal year 2002, 109 drug product applications and 46 biological products had Fast Track designation. FDA anticipates that approximately 85 drug product applicants (respondents) and approximately 29 biological product applicants (respondents) will submit at least one pilot 2 application. Based on information collected from offices within CDER and CBER, the agency further anticipates that the total responses, i.e., the total number of applications received for pilot 2, will be 90 for drug products and 35 for biological products. The hours per response, which is the estimated number of hours that a respondent would spend preparing the information to be submitting in a pilot 2 application in accordance with the guidance, is estimated to be approximately 80 hours. Based on FDA's experience, we expect it will take respondents this amount of time to obtain and draft the information to be submitted with a pilot 2 application. Therefore, the agency estimates that applicants will use approximately 10,000 hours to complete the pilot 2 applications.

On September 29, 2003, this guidance was approved on an emergency basis, which expires on March 30, 2004. This notice of request is to receive approval in the normal PRA process.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Pilot 2 Application	No. of Respondents	No. of Responses per Respondent	Total Responses	Hours per Response	Total Hours
CDER	85	1.06	90	80	7,200
CBER	29	1.20	35	80	2,800
Total					10,000

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

Dated: November 14, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–28984 Filed 11–19–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of 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 meeting of the National Cancer Advisory Board.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

A portion of the meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4), and 552b(c)(6), as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant application, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Advisory Board.

Open: December 2, 2003, 8 to 4.

Agenda: Program reports and presentations; Business of the Board.

Place: National Cancer Institute, 9000 Rockville Pike, Building 31, C Wing, 6th Floor, Conference Room 10, Bethesda, MD 20892.

Contact Person: Dr. Paulette S. Gray, Executive Secretary, National Cancer Institute, National Institutes of Health, 6116 Executive Boulevard, 8th Floor, Room 8141, Bethesda, MD 20892–8327, (301) 496–4218.

Name of Committee: National Cancer Advisory Board.

Closed: December 2, 2003, 4 to Recess.

Agenda: Review intramural program site visit outcomes; Discussion of confidential personnel issues.

Contact Person: Dr. Paulette S. Gray, Executive Secretary, National Cancer Institute, National Institutes of Health, 6116 Executive Boulevard, 8th Floor, Room 8141, Bethesda, MD 20892–8327, (301) 496–4218.

Name of Committee: National Cancer Advisory Board.

Open: December 3, 2003, 8 to Adjournment.

Agenda: Program reports and presentations; Business of the Board.

Contact Person: Dr. Paulette S. Gray, Executive Secretary, National Cancer Institute, National Institutes of Health, 6116 Executive Boulevard, 8th Floor, Room 8141, Bethesda, MD 20892–8327, (301) 496–4218.

This meeting is being published less than 15 days prior to the meeting due to scheduling conflicts.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's Home page: *deainfo.nci.nih.gov/advisory/ncab.htm,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: November 13, 2003.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 03–28982 Filed 11–19–03; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meetings

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 meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel, Transplant Immunology.

Date: December 10, 2003.

Time: 5 p.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Maria E. Davila-Bloom, PhD, Scientific Review Administrator, Review Branch, DEA, NIDDK, National Institutes of Health, Room 758, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 594–7637, *davila-bloomm@extra.niddk.nih.gov.*

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel, Multi-Center Clinical Trial on Liver Disease.

Date: December 12, 2003.

Time: 11 a.m. to 12 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Carolyn Miles, PhD, Scientific Review Administrator, Review Branch, DEA, NIDDK, National Institutes of Health, Room 755, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 594–7791, *milesc@extra.niddk.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: November 13, 2003.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 03–28976 Filed 11–19–03; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Alcohol Abuse and Alcoholism; Notice of Closed Meetings

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 meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which